VENTURA COUNTY MEDICAL CENTER
SANTA PAULA HOSPITAL
A Division of Ventura County Health Care Agency

Ventura County Health Care System Oversight Committee
Administrative Policies
February 8, 2024

The following administrative policies were reviewed and recommended for approval by appropriate departments and committees.

1. 100.011 Hospital Visitation
2. 101.008 General Dress Policy
3. 107.003 Emergency Department Saturation and Ambulance Diversion
4. 107.087 Equipment and Supply-Related Incident Investigation
5. 108.052 Belonging Searches
6. L.55 Newborn Screening Specimen Handling
7. L.56 HemoCue® Hb 801 Analyzer System
8. L.57 First Sign Drugs of Abuse Test Cups
9. L.BB.18 Reporting of Transfusion Fatalities
10. L.BB.35 Hematype Segment Device
11. L.BB.36 Check Type - ABO/Rh Confirmation
12. L.BB.59 Rh (D) Typing
13. L.BB.62 Cryoprecipitated Antihemophilic Factor (AHF)
14. L.BB.78 Blood Bank Correlation of Methods
15. L.BB.96 Quality Control of Blood Bank Reagents
16. L.BB.100 Critical Supplies and Services
17. L.CHEM 1.11 Beta Human Chorionic Gonadotropin (BHCG)
18. L.CHEM 1.14 C3 Complement (C3)
19. L.CHEM 1.15 C4 Complement (C4)
20. L.CHEM 1.23 C- Reactive Protein (CRP)
21. L.CHEM 1.25 Direct Bilirubin (DBIL)
22. L.CHEM 1.26 Digoxin (DIGXN)
23. L.CHEM 1.27 Alcohol (ETOH)
24. L.CHEM 1.28 Ferritin (FERR)
25. L.CHEM 1.29 Folate (FOL)
26. L.CHEM 1.30 Free Prostate Specific Antigen (FPSA)
27. L.CHEM 1.32 Gentamicin (GENT)
28. L.SPH.10 Amylase
29. L.SPH.29.1 DIMENSION LIPASE ASSAY
30. L.SPH.39 Total Bilirubin
31. PH.16 Pharmaceutical Borrowing and Loaning
32. PH.18.02 340B Drug Pricing Program: Federally Qualified Health Center
33. R.09 Arterial Blood Gas Sampling and Testing Proficiency Program
34. R.20 Blood Gas Laboratory RapidPoint 500 Analyzer Quality Control Program
35. R.54 Designees in the Blood Gas Laboratory

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Administrative Policies - February 8, 2024
Summary of Changes

#	Title	Summary of Changes	Review Period
1	100.011 Hospital Visitation	Adding language stating visitors may be asked to mask.	Triennial
2	101.008 General Dress Policy	Reviewed and made changes in discussion with Labor Relations.	Triennial
3	107.003 Emergency Department Saturation and Ambulance Diversion	Edited to add trauma diversion language and title change.	Triennial
4	107.087 Equipment and Supply-Related Incident Investigation	Broadened scope of policy from Facilities to Administrative-Operating policy. Revised policy statement and procedures to reflect contemporary practice. Added requirement to sequester failed equipment/supply and any related packaging.	Triennial
5	108.052 Belonging Searches	Added illicit drugs and alcohol removal	Triennial
6	L.55 Newborn Screening Specimen Handling	New Policy	Biennial
7	L.56 HemoCue® Hb 801 Analyzer System	New Policy	Biennial
8	L.57 First Sign Drugs of Abuse Test Cups	New Policy	Biennial
9	L.BB.18 Reporting of Transfusion Fatalities	Revised with latest practices. Renamed this Policy Area from Blood Bank to Laboratory Services - Blood Bank.	Biennial
10	L.BB.35 Hematype Segment Device	Updated material section. Renamed this Policy Area from Blood Bank to Laboratory Services - Blood Bank.	Biennial
11	L.BB.36 Check Type - ABO/Rh Confirmation	Minor language update. Renamed this Policy Area from Blood Bank to Laboratory Services - Blood Bank.	Biennial
12	L.BB.59 Rh (D) Typing	Minor editing. Renamed this Policy Area from Blood Bank to Laboratory Services - Blood Bank.	Biennial
13	L.BB.62 Cryoprecipitated Antihemophilic Factor (AHF)	Incorporated ISBT labeling process. Renamed this Policy Area from Blood Bank to Laboratory Services - Blood Bank.	Biennial
14	L.BB.78 Blood Bank Correlation of Methods	Added policy hyperlink. Updated references. Renamed this Policy Area from Blood Bank to Laboratory Services - Blood Bank.	Biennial
15	L.BB.96 Quality Control of Blood Bank Reagents	Minor language changes. Renamed this Policy Area from Blood Bank to Laboratory Services - Blood Bank.	Biennial
16	L.BB.100 Critical Supplies and Services	Minor language revisions. Renamed this Policy Area from Blood Bank to Laboratory Services - Blood Bank.	Biennial
17	L.CHEM 1.11 Beta Human Chorionic Gonadotropin (BHCG)	Migrated from paper format to PolicyStat	Biennial
18	L.CHEM 1.14 C3 Complement (C3)	Migrated from paper format to PolicyStat. Format updated	Biennial
19	L.CHEM 1.15 C4 Complement (C4)	Migrated from paper format to PolicyStat	Biennial
20	L.CHEM 1.23 C- Reactive Protein (CRP)	Migrated from paper format to PolicyStat	Biennial
21	L.CHEM 1.25 Direct Bilirubin (DBIL)	Migrated from paper format to PolicyStat	Biennial
22	L.CHEM 1.26 Digoxin (DIGXN)	Migrated from paper format to PolicyStat	Biennial
23	L.CHEM 1.27 Alcohol (ETOH)	Migrated from paper format to PolicyStat. Spelling out Ethyl Alcohol in opening statement of policy.	Biennial
24	L.CHEM 1.28 Ferritin (FERR)	Migrated from paper format to PolicyStat	Biennial
25	L.CHEM 1.29 Folate (FOL)	Migrated from paper format to PolicyStat	Biennial
26	L.CHEM 1.30 Free Prostate Specific Antigen (FPSA)	Migrated from paper format to PolicyStat	Biennial
27	L.CHEM 1.32 Gentamicin (GENT)	Migrated from paper format to PolicyStat	Biennial
28	L.SPH.10 Amylase	Removed urine amylase from testing menu at Santa Paula Hospital Clinical Laboratory effective 07.16.2023	Biennial
29	L.SPH.29.1 DIMENSION LIPASE ASSAY	New Policy	Biennial
30	L.SPH.39 Total Bilirubin	Added Section "Neonatal Bilirubin Testing" to meet College of American Pathologists Checklist LSV.40675.	Biennial
31	PH.16 Pharmaceutical Borrowing and Loaning	Update for new DSCSA requirements. Approved Dec 2023 Pharnacy & Therapeutics Committee	Triennial
32	PH.18.02 340B Drug Pricing Program: Federally Qualified Health Center	New policy	Annual
33	R.09 Arterial Blood Gas Sampling and Testing Proficiency Program	Minor changes per College of American Pathologists	Biennial
34	R.20 Blood Gas Laboratory RapidPoint 500 Analyzer Quality Control Program	Updated procedure section	Biennial
35	R.54 Designees in the Blood Gas Laboratory	Revised attached org chart	Biennial

Status **Active** PolicyStat ID **14958592**

Origination	11/22/2017	Owner	Jason Arimura: Associate Hospital Administrator-AncillaryServices
Last Approved	1/2/2024		
Effective	1/2/2024	Policy Area	Administrative - Operating Policies
Last Revised	1/2/2024		
Next Review	1/1/2027		

100.011 Hospital Visitation

POLICY:

In order to ensure the safety and security of patients, employees and volunteers of Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH), to maintain an orderly environment and assist patients and visitors with finding their destination, there is controlled access to both facilities. Hospital visitation guidelines are available in English and Spanish in the Patient Information Booklet.

At designated entrances only, all guests will be required to check in as either a visitor or a vendor and will then be issued a wrist band or vendor identification (ID) badge.

PROCEDURE:

There are specific designated entrances at both VCMC and SPH available for patients, visitors, vendors and employees. Any person in the hospital without a visitor or vendor wrist band, vendor ID badge or employee badge should be directed to one of the hospital entrances so that they may sign in and be issued a wrist band or vendor ID badge.

HOSPITAL VISITATION GUIDELINES

For the welfare of our patients and to contribute to each patient's recovery, we urge all visitors to observe the following visitation guidelines:

A. Regular visitation hours are from 9:00 a.m. to 9:00 p.m. daily.

B. Patient visits should not exceed two (2) visitors at any given time, unless there is a special circumstance and approved by the Department Manager or House Supervisor.

C. Visitors must be in good health. Visiting is not allowed if the visitor is ill.

D. Visitors are required to comply with all hospital infection control policies.
    1. Visitors of Neonatal Intensive Care Unit (NICU), Pediatrics Unit, Pediatric Intensive Care Unit (PICU), immunocompromised or other high-risk patients may be asked to mask based on community prevalence of respiratory illnesses or at the discretion of the provider or nurse in charge.

E. Service animals will continue to be allowed entrance.

F. No visitors under the age of 13 are permitted in patient care areas unless they are the parents of hospitalized children, the significant other of a laboring person, a brother or sister of a child who is a patient in NICU, Pediatrics Unit, PICU, Obstetrics Unit (OB) or family members of a terminally ill patient. Visitors meeting this criteria may visit under these conditions:
    1. Siblings may visit during regular visitation hours only. They must be accompanied by a responsible adult.
    2. Siblings must be in good health, as determined (when necessary) by a nurse or physician on the unit.

G. Shoes and shirts are required for all visitors.

H. Noise levels should be kept to a minimum in the corridors and while in patient rooms.

I. No food should be brought in from outside the hospital unless approved by physician and/or nursing staff. Visitors should only eat in patient areas after conferring with nursing staff. Visitors may go to the cafeteria to purchase food.

J. Smoking is prohibited anywhere on hospital grounds, including all parking areas. Smoking includes the use of cigarettes, cigars, water pipes, pipes, hookahs, marijuana (including medical marijuana) and electronic smoking devices, such as e-cigarettes and vaping pens. There are no designated smoking areas on Hospital property. See policy *106.004 Smoking Policy* for more information.

K. Fresh or dried flowers, or potted plants, are not allowed in patient-care areas for immunosuppressed patients.

L. Pediatrics Unit and Pediatric Intensive Care Unit (PICU) - We invite parent participation in the Pediatrics and PICU Unit. One parent may stay with the patient at all times as space allows. Grandparents or other significant adult(s) may visit with a parent, unless otherwise specified. Prior to sibling visitation in the PICU, a joint discussion concerning the risks and benefits of visitation will be had with the charge nurse, Child Life Specialist, physician and parents. See policy *P.32 PICU, NICU and PEDS Visiting Policy* for more information.

M. Neonatal Intensive Care Unit (NICU)-We invite parent participation in the NICU Unit. Parents will be required to wear their identification armband when visiting. One parent may stay with the patient at all time as space allows. Grandparents or other significant adult(s) may visit with a parent unless otherwise specified. See policy *P.32 PICU, NICU and PEDS Visiting Policy* for more information.

N. Emergency Department
    1. No children under the age of 13 unless they are the patient, the parent of a patient, or the support person of a pregnant person.
    2. Children must be accompanied by an adult, when in the ED or the waiting room.

3. In critical situations, family members can stay at bedside at the nurse's discretion.
4. The Quiet Room may be utilized for families in critical situations.
5. To provide a safe environment, visitors are asked to refrain from multiple entries and exits from the patient care area.
6. The ED is not to be used as a thoroughfare to other areas of the hospital. Visitors should use an alternate entrance to gain entry into the hospital, with the exception of off hours when the front lobby is closed.
7. Visitation for ED Hold patients will follow the rules for visitation in the ED.

O. Obstetrics Unit
    1. The support person of the patient may stay in post-partum or ante-partum overnight. A sibling must be accompanied by an adult. The support person will receive an identification bands at the time of delivery.

P. Post Anesthesia Care Unit (PACU) - Visitors will be restricted to the parent(s) of a minor, the parents(s) or caregiver of persons with special needs and under special conditions.

Q. Visitation hours for the Inpatient Psychiatric Unit (IPU) are Monday through Friday, 5:30 p.m. through 7:20 p.m., and on weekends and holidays, 12:30 p.m. to 2:30 p.m. We do attempt to accommodate visits during times other than those posted on an individual basis. It requires a physician's order and should be arranged in advance.

R. Exceptions to the visitation policy may be made in extenuating circumstances. This will be done with collaboration between Medical Staff, Nursing Supervisor, the patient and their family.

S. In the event of an infectious disease outbreak, the visitor policy may be adjusted at the recommendation of the Infection Control Committee, the Medical Director of Infection Control and Prevention, or the Hospital Chief Medical Officer. If adjusted, the policy will be reviewed on a monthly basis.

The VCMC entrance will be open daily from 5:00 am until 9:00 pm. The Customer Service desk at VCMC will be staffed by one to two Security Guards 24 hours a day, 7 days a week, as well as a Customer Service employee from 5:00 am to 9:00 pm. At SPH the entrance will be open from Monday through Friday 6:30 am to 9:00 pm and Saturday through Sunday 8:30 am to 6:30 pm. Entrance can be gained through the Emergency Department when the front lobby is closed.

Upon entering, guests will check in as a visitor or a vendor and be issued either a wrist band or vendor ID badge. Employees entering the facility through the Main Entrance must wear hospital ID badges. Employees without hospital ID badges will be issued a visitor wrist band which must be worn for the duration of their time spent in the Hospital. If a visitor or vendor is noted anywhere in either hospital without an wrist band or vendor ID badge, they will be instructed to obtain a wrist band or vendor ID badge. All vendors shall comply with policy *106.083 Vendor Access and Registration*.

Emergency Department Entrance. The ED at VCMC and SPH will be staffed with a Security Guard 24 hours a day, 7 days a week.

VCMC Hillmont Surgery Entrance. This entrance will be designated for staff and providers only via

badge access. No patients, visitors or vendors will be permitted to enter the Hospital through this entrance. Staff and providers may enter through this entrance 24 hours a day, 7 days a week.

VCMC Loma Vista MRI Trailer Entrance. This entrance will be designated for staff and providers only via badge access. No patients or visitors will be permitted to enter the Hospital through this entrance. Staff may enter through this entrance 24 hours a day, 7 days a week.

VCMC Radiology Entrance. This entrance is closed to everyone.

VCMC Lab Entrance. This entrance will be designated for staff and providers only via badge access. No patients or visitors will be permitted to enter the Hospital through this entrance. Staff and providers may enter through this entrance 24 hours a day, 7 days a week.

VCMC Boardwalk Entrance. This entrance will be designated for staff and providers only via badge access. No patients or visitors will be permitted to enter the Hospital through this entrance. Staff and providers may enter through this entrance 24 hours a day, 7 days a week.

SPH Staff Entrance. This entrance will be designated for staff and providers only via badge access. No patients or visitors will be permitted to enter the Hospital through this entrance. Staff may enter through this entrance 24 hours a day, 7 days a week.

REFERENCE:

Patient Information Booklet. Ventura County Medical Center and Santa Paula Hospital. [VCHCA-505-050 (01/2020)]

All Revision Dates

1/2/2024, 9/18/2023, 7/6/2023, 3/8/2023, 11/22/2017

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Diana Zenner: Chief Operating Officer, VCMC & SPH	1/2/2024
Policy Owner	Jason Arimura: Associate Hospital Administrator-AncillaryServices	12/29/2023

Status **Active** PolicyStat ID **7441524**

Origination	12/1/1993	Owner	Jason Arimura: Associate Hospital Administrator-AncillaryServices
Last Approved	1/16/2024		
Effective	1/16/2024	Policy Area	Administrative - Employee
Last Revised	1/16/2024		
Next Review	1/15/2027		

101.008 General Dress Policy

POLICY:

Staff shall dress in a manner that promotes patient care, safety and comfort. It is the intent of the policy to provide standards that must be adhered to by all personnel while on duty. It is not the intent of this policy to cover every item or style of dress that is available, but rather to provide guidelines for decisions and interpretations regarding the appearance of Ventura County Medical System staff.

PROCEDURE:

Specific expectations include, but are not limited to:

1. Dress: Employees purchase and care for their own work clothes unless certain items are required for safety, infection control or other specified purposes. Clothing must be clean and unwrinkled. Dress is to be suitable for the position and department. Specifically:
    a. Clothing must cover the body and undergarments at all times when the wearer is standing, sitting, bending or stretching.
    b. Blue denim jeans are not permitted. Faded or worn denim or faded or worn look fabric of any color is not permitted.
        a. Colored jeans will be permitted.
    c. T-shirts are not permitted, except those pre-approved by the Ventura County Medical System.
    d. Individuals required to wear uniforms shall adhere to the department specific dress code.
2. Shoes: Shoes must be worn which are safe for the working conditions according to department requirements, and appropriate for the type of clothing worn.

a. Clogs and sandals may be worn if they are appropriate for the work setting and conditions. Certain positions may necessitate the wearing of only closed toe footwear to ensure safety for the wearer. Footwear will not impede the ability of the wearer to carry out the functions of the position and respond appropriately to an emergent situation. Thongs may not be worn.

b. Clean athletic or duty shoes of an appropriate color may be worn.

3. Hair: Hair must be clean and neatly groomed.
    a. In patient care areas, if hair is longer than shoulder length, it must be pulled back away from the face during the performance of care or procedures that would pose a risk to the patient or employee.
    b. In those areas where law requires, nets and/or caps must confine hair.
4. Tattoos: Tattoos which may be considered offensive by patients or visitors must be covered by clothing or another method of covering, i.e. Band-Aid, makeup. Examples of tattoos that can be construed as offensive include but are not limited to profanity, nudity, hate or gang symbols.
5. Jewelry: Jewelry must not compromise safety.
6. Hand Hygiene: Artificial nails, tips and/or fillers will not be allowed for any staff who have direct contact with patients. Natural nails will be no longer than ¼" beyond the tip of the finger.
7. ID Badge: Hospital or clinic identification badge is to be worn at all times when on duty. It must remain free of pins and decorations that cover any of the identifying information. The badge will be worn above the waist at all times where it is easily readable for patient, visitor and co-worker convenience.
8. Nursing and Clinical Staff: Staff who provide direct patient care must wear clothing that is immediately recognizable by the general public as a patient-care uniform/scrubs. Other clinical staff, while carrying out patient care responsibilities, may wear white or colored uniforms, or professional attire covered by a clean, lab-style coat.
    a. Clean duty or athletic shoes of an appropriate color in good repair with closed toe and heel are to be worn.
    b. Direct patient care staff are required to wear stocking or socks.
    c. When lab coats are worn the general provisions of the dress policy also apply.
9. Meetings, Education Classes: Personnel who attend staff meetings and education classes on campus are on paid time and must be attired appropriately. Those who choose to wear "casual attire" for these purposes should confine their activities to the classrooms/meeting rooms and avoid contact with the public.
    a. Acceptable: Clothing which is clean and neat, laundered, pressed and unwrinkled, in good repair, without the "worn" look of appropriate length and fabric. Neat and clean jeans in good repair are allowed during attendance at meetings and education classes.
    b. Unacceptable: Plunging necklines, open backs, tank tops, bare midriffs, strapless dresses, shorts and spandex, sweat shirts and sweat pants.
10. Personal Grooming: Personal cleanliness is mandatory for all employees. Makeup and the use

of perfume shall be in moderation. Perfume sensitive individuals should inform their supervisor and discuss options.

11. Standards Not Met: The ultimate responsibility for determining the appropriateness of attire is that of the department manager, house supervisor or designee.
    a. An employee who reports to work, meeting or class not meeting the standard set forth in this policy may be sent home by the individuals identified above to correct the inappropriate attire or grooming.
    b. Lost time from work may be without pay.
    c. An individual who repeatedly reports to work in inappropriate dress may be subject to disciplinary action.

Any individual who believes that this policy is not being uniformly implemented should discuss these concerns with his/her immediate supervisor or department manager.

All Revision Dates

1/16/2024, 1/1/2010, 5/1/2006, 1/1/2004, 11/1/2003, 11/1/1998

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Diana Zenner: Chief Operating Officer, VCMC & SPH	1/16/2024
Ambulatory Care Administration	Lizeth Barretto: Chief Operating Officer, Ambulatory Care	1/11/2024
Ambulatory Care Administration	Cynthia Fenton: AC Director of Nursing	1/5/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	1/4/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	1/4/2024
Policy Owner	Jason Arimura: Associate Hospital Administrator-AncillaryServices	1/4/2024

Status **Active** PolicyStat ID **14780583**

Origination	12/1/1998
Last Approved	12/4/2023
Effective	12/4/2023
Last Revised	12/4/2023
Next Review	12/3/2026
Owner	Julia Feig: Clinical Nurse Manager, Emergency Services
Policy Area	Administrative - Operating Policies

107.003 Emergency Department Saturation and Ambulance Diversion

POLICY:

In accordance with Emergency Medical Services (EMS) Policy Number 402 (see Attachment A), Ventura County Medical Center (VCMC)/Santa Paula Hospital (SPH) has developed procedures to initiate, update, or cancel diversion restriction status.

PROCEDURE:

A. The Emergency Department (ED) Charge Nurse will assess, document and communicate the need for diversion to the Clinical Director or House Supervisor.

B. The Clinical Director or House Supervisor will call and discuss with the ED charge nurse the need for diversion in one (1) or more of the following four (4) categories, and will notify the Administrator on Duty (AOD):

    1. Internal disaster
    2. ED saturation
    3. Lack of CT scanner capabilities
    4. ICU/CCU saturation

C. The REDDINET (Rapid Emergency Digital Data Information Network) will be used to initiate, update, or cancel diversion, as well as notify EMS, all hospitals, and ambulance dispatch agencies of the diversion status.

D. The ED Charge Nurse shall document and assess the diversion status and will remove the status as soon as possible. The House Supervisor will check hourly to determine the ability to go off diversion and will be made aware of any changes to the diversion status.

E. This policy does not negate previous triage agreements arranged with other hospitals.

F. This policy does not effect those situations where a patient at another facility requires special services offered only at VCMC.

G. VCMC will make every effort to not divert any trauma patients. If staff believes that trauma diversion may be needed (ie in case of internal disaster only), it requires approval from the both the AOD and the trauma program medical director or designee.

All Revision Dates

12/4/2023, 2/23/2021, 10/1/2016, 6/1/2008, 6/1/2006, 1/1/2005, 7/1/2001

Attachments

107.003 - Attachment A.pdf

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Diana Zenner: Chief Operating Officer, VCMC & SPH	12/4/2023
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	12/4/2023
Policy Owner	Julia Feig: Clinical Nurse Manager, Emergency Services	12/4/2023

Status **Active** PolicyStat ID **14905005**

VENTURA COUNTY HEALTH CARE AGENCY

Origination	12/10/1992
Last Approved	12/19/2023
Effective	12/19/2023
Last Revised	12/19/2023
Next Review	12/18/2026
Owner	Jason Arimura: Associate Hospital Administrator-AncillaryServices
Policy Area	Administrative - Operating Policies

107.087 Equipment and Supply-Related Incident Investigation

POLICY:

Any incident related to equipment or supplies that poses a risk to patient, visitor or employee safety shall be properly investigated and documented.

PROCEDURE:

1. Staff shall notify their department manager or designee anytime there is a failure of equipment or supply and poses a risk to patient, visitor or employee safety.
2. Staff shall sequester the failed equipment or supply, including any packaging, for further investigation. The failed equipment or supply shall not be used until the investigation is complete and the equipment or supply is fixed.
    1. See policy *107.044 Surgical Pathology Specimen Procedure* for any incident that results in a retained foreign object that needs removal.
3. The department manager or designee shall notify either the Facilities or Biomedical Engineering department for equipment-related issues, or the Central Supply department for supply-related issues.
4. The department manager or designee shall submit a notification report containing at least the following information:
    - The date, time and location of the incident.
    - The generic description of the equipment (cardiac monitor, defibrillator, etc.), trade name, model, and serial number.
    - The equipment identification number.

- Lot number for supplies.
- A brief description of the incident.
- Unusual sounds or other abnormalities exhibited by the equipment at or before the incident.
- Perform physical inspection of the equipment to identify obvious defects or damage.
- The results of any electrical safety and/or functional testing done following the incident.
- A determination as to whether the equipment was actually responsible for the incident.
- Whether the equipment is to be held with the Facilities Maintenance Department, Biomedical Engineering Department or returned to service.
- The name and position of the person completing the report.

5. If it is suspected that the incident was caused by an equipment malfunction, the Facilities Manager or designee stores the equipment in a secure area until advised otherwise by hospital administration.
6. If the incident is not related to an equipment malfunction or is caused by improper use of the equipment, the Facilities Manager or designee shall return the equipment to the department and advise the department manager accordingly.

All Revision Dates

12/19/2023, 12/9/2013, 8/25/2009, 1/4/2008, 12/7/2004, 12/10/1992

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Diana Zenner: Chief Operating Officer, VCMC & SPH	12/19/2023
Policy Owner	Jason Arimura: Associate Hospital Administrator-AncillaryServices	12/18/2023

Status **Active** PolicyStat ID **14915572**

Origination	8/24/2023	Owner	Danielle Gabele: Chief Nursing Executive, VCMC & SPH
Last Approved	12/20/2023	Policy Area	Administrative - Nursing
Effective	12/20/2023		
Last Revised	12/20/2023		
Next Review	12/19/2026		

108.052 Belonging Searches

Purpose

To maintain the safety of all patients and staff and to decrease the possibility of any contraband being brought into the hospital, all patient belongings will be thoroughly searched by staff for any patient upon admission and transfers. The unit staff will secure any potentially dangerous items or contraband. This routine search can be completed without a physician's order to assure safety within the unit. The search is completed at time of admission and/or any time new items are received during a patient's continued inpatient stay. This process can also be initiated or repeated by staff at the discretion of said staff members caring for patients in any unit in the hospital. NOTE: Inpatient Psychiatry Unit (IPU) and 3FST have separate contraband policies. See policy Z.19 and 108.053.

Procedure

1. A search includes asking the patient to remove all items from their pockets and turn out their pockets on all jackets, shirts/sweatshirts and or pants. Patients will remove their shoes and socks to ensure that any contraband or other items are removed.
    a. Explain to the patient what you will do and why.
    b. Explain where things will be stored and how the patient may gain access to them.
    c. The search should be conducted in a professional manner and maintain the patient's privacy and dignity during the search.
    d. Remove all items from pockets, purses, luggage, etc.
    e. Check linings of suitcases and purses for contraband
    f. Clothing and other items should be checked carefully
    g. Clothing is to be unfolded and zippers unzipped; look for belts or drawstrings
    h. Clothing with pockets and hems should be checked thoroughly for hidden items

i. Open toiletry containers, cosmetic cases and other items that may contain other objects and check them thoroughly

j. Be aware of mouthwashes, toothpaste, hygiene items with alcohol, check to assure that wells of powders, eye shadows, etc. are secure and do not have hollow bottoms

k. Shoes should be checked inside

l. Belts, shoelaces, hooded sweatshirts and drawstrings will be removed

2. Items deemed as unsafe and not for use in the facility should be sent home with family or secured to be locked in safe storage on the unit. Items deemed as potentially unsafe but appropriate for periodic use for supervised patients should be placed in a container to be locked in the patient belongings area on the unit. All items retained in the facility's possession are to be listed on the Patient Belonging Form.
3. If there is a suspicion that a patient may be harboring contraband on his/her person, the staff should contact department leadership (or nursing supervisor after hours). Security may be called to stand by. The manager/nursing supervisor/AOD will determine if local law enforcement should be called for body search.
4. For a list of contraband items, please see the IPU and Acute Detoxification Services contraband policies.
5. Illegal substances shall be reported to police department including illicit drugs. Alcohol will also be sequestered if found and disposed of.
6. Wallets, money, and valuables will be placed in a sealed plastic bag, sealed, stored, and signed off on by Security.
7. Patients with 1:1 safety attendants for danger to self or others will NOT be permitted to have belongings in the room (see policy 100.268 for C.A.S.E Safety Checklist).
8. Admission belonging checks will be performed and the form will be completed within the shift completing the admission of the patient to the unit and at any time, additional items are received.
9. Luggage, clothes, toiletries are to be checked in the following manner as well as logged on the Patient Belongings Form.
10. Weapons brought into the facility are to be sent home with family or significant other. In the event that the weapon cannot be sent home it will be stored in the unit safe, and Risk Management should be notified that a weapon is on the premise.
11. Patient medications brought from home will be given to the Pharmacy to be processed. The RN will encourage the family or significant other to take medications home.
12. All patients will have a routine patient search conducted by a member of the staff on admission and upon transfer. The procedure outlined in this policy describes the search/ belongings check performed when a patient enters the unit, moves within units, or brings new belongings to the hospital (including items from visitors).
13. Visitors are not permitted to bring items to any patient undergoing acute detoxification services or any patients who are suicidal or homicidal (voluntary or on a hold).
14. Two staff will be present during searches if clinically indicated.
15. Any assistive devices including eyewear, dentures, etc. brought from home will be indicated on

the form.

16. At the time of discharge, items will be returned to the patient. The units will not be responsible for any belongings left behind.
    a. Belongings left after patient is discharged:
        i. Belongings shall be bagged and marked with patient's information, time, and date.
        ii. Inform patient/representative that they may pick up belongings within thirty days after discharge
        iii. If items are not redeemed within 30 days of discharge, they may be disposed of by hospital staff or donated.
        iv. Under rare conditions, hospital may assume responsibility of mailing personal items to discharged patients.

All Revision Dates

12/20/2023, 12/19/2023, 12/19/2023, 11/2/2023, 10/31/2023, 10/25/2023, 10/23/2023, 8/24/2023

Approval Signatures

Step Description	Approver	Date
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	12/20/2023
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	12/20/2023
Policy Owner	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	12/20/2023

Status **Active** PolicyStat ID **14797473**

Origination	12/12/2023	Owner	Erlinda Roxas: Director, Laboratory Services
Last Approved	12/12/2023		
Effective	12/12/2023	Policy Area	Laboratory Services
Last Revised	12/12/2023		
Next Review	12/11/2025		

L.55 Newborn Screening Specimen Handling

PURPOSE:

To ensure proper and timely handling and disposition of newborn screening specimens.

POLICY:

Upon receipt of newborn screening specimens, lab personnel shall log and package newborn screening specimens for courier pick up.

See also policy *MCH.02 Newborn Screening of Infants*.

MATERIALS:

A. California Newborn Screening Test Request Form
B. Newborn screening specimen bar code labels
C. VCMC/SPH Newborn Screen Log (Attachment A)
D. VCMC/SPH Newborn Screening Transport Log (Attachment B)
E. State of California Newborn Screening Transport Log & Instructions [CDPH 4406] (Attachment C)

PROCEDURE(S):

A. Receiving Specimens From the Labor & Delivery Department
    1. Log receipt of newborn screening specimens into VCMC Newborn Screen Log (Attachment A).
    2. Complete the VCMC Newborn Screening Transport Log (Attachment B)

3. Print from Cerner, newborn screening specimen bar code labels for each specimen received.
    a. Affix newborn screening specimen bar code labels to the VCMC Newborn Screening Transport Log (Attachment B)
    b. Document the NBS Form Number.
4. Document the courier tracking number on the VCMC Newborn Screening Transport Log (Attachment B).
5. Create a photocopy of the VCMC Newborn Screening Transport Log (Attachment B) and the front page of the California Newborn Screening Test Request Form for each specimen.
    a. Retain these records for one year.

B. Complete the Newborn Screening Specimen Transport Log
1. Fill in the name and code of facility collecting specimens.
2. Enter the date the log is prepared.
3. Enter the name of the person who prepared the list.
4. For each specimen to be sent to the screening laboratory; enter the:
    a. newborn's name
    b. sex (M or F)
    c. NBS form number
    d. newborn's medical record number
5. Enter the number of specimens. Check to ensure that the number of specimens listed on the log matches the number of specimens placed in the courier envelope.
6. On Sender's Copy, affix copy of the Courier's Tracking Number to use for tracking shipment.
7. On Sender's Copy, the Courier prints his name, signs, and indicates date and time of pick-up.
8. Keep the Sender's Copy for your records.
9. Note: Do not list more than 12 specimens per transport log. Put only one transport log and associated samples per envelope. If you are using more than one envelope, apply a shipping label to each envelope/package. Seal envelope(s) and place in the designated spot for Courier collection.

C. Prepare the envelope for final shipment.
1. Obtain courier envelope.
2. Adhere the courier tracking number label onto the front of the envelope.
3. Insert the completed State of California Newborn Screening Transport Log .
4. Insert the California Newborn Test Request Forms/Specimens.
5. Seal the envelope and place the envelope in the Apollo Courier outbox.

6. Document on the VCMC Newborn Screen Log the following:
    a. Prepared by
    b. API Package Number (Courier Tracking Number)
    c. Date Sent

D. Courier will pick up the envelope daily and deliver to the California Newborn Screening Lab.
    1. Upon courier pick up, the courier shall record the date and time of pick up, name, number of packages, API Package Number (courier tracking number).

E. Designated lab personnel to review the VCMC Newborn Screen Log (Attachment A) daily.
    1. Lab personnel performing this function shall sign and date at the bottom of the form.

REFERENCE(S):

California Department of Health - Newborn Screening Program

All Revision Dates

12/12/2023

Attachments

Attachment A - VCMC/SPH Newborn Screen Log

Attachment C - State of California Newborn Screening Transport Log & Instructions

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	12/12/2023
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	12/12/2023
Laboratory Services Department	Erlinda Roxas: Director Laboratory Services	11/30/2023

Status **Active** PolicyStat ID **14656074**

Origination	12/12/2023	Owner	Erlinda Roxas: Director, Laboratory Services
Last Approved	12/12/2023		
Effective	12/12/2023	Policy Area	Laboratory Services
Last Revised	12/12/2023		
Next Review	12/11/2025		

L.56 HemoCue® Hb 801 Analyzer System

I. PURPOSE:

To provide step-by-step instructions for using the HemoCue® Hb 801 System. The test is for quantitative determination of hemoglobin in capillary whole blood in point-of-care settings. The HemoCue® Hb 801 System is intended to be used to determine the hemoglobin concentration for adults, adolescents, children, and infants above 1 month old. The HemoCue® Hb 801 System is for professional in vitro diagnostic use only.

II. EXPLANATION OF TEST:

The HemoCue® Hb 801 System consists of an analyzer together with microcuvettes. The microcuvette serves as both a pipette and as a sample carrier. Blood is drawn into the microcuvette cavity by capillary action. The measurement takes place in the analyzer, which measures the absorbance of whole blood at an Hb/HbO2 isosbestic point (506nm), and at a wavelength (880nm) to compensate for possible interfering background (e.g. turbidity).

The HemoCue® Hb 801 System is calibrated against the hemiglobincyanide (HiCN) method, the international reference method recommended by ICSH (International Council for Standardization in Haematology), for the determination of the hemoglobin concentration in blood. The system is factory calibrated and needs no further calibration.

III. EQUIPMENT & SUPPLIES:

A. Patient Test Materials:
    1. HemoCue® Hb 801 Analyzer
    2. HemoCue® Hb 801 Microcuvettes

3. High-flow Lancets
4. Alcohol Wipes
5. Protective Gloves

B. Quality Control Materials:
    1. EuroTrol: HemoTrol Duo Control- Low Level
    2. EuroTrol: HemoTrol Duo Control- High Level

C. Cleaning & Disinfection Materials:
    1. Lint-free tissue such as Mesoft or gauze
    2. Cotton tipped swab
    3. Water, alcohol (20-70%), or mild detergent (Cleaner)
    4. Super Sani-Cloth Germicidal Wipes (Disinfectant)

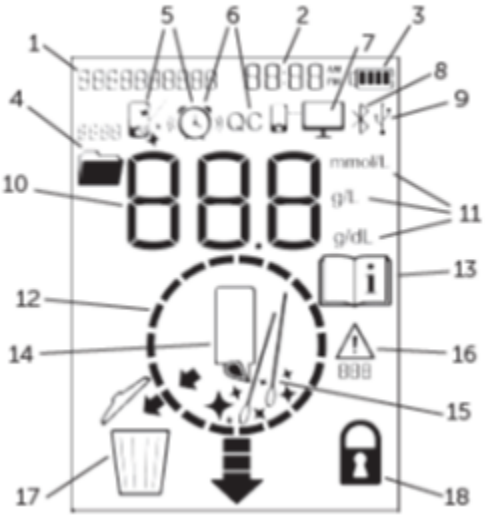
IV. PRECAUTIONS:

A. Follow universal precautions while collecting and handling blood samples. Always wear protective gloves.
B. Only use the HemoCue® Hb 801 Analyzer together with HemoCue® Hb 801 Microcuvettes.
C. The HemoCue® Hb 801 Microcuvettes are for single use only.
D. To achieve accurate capillary sampling results, always follow the procedure in the operating manual.
E. Always visually inspect the microcuvette after filling. Discard if air bubbles present or if not filled completely.
F. Do not let more than 40 seconds pass between filling and inserting the microcuvette into the holder.
G. Follow local safety procedures for disposal of used microcuvettes.

V. SPECIMEN COLLECTION & ANALYSIS:

A. START UP PROCEDURE
    1. Place the analyzer on a horizontal and stable surface
    2. Press and hold the on/off button until all display segments show.
    3. Release and wait a few seconds, until the analyzer is in the ready state.

4. The display during start-up, when all display segments are lit:



1. date
2. time
3. battery status
4. previous results, sequence
5. cleaning reminder*
6. QC reminder*
7. connectivity*
8. Bluetooth setting; on
9. USB cable connected
10. measurement result
11. unit
12. analyzer busy
13. consult instructions for use
14. ready for measurement
15. cleaning needed
16. error code
17. discard microcuvette
18. analyzer lockout*

Ready State

Starting position for most actions.

B. SAMPLE COLLECTION

1. Capillary or venous whole blood samples collected with HemoCue® Hb 801 Microcuvettes are acceptable.
2. The analyzer should be in the “ready state” prior to filling the microcuvette.
3. Remove a microcuvette from the vial and recap the vial immediately.
4. Make sure the patient’s hand is warm and relaxed. Use only the middle or ring finger for sampling. Avoid fingers with rings on. Sample at the side of the fingertip for best blood flow and comfort.
5. Clean the puncture site with an alcohol swab and allow to dry.
6. Using your thumb, lightly press the finger from the top of the knuckle towards the fingertip to stimulate blood flow.
7. While applying light pressure towards the fingertip, puncture the fingertip using a high flow lancet.
8. Using a dry gauze or other lint-free tissue, wipe away the first two or three large drops of blood, applying light pressure as needed again until another drop of blood appears.
9. Make sure that the drop of blood is big enough to fill the microcuvette completely. Hold the microcuvette opposite the filling end and introduce the microcuvette tip and fill the microcuvette in one single step. Do not refill.
10. Wipe off any excess blood from the outside of the microcuvette using a clean, lint-free wipe. Do not touch the open end of the microcuvette.

C. SAMPLE ANALYSIS

1. Look for air bubbles in the filled microcuvette. If present, discard the microcuvette and fill a new microcuvette from a new drop of blood.
2. Place the microcuvette into the cuvette holder and start the measurement as soon as possible, but no later than 40 seconds after filling the microcuvette, by gently pressing the cuvette into the microcuvette holder.
3. The hemoglobin value is displayed within a second. The result will remain on the display for 10 seconds after the measurement.
4. Remove and discard the microcuvette in an appropriate biohazard container.
5. When the display shows the “ready state” symbol, the analyzer is ready for the next measurement.

D. INTERPRETATION OF PATIENT TEST RESULTS:
    1. The analyzer’s display window shows the hemoglobin result. No calculation is needed.
    2. The reportable range of the Hemocue Hb 801 system is 1.0–25.6 g/dL.
        a. Results will display as LLL when below the measuring range.
        b. Results will display as HHH when above the measuring range.
    3. Results outside of the normal range will be immediately reported to the ordering provider.
    4. A capillary blood sample that generates a critically low or critically high hemoglobin result should be confirmed with a STAT venous sample for laboratory analysis.
        a. Critical Low if 65 years of age or younger: ≤ 6.5 g/dL
        b. Critical Low if older than 65 years of age: ≤ 6.8 g/dL
        c. Critical High regardless of age: ≥ 23.0 g/dL

VI. QUALITY CONTROL:

A. SELF-TEST- The HemoCue® Hb 801 Analyzer has an internal quality control, a self-test. It automatically verifies the performance of the analyzer every time the analyzer is turned on, when the microcuvette holder is put into place after removal, and every hour when in use.

B. EXTERNAL QUALITY CONTROL- Two levels of controls (low/high) should be run with each new shipment, each new lot, upon opening a new bottle of Microcuvettes and monthly on open bottles to check storage conditions.
    1. The analyzer should be in the “ready state” prior to filling the microcuvette.
    2. Dispense a drop of control onto a hydrophobic surface and follow Steps 9-14 of the “Sample Collection & Analysis” procedures described above.
    3. Record the results on the quality control log.
    4. If the results do not fall within the established range, do NOT proceed to patient testing.

C. INTERPRETATION OF QUALITY CONTROL TEST RESULTS

1. For expected control values, refer the batch code specific table located on the package insert.
2. The hemoglobin level that appears on the HemoCue® Hb 801 Analyzer should be within the acceptable range provided for that control.
3. Do NOT proceed to patient samples unless both the Low-Level and High-Level control results are within the expected ranges.

VII. CLEANING & DISINFECTION:

A. Approved Cleaning Agents & Disinfectants
    1. Cleaning Agents: water, alcohol (20-70%), mild detergent or recommended disinfectant.
    2. Disinfectant: Super Sani-Cloth Germicidal Wipe, EPA Reg. No. 9480-4. Only use disinfectant recommended by HemoCue. Read and follow instructions for the disinfectant used.

B. CLEANING
    1. Turn off the analyzer and remove the microcuvette holder.
    2. Lightly dampen a cotton swap with cleaning agent and clean all surfaces of the microcuvette holder cavity. Clean all the way down to the bottom of the cavity. Clean the microcuvette holder cavity when the following displays:

    3. Clean the microcuvette holder with the cleaning agent and air dry.
    4. Wipe the exterior/outer surface of the analyzer with a wipe moistened with cleaning agent.

C. DISINFECTION- Before disinfection, the analyzer must be cleaned.
    1. Wipe the microcuvette holder repeatedly with a new Super Sani-Cloth Germicidal Wipe. Make sure all surfaces stay wet for 2 minutes.
    2. Wipe all outer surfaces repeatedly with a new Super Sani-Cloth Germicidal Wipe. Make sure all surfaces stay wet for 2 minutes.
    3. Remove any excess disinfectant or allow to air dry. Make sure all parts are completely dry before reattaching the microcuvette holder and turning on the analyzer.

VIII. STORAGE & STABILITY

A. MICROCUVETTES
    1. Microcuvettes are to be stored at 50-104°F (10-40°C). The vial should be kept tightly capped and microcuvettes should be removed as needed for testing just prior to use. Microcuvettes in the vial (opened or unopened) are stable until the expiration

date printed on the package.

2. Microcuvettes in the vial (opened or unopened) can be stored for a shorter period of time (6 weeks) between 0-122°F (-18-50°C).

B. EXTERNAL CONTROLS

1. Controls are stable at 2° to 8°C (36° to 46°F) until the expiration date on the vial label.
2. After opening, the controls are stable at 2° to 30° C (36°-86° F) for 31 days.

PROBLEM SOLVING & TECHNICAL SUPPORT

1. Refer to the "Troubleshooting" section of the Operating Manual if problems arise.
2. If problems persist, contact HemoCue America Technical Support at 800-426-7256 for additional assistance.

REFERENCES

1. HemoCue® Hb 801 Operating Manual (901912 190204 US)
2. HemoCue® Hb 801 System Package Insert (151904 191112 US)
3. HemoTrol® Duo Package Insert, November 4, 2019

All Revision Dates

12/12/2023

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	12/12/2023
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	12/12/2023
Laboratory Services Department	Erlinda Roxas: Director Laboratory Services	11/4/2023

Status Active PolicyStat ID 14553705

VENTURA COUNTY HEALTH CARE AGENCY

Origination	12/12/2023
Last Approved	12/12/2023
Effective	12/12/2023
Last Revised	12/12/2023
Next Review	12/11/2025
Owner	Erlinda Roxas: Director, Laboratory Services
Policy Area	Laboratory Services

L.57 First Sign Drugs of Abuse Test Cups

Intended Uses:

A. First Sign® Drug of Abuse Cup Test is a rapid test for the qualitative detection of D-Amphetamine 1000, 0-Amphetamine 500, Benzoylecgonine 300, Benzoylecgonine 150, 11-nor-119-THC-9-COOH, Oxazepam, Methamphetamine 1000, Methamphetamine 500, Morphine 2000, Methadone, Phencyclidine, Propoxyphene, Oxycodone, Butalbital, Buprenorphine, Morphine 300, 2-Ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine, Methylenedioxymethamphetamine, and Nortriptyline in human urine at a cutoff concentration indicated in the table below.

B. The First Sign® Drug of Abuse Cup Test may yield preliminary positive results when prescription drugs are ingested at prescribed doses. It is not intended to distinguish between prescription use and abuse of any drug. There are no uniformly recognized cutoff concentration levels for any drug in urine.

Drug (Identifier)	Cutoff Level	Minimum Detection Time	Maximum Detection Time
0-Amphetamine (AMP)	1000ng/mL	4-6 hours	2-3 days
D-Amphetamine (AMP 500)	500ng/ml	4-6 hours	2-3 days
Benzoylecgonine (COC)	300ng/ml	2-6 hours	2-3 days
Benzoylecgonine (COC 150)	150ng/ml	2-6 hours	2-3 days
11-nor-ll'-THC-9-COOH (THC)	song/ml	1-3 hours	1-7 days
Oxazepam (BZO)	300ng/ml	2-7 hours	1-4 days
Methamphetamine (mAMP)	1000ng/ml	4-6 hours	2-3 days

Methamphetamine (mAMP 500)	500ng/ml	4-6 hours	2-3 days
Morphine (OPI)	2000ng/ml	2-6 hours	1-3 days
Methadone (MTD)	300ng/ml	3-8 hours	1-3 days
Oxycodone (OXY)	100ng/ml	1-3 hours	1-2 days
Phencyclidine (PCP)	25ng/ml	4-6 hours	7-14 days
Propoxyphene (PPX)	300ng/ml	6-12 hours	1-3 days
Butalbital (BARB)	300ng/ml	2-4 hours	1-3 weeks
Buprenorphine (SUP)	10ng/ml	2-6 hours	2-4 days
Morphine (MOR)	300ng/ml	2-6 hours	1-3 days
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300ng/ml	3-8 hours	1-3 days
Methylenedioxymethamphetamine (MOMA)	500ng/ml	2-7 hours	2-4 days
Nortriptyline (TCA)	1,000ng/mL	8-12 hours	2-7 days

Explanation of Test:

A. The First Sign® Drug of Abuse Cup Test is an immunoassay. During testing, a urine specimen migrates upward on the test strip. A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip, while a drug-negative urine specimen will generate a line in the test line region. A colored line will always appear at the control line region, indicating that proper volume of specimen has been added.

B. The adulterant test strip contains chemically treated reagent pads. Observation of the color change on the strip compared to the color chart provides a semi-quantitative screen for oxidants, specific gravity, pH, creatinine, nitrite and glutaraldehyde in human urine which can help to assess the integrity of the urine specimen.

C. Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants in the urine specimen can cause false negative results by either interfering with the test and/or destroy the drugs present in the urine. Dilution may also be used to produce false negative drug test results. Tests that detect urinary characteristics such as specific gravity, pH, oxidants, nitrite, glutaraldehyde and creatinine are considered the best ways to detect adulteration or dilution.

Warnings & Precautions:

A. For in vitro diagnostic use.

B. For external use only.

C. For single use. Discard after first use.

D. Do not use the test if the pouch is punctured or not well sealed.

E. Do not use after expiration date.

F. Keep out of the reach of children.

G. The used test cup and urine specimen should be discarded according to federal, state and local regulations.

Specimen Collection:

Normal procedures for collecting urine may be used for specimens to be tested with the First Sign® Drug of Abuse Cup Test.

A. Urine from any time of day can be used. The minimum detection time varies for different drugs. (Refer to the approximate detection timetable above).

B. Freshly voided urine specimens should be used. If not analyzed immediately, specimens should be stored refrigerated for less than 24 hours. Specimens should be frozen if storage longer than 24 hours is required.

C. Urine specimens should be collected in clean, unbreakable, and leak proof containers.

D. Adulteration of the urine specimen may cause erroneous results. If adulteration is suspected, obtain a fresh specimen.

Materials:

A. Included in Test Kit

1. User Instruction
2. Test Cup (inside foil pouch)
3. Security Seal Label
4. Color Chart Card for Adulterants Interpretation (when applicable)

B. Not Included in Test Kit

1. Watch, Timer or Clock
2. First Sign® Drug of Abuse Urine Controls (Positive & Negative)

Patient Test Steps:

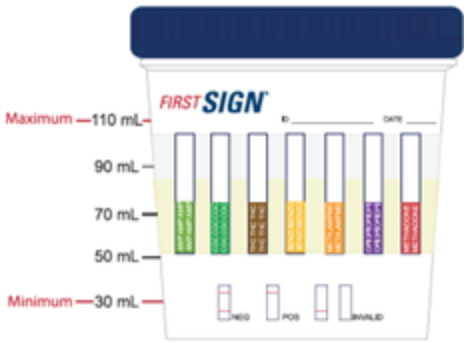
A. Remove the test cup from the sealed foil pouch. Peel back and remove the label from the test cup to show the drug test strips. Notice the colored tape on each strip correlates to the name of the drug you are testing for.

B. Remove the cap from the test cup. Fill the test cup with a minimum of 30 ml (see the minimum line mark) fresh urine sample. Do not over-fill (the maximum-line mark).

C. When finished, recap the test cup (be sure to tighten fim1ly) and place the test cup on a flat surface. Be sure NOT to tilt or flip it over.

D. After filling the test cup with a fresh urine sample, wait for 5 minutes (start timing immediately

after sample is collected) and read the results. DO NOT read results after 5 minutes.

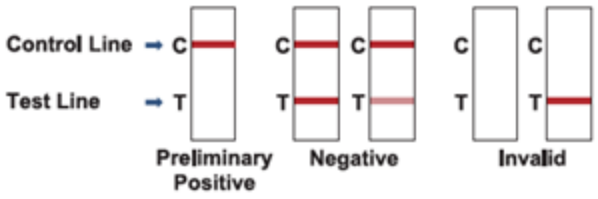


Patient Test Results:

A. **Preliminary positive(+):** If a line appears in the C - Control area but NO line appears in the T - Drug Test area, then it indicates a Preliminary Positive result for the corresponding drug.

B. **Negative(-):** If a line appears in both the C - Control and T - Drug Test area, then it indicates a Negative result for the corresponding drug regardless of how dark or light the line may appear.

C. **Invalid:** If at 5 minutes, NO line appears in the C - Control area, then the results are Invalid.



Note: Each test strip needs to be looked at individually. Each line may vary in color and darkness or the rate at which the line appears. (DO NOT compare lines within the same test strip or between different test strips).

Test Limitations:

A. The First Sign® Drug of Abuse Cup Test provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

B. There is a possibility that interfering substances in the urine specimen may cause erroneous results.

C. Substances, such as bleach and/or alum, in urine specimens may produce erroneous results.

D. A positive result does not indicate intoxication, the concentration of drug in the urine, or the route of drug administration.

E. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cutoff level of the test.

F. Test does not distinguish between drugs of abuse and certain medications.

G. A positive test result may be obtained from certain cross reactants. The most common causes

of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may also cause a false positive test result with this product.

H. If the sample is diluted, or if the sample is tainted or contaminated with a substance this could cause false negative results.

Adulterant Results:

A. Semi-quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color indicator on the color chart.

B. No instrumentation is required. Refer to the color chart card included in the test kit.

Adulterant Test Limitations:

A. The adulterant tests included with the product are meant to aid in the determination of abnormal specimens but may not cover all the possible adulterants.

B. Oxidants: Nom1al human urine should not contain oxidants. The presence of high level of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants pad.

C. Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values.

D. Nitrite: Nitrite is not a normal component of human urine. However, nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of > 20mg/dl may produce false positive glutaraldehyde results.

E. Glutaraldehyde: Glutaraldehyde is normally not found in a urine specimen. However, certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high-protein diets) may interfere with the test results.

F. Creatinine: Creatinine tests for the specimen for dilution and flushing. Nom1al creatinine levels are between 20 and 350mg/dl. Under rare conditions, certain kidney diseases may show dilute urine.

Confirmatory Testing:

This urine drug screen provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/Mass Spectrometry (GCMS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

A. **Ambulatory Care Clinics:** Confirmation of positive urine drug screen results will be routinely performed on every specimen.

B. **Ventura County Medical Center/Santa Paula Hospital**: Confirmation of positive urine drug screen results will be routinely performed on medicolegal specimens only.

Quality Control Testing Schedule:

A. **Internal Controls**- A procedural control is included in the test. A color line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

B. **External Controls**- Per the manufacturer's recommendations, Quality Control Testing with positive and negative controls will be performed by the Ventura County Medical Center Laboratory with each new shipment and each new lot of test cups, as well as every thirty days to verify test performance, including storage conditions..

Quality Control Test Steps:

A. If frozen, thaw controls and allow to come to room temperature followed by light swirling before use. Do not shake.

B. Remove two test cups from the sealed foil pouch. Peel back and remove the labels from the test cups to show the drug test strips. Label on cup "Positive" and the other cup "Negative".

C. Remove the cap from the test cup labeled "Positive" and fill with a minimum of 30 ml of the Positive control. Do not over-fill.

D. Recap the test cup and place on a flat surface. Be sure NOT to tilt or flip it over.

E. Wait for 5 minutes and read the results. DO NOT read results after 5 minutes.

F. Repeat steps 2-5 with the Negative Control.

Quality Control Test Results:

A. Positive controls must test positive on First Sign® Drug of Abuse Test device.

B. Negative controls must test negative on First Sign® Drug of Abuse Test device.

Storage & Stability:

A. Test Cups

1. Store as packaged in the sealed pouch at 39°F - 86°F (4°C - 30°C).
2. The test is stable through the expiration date printed on the sealed pouch.
3. The test cup must remain in the sealed pouch until use.
4. Keep away from direct sunlight, moisture and heat. DO NOT FREEZE. Do not use beyond the expiration date.

B. Controls

1. Unopened Bottles:
    a. The controls are stable for at least 1 year or until the expiration date printed on the bottle label when stored at -20°C to -10°C and are not exposed to the light.
    b. Oxazepam controls' stability cannot be assure due to its deterioration over

time even when stored in refrigeration; all other controls are stable until the expiration date when stored at 2°C to 8°C.

2. Opened Bottles:
    a. The controls are stable for 6 months after they are opened or until the expiration date, whichever one comes first, when they are stored at -20°C to -10°C.
    b. The controls are stable for 31 days after they are opened or until the expiration date, whichever one comes first, when the bottles are tightly capped and are stored at 2°C and 8°C.

References:

1. First Sign® Drug of Abuse Cup Test Package Insert, February 8, 2021.
2. First Sign® Drug of Abuse Urine Controls Package Insert, September 15, 2022.

All Revision Dates

12/12/2023

Attachments

FIRST SIGN FENTANYL DIP CARD FORM.docx

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	12/12/2023
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	12/12/2023
Laboratory Services Department	Erlinda Roxas: Director Laboratory Services	10/16/2023

Status **Active** PolicyStat ID **10084361**

Origination	8/10/1995	Owner	Erlinda Roxas: Director, Laboratory Services
Last Approved	1/11/2024		
Effective	1/11/2024	Policy Area	Laboratory Services - Blood Bank
Last Revised	1/11/2024		
Next Review	1/10/2026		

L.BB.18 Reporting of Transfusion Fatalities

POLICY:

The current good manufacturing practice (CGMP) regulations for blood and blood components require that a transfusion facility report fatalities related to transfusion to Center for Biologics Evaluation and Research (CBER) (21 CFR 606.170(b)). Section 606.170(b) states:

When a complication of blood collection or transfusion is confirmed to be fatal, the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, shall be notified by telephone, facsimile, express mail, or electronically transmitted mail as soon as possible; a written report of the investigation shall be submitted to the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, within 7 days after the fatality by the collecting facility in the event of a donor reaction, or by the facility that performed the compatibility tests in the event of a transfusion reaction.[3]

These reports will be made by the Medical Director of the Ventura County Medical Center Laboratory and the Santa Paula Hospital Laboratory.

PROCEDURE

A. To report a fatality during regular business hours, call or email the fatality program contact within the Division of Inspections and Surveillance. Outside of regular business hours, the initial notification may be made by leaving a voice message, or sending an email or facsimile.

B. Notify FDA/CBER within 24 hours:

Voicemail	240-402-9160
Email	fatalities2@fda.hhs.gov
Fax	301-837-6256

	ATTN: CBER Fatality Program Manager
Express mail	Send 7-day written report to: Office of Compliance and Biologics Quality/CBER Attn: Fatality Program Manager 10903 New Hampshire Avenue Bldg. 71, Rm. 3128 Silver Spring, MD 20993-0002

C. A notification shall be submitted in accordance with policy *107.037 Notification Forms*.

D. The Director of Laboratory Services and Hospital Administration shall be notified immediately of a transfusion related fatality.

REFERENCES:

1. https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/transfusiondonation-fatalities. Retrieved November 18, 2021.
2. Standards for Blood Banks and Transfusion Services. Bethesda, MD: American Association of Blood Banks, 2020. 32nd Edition.
3. Cohn et.al.. Technical Manual. Bethesda, MD: American Association of Blood Banks, 2020. 20th Edition.
4. AABB (October 2007) *Code of Federal Regulations*.
5. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda-fatalities-related-blood-collection-or-transfusion. Retrieved November 18, 2021. U.S. Department of Health and Human Services, FDA, Center for Biologics Evaluation and Research, *Guidance for Industry, Notifying FDA of Fatalities Related to Blood Collection or Transfusion, August 2021.*.

All Revision Dates

1/11/2024, 12/1/2016, 11/1/2016, 8/1/2010

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	1/11/2024
Laboratory Services Department	Brad Adler, MD	8/30/2022

Laboratory Services Department	Erlinda Roxas: Director Laboratory Services	8/14/2022

Status Active PolicyStat ID 13315494

Origination	7/1/2004	Owner	Erlinda Roxas: Director, Laboratory Services
Last Approved	12/12/2023		
Effective	12/12/2023	Policy Area	Laboratory Services - Blood Bank
Last Revised	12/12/2023		
Next Review	12/11/2025		

L.BB.35 Hematype Segment Device

PRINCIPLE:

The Hematype Segment Device is used to access a blood sample from a donor red blood cell segment.

SPECIMEN COLLECTION:

Donor Red Blood Cell unit segment.

MATERIALS:

1. Hematype Segment Device (Fenwal).
2. Segment from a donor unit of blood.H12 x 75 mm glass tubes.

PROCEDURE:

1. Steps:
    a. Label as many test tubes as you will need with the last 3 digits of the unit identification numbers which you intend to crossmatch. These will be the unit cell suspension test tubes.
    b. Set the labeled tubes into a test tube rack.
    c. Place a Hematype Segment Device on top of each labeled test tube.
    d. Remove two segments from each unit of blood, labeling each segment with a donor identification number label from the back of the donor unit (check the sticker number against the unit number on the unit's ABO-Rh label) and place both segments into a test tube.
    e. After comparing the sticker number on the labeled segment against the 3 digits on

the unit cell suspension test tube, insert the segment into the Hematype Segment Device.

f. Cover the segment with your gloved hand, push the segment down and squeeze it to obtain a blood sample.

g. Place the Hematype Segment Device into a biohazard medical waste container and return the segment to the labeled tube for retention.

h. Add enough saline to the unit cell suspension test tubes to create 3-5% cell suspensions.

CALIBRATION:

N/A

CALCULATIONS:

N/A

QUALITY CONTROL:

N/A

RESULTS:

N/A

NOTES:

1. Always use protective safety attire.
2. Use **one** Hematype Segment Device for each segment.
3. When you insert the segment into the Hematype Segment Device, hold the device and **never** touch the test tube.

REFERENCES:

HEMATYPE SEGMENT DEVICE for obtaining blood samples from blood bag tubing segments. Baxter Healthcare Corporation, Deerfield, IL 60015.

All Revision Dates

12/12/2023, 12/1/2016, 12/1/2011

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	12/12/2023
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	12/12/2023
Laboratory Services Department	Erlinda Roxas: Director Laboratory Services	4/22/2023

Status **Active** PolicyStat ID **13315495**

Origination	12/1/2015	Owner	Erlinda Roxas: Director, Laboratory Services
Last Approved	1/11/2024		
Effective	1/11/2024	Policy Area	Laboratory Services - Blood Bank
Last Revised	1/11/2024		
Next Review	1/10/2026		

L.BB.36 Check Type - ABO/Rh Confirmation

PRINCIPLE:

Current FDA guidelines and The Joint Commission and College of American Pathologists (CAP) accreditation standards require a second ABO/Rh type for confirmation to be performed on blood from a separate blood draw before the patient can be issued ABO type specific red blood cells and before the Blood Bank can employ a rapid computer-supported blood crossmatch that speeds the delivery of safe blood. This policy is designed to reduce the incidence of mistransfusion of ABO-incompatible red blood cells due to the wrong patient's blood being drawn for type and crossmatch, an event that happens with 1/2000-blood specimens.

POLICY:

Upon completion of an initial ABO/Rh typing on a current specimen submitted for pre-transfusion testing, the Blood Bank staff will compare the current specimen's ABO/Rh typing result with existing VCMC/SPH historical Blood Bank records to ensure that they are identical. If there are no historical ABO/Rh typing records on file, or if the current sample does not agree with historical records, the Blood Bank will initiate a Check Type by ordering the reflex test, "***ABO/Rh retype***," for the collection of a second sample to verify the ABO/Rh of the patient.

A second sample can be obtained from the Hematology Department if the sample is from a different draw and if the sample is labeled appropriately. If a second sample, drawn at a different time, is unavailable in the laboratory or the patient is unable to have a second sample collected, group O Rh Negative red blood cells will be crossmatched for transfusion.

The Blood Bank will help to minimize delays in blood availability by notifying the appropriate location and requesting a 2nd blood specimen to be drawn for ABO/Rh confirmation on all patients for whom a Check Type is required.

SPECIMEN COLLECTION:

1. Lavender top EDTA (3 mL) or a pink top EDTA
2. No special preparation of the patient is necessary.
3. Specimens for confirmation of blood type are labeled with the Laboratory label generated by the "ABO/Rh retype" request.
4. Blood Bank recipient wristbands are not required for confirmatory specimens.

PROCEDURE:

1. Perform the ABO/Rh test for Type and Screen or Type and Crossmatch orders received.
2. Perform a computer search for previous historical records in the Laboratory Information System and the Legacy System.
3. If the patient has a prior ABO/Rh type on file, and the current specimen confirms the historical blood type, no Check Type is required and the Type and Screen or Type and Cross match testing can be completed with type specific/type compatible red blood cells being cross matched and issued for transfusion.
4. A patient requires a second ABO/Rh type to confirm their blood type prior to issuing type specific red blood cells if any the following apply:
    a. There is no blood type (ABO/Rh) in the patient's historical record in the laboratory information system,
    b. There is a discrepancy between the historical blood type and the current typing,
    c. Patient is greater than 4 months of age (less than 4 months of age follow a different policy).
    d. Patient does not have autologous blood at VCMC/SPH at this time.
5. The Blood Bank staff will perform the Type and Screen and/or Type and Crossmatch testing and determine if a confirmatory sample will be required prior to compatibility testing and dispensing of type specific red blood cells.
    a. ABO/Rh retype confirmation is **not** required:
        - ABO/Rh history on file and current typing confirms historical typing.
        - Patient has autologous red blood cells.
    b. ABO/Rh retype confirmation **is** required:
        - Reflex order a STAT "ABO/Rh retype."
        - Print the laboratory label.
        - Search the Laboratory Information System for a recent CBC order from a different phlebotomy. If a second sample from a different phlebotomy is available, add-on a STAT "ABO/Rh retype" order to the sample and perform testing. If a second sample from a different phlebotomy is unavailable, reflex order a STAT "ABO/Rh retype" and send a phlebotomist to collect the specimen.

- Perform testing and confirm the ABO/Rh type of the second sample matches the current ABO/Rh type.
- Cross match type specific or type compatible red blood cells.

6. **PRE-OP PATIENTS**:

   Patients presenting to the laboratory with pre-op orders for Blood Bank.

   a. **TYPE AND SCREEN ORDERS:**

      - A second ABO/Rh will not be collected at this time. The policy will be implemented if a physician places an order to convert a type and screen to a type and cross match.

   b. **TYPE AND CROSSMATCH ORDERS – *Check Type required***

      The phlebotomist, drawing a patient with Type and Crossmatch orders, will let the patient know that a second sample may need to be drawn for Blood Bank if the Blood Bank does not have a blood type history on file. The phlebotomist will ask the patient to wait while they go check with the Blood Bank.

      a. ***2nd Sample is not required***: Blood Bank has an ABO/Rh history on file. The phlebotomist will return to the drawing room and inform the patient a second sample is not required and they may leave.

      b. ***2nd Sample is required*:** Blood Bank does not have an ABO/Rh history on file.

         i. The Blood Bank will order an ***ABO/Rh retype***, print a laboratory label, and give this label and a lavender EDTA 3mL tube to the phlebotomist.

         ii. The phlebotomist will return to the drawing room and perform a second phlebotomy to obtain a second specimen drawn at a different collection time.

PROCEDURAL NOTES

1. Exception is made for trauma patients for whom the Blood Bank recipient blood banding system is used as a means to prevent identification errors.
2. All patients receiving blood products must have a Blood Bank recipient blood band on as an additional means to prevent identification errors.
3. Patients receiving Autologous Units – Confirm the current sample testing with the labeled ABO/Rh typing on the unit.
4. Patients receiving Directed Donor Units are subject to the Check Type policy.

REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: American Association of Blood Banks, 2015. 30th Edition.

2. Fung, Mark K MD, PhD. Technical Manual. Bethesda, MD: American Association of Blood Banks, 2014. 18th Edition.
3. College of American Pathologist (CAP) current 7/28/15 checklist, TRM.30575.

All Revision Dates

1/11/2024, 12/1/2016

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	1/11/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	12/12/2023
Laboratory Services Department	Erlinda Roxas: Director Laboratory Services	4/22/2023

Status **Active** PolicyStat ID **13315498**

Origination	6/19/1991	Owner	Erlinda Roxas: Director, Laboratory Services
Last Approved	12/12/2023		
Effective	12/12/2023	Policy Area	Laboratory Services - Blood Bank
Last Revised	12/12/2023		
Next Review	12/11/2025		

L.BB.59 Rh (D) Typing

PRINCIPLE:

An individual's D typing is determined by testing the cells with Anti-D. The presence of agglutination indicates that the cells are D-positive and the absence of agglutination indicates that the cells are D-negative, subject to a negative test for weak D.

POLICY:

When the D type of a patient is determined, a weak D test is not necessary except to assess the red cells of an infant whose mother is at risk of D immunization. All HDN workups will be tested for D and if the immediate spin results are negative, a weak D test will be performed.

Exceptions:

1. Weak D testing will be performed on positive Feto-Maternal Hemorrhage (FMH) Rapid Screens from postpartum specimens. Maternal weak D types that are reactive only in the Indirect Antiglobulin Test (IAT) phase can result in a false-positive rosette test.
2. The elimination of weak D testing may lead to discrepancies in historical Rh types performed by other laboratories or at VCMC/SPH. The weak D test will be performed to confirm the previous historical Rh type.

SPECIMEN COLLECTION:

EDTA whole blood.

REAGENTS:

1. Reagents:

a. Anti-D serum.
b. D Control serum.
c. Physiologic Saline.
d. Anti-IgG (green).
e. Coombs Control Cells.

2. Storage – 2 to 8°C when not in use. Do not freeze.
3. Do not use if markedly turbid.
4. Materials and Equipment:
    a. 12x75 mm test tubes.
    b. Serofuge.

PROCEDURE:

I. **D Typing:**

1. Label tube with first letter of patient's last name and the letter D.
2. Make a 3-5% suspension of cells to be tested in normal saline, using EDTA whole blood (after checking the patient's name, medical record number, and Blood Bank identification number) in a tube labeled with the first letter of the patient's last name.
3. Add one drop of Anti-D to the appropriately labeled tube.
4. Add one drop of cell suspension to the tube.
5. Mix well and centrifuge at 3400 rpm for 15 seconds.
6. Re-suspend the cells with gentle agitation and examine for agglutination. Record results in Result Entry application in the computer. All testing results are entered concurrently with testing.
7. Dispose of the tubes.
8. Repeat steps 3-7 with D Control serum if necessary (AB Pos) and record results in Result Entry application in the computer. All testing results are entered concurrently with testing.
9. If D Positive, enter the interpretation of results into the computer.
10. D-negative cells – enter the interpretation of results into the computer.
11. D-negative cells of newborn infants – proceed to test for Weak D

II. **Weak D Testing:**

1. Incubate D-negative cells from above procedure for 15 minutes at 37°C.
2. Centrifuge the tubes at 3400 rpm for 15 seconds.
3. Read and record results as in Step 6 above.
4. Wash any cells showing negative or questionable results four times in saline.
5. Add two drops Anti-IgG to each tube.

6. Mix well and centrifuge at 3400 rpm for 15 seconds.
7. Read macroscopically. Record results in Result Entry application in the computer. All testing results are entered concurrently with testing.
8. Check all negative results with Coombs Control Cells. Add one drop of Coombs Control Cells to each negative tube.
9. Mix well and centrifuge at 3400 rpm for 15 seconds.
10. Read and record check cell results from the tubes, and then discard tubes.
11. Order and perform a DAT on any apparent weak D-positive cells, use Anti-IgG only.
12. Enter results into the computer.

CALIBRATION:

N/A

CALCULATIONS:

N/A

QUALITY CONTROL:

1. See Reagent Daily Quality Control.
2. The D Control Serum must be run on group AB D-positive cells.
3. A direct anti-globulin test (DAT) must be run before interpreting a weak D as positive.

RESULTS:

Interpretation of Results:

I. **D Typing**

	Anti-D	D Control	Result
Group A,B, or O	Pos	NA	D-positive
Group AB	Pos	Neg	D-positive
Group AB	Pos	Pos	Invalid*
Any ABO Group	Neg	NA	Proceed to weak D

*Spontaneous agglutination of immunoglobulin-coated red cells (cold agglutinin or protein imbalance). Wash cells several times (pre-warm if appropriate) and retest. If D Control is still positive, the D antigen status cannot be determined. Patient should receive D-negative blood.

II. **Weak D Test**

Test	DAT	Results
Pos	Neg	D-Positive

Test	DAT	Results
Neg	Neg	D-negative
Pos	Pos	Invalid**

1. **Patient has a positive DAT-D antigen status cannot be determined and the patient should be considered D-negative for transfusion.
2. Mixed field agglutination when testing cells of a recently delivered woman may be due to a fetal-maternal bleed. This should be confirmed with a Fetal Cell Stain.

PROCEDURE NOTES:

The following factors may cause false reactions:

1. Contamination of specimens or reagents.
2. Aged blood specimen.
3. Too light or too heavy a cell suspension.
4. Inaccurate centrifuge calibration.
5. Too vigorous shaking.
6. Inadequate washing (weak D test).

REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: American Association of Blood Banks, 2015. 30th Edition
2. Fung, Mark K MD, PhD. Technical Manual. Bethesda, MD: American Association of Blood Banks, 2014. 18th Edition.
3. Current manufacturer's package inserts.

All Revision Dates

12/12/2023, 12/1/2016, 12/1/2015, 12/1/2011, 1/1/2008, 2/1/2005, 2/1/1994

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	12/12/2023

Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	12/12/2023
Laboratory Services Department	Erlinda Roxas: Director Laboratory Services	4/22/2023

Status **Active** PolicyStat ID **11421649**

Origination	4/11/2001	Owner	Erlinda Roxas: Director, Laboratory Services
Last Approved	12/12/2023		
Effective	12/12/2023	Policy Area	Laboratory Services - Blood Bank
Last Revised	12/12/2023		
Next Review	12/11/2025		

L.BB.62 Cryoprecipitated Antihemophilic Factor (AHF)

PRINCIPLE:

Cryoprecipitated Antihemophilic Factor (AHF) is a concentrated source of certain plasma proteins. It is prepared by thawing 1 unit of Fresh Frozen Plasma (FFP) at 1 to 6 C. After it is thawed, the supernatant plasma is removed, which leaves the cold-precipitated protein plus 10 to 15 mL of plasma in the bag. This material is then refrozen at -18 C or colder within 1 hour and has a shelf life of 1 year from the original collection date.

Cryoprecipitated AHF contains concentrated Factor VIII:C (the procoagulant activity), Factor VIII:vWF (von Willebrand factor), fibrinogen, and Factor XIII. Each bag of Cryoprecipitated AHF contains approximately 80 to 120 units of factor VIII, at least 150 mg of fibrinogen, and about 20% to 30% of the Factor XIII present in the initial unit. Approximately 40% to 70% of the vWF present in the initial unit of FFP is recovered in the cryoprecipitate. The main source of concentrated fibrinogen is Cryoprecipitated AHF.

Cryoprecipitated AHF may be indicated for the treatment of congenital or acquired fibrinogen deficiency or Factor XIII deficiency. When fibrinogen consumption (eg, DIC) or loss (eg, massive hemorrhage), or both, are occurring, exogenous replacement may be necessary to maintain plasma's coagulation potential. Dysfibrinogenemias are rare congenital abnormalities that result in dysfunctional fibrinogen molecules and can lead to increased tendencies to thrombosis or bleeding or both or to no clinical manifestations. Patients may require administration of cryoprecipitate to correct the deficiency.

Cryoprecipitated Antihemophilic Factor (AHF) is routinely prepared by the blood supplier and contains a volume of 5 to 15 ml per unit. Contracted blood supplier also provides pooled units of Cryoprecipitated AHF. Each pooled unit contains the equivalent of 5 individual units of Cryoprecipitated AHF.

SPECIMEN COLLECTION:

- 1 pink top (7 mL) EDTA tube
- Patient must be banded with a current blood bank wristband.
- Type and screen testing performed for current admission.

SUPPLIES AND EQUIPMENT:

1. Water bath – 30-37 C.
2. Waterproof plastic Helmer bags.
3. ISBT printer

PROCEDURE:

1. Select units of cryoprecipitate. ABO compatible is preferred but not required and Rh need not be considered.
2. Modify the expiration date, prior to thawing the unit, in the computer:
    a. ***Health-e-Connect: Thawing and assigning***
        i. Open Modify Products application.
        ii. In modification field select "Thaw Product" from the drop down list.
        iii. Scan the unit Donor Identification number under Product Number in Original Products.
        iv. The new product will appear in the New Product table below.
        v. Edit the volume of the component by entering the volume shown on the component label located on the lower left of the unit label.
        vi. Use ISBT label generated from the modification or handwrite the new expiration date and time on the unit (downtime procedure). Verify ISBT label for completeness.
            1. Thawed single units, if not entered, must be administered within 6 hours of thawing.
            2. Pre-storage pooled Cryoprecipitated AHF has an expiration time of 4 hours once thawed. (This time is in contrast to 6 hours for thawed single units.)
        vii. The product expiration date and time has been updated by the system and this date and time should be visible on the newly generated ISBT label or can be written on the unit label (downtime procedure).
        viii. In the New Product table, highlight the new product and click the "assign to person" icon at the top.
        ix. Click <Save>
3. Thaw units rapidly at 30-37 C in plastic bags (do not exceed 15 minutes of thawing).

4. Thawed Cryoprecipitated AHF prepared for transfusion must be stored at room temperature.
5. Label Verify the thawed product and affix the corresponding ISBT label if available over the initial product label. Do not relabel the unit number.
6. Place a patient requisition label and a blood bank wristband identification number on the thawed unit.

REFERENCES:

1. Roback, John D. *Technical Manual*. Bethesda, MD: American Association of Blood Banks, Current Edition
2. *Standards for Blood Banks and Transfusion Services*. Bethesda, MD: American Association of Blood Banks, Current Edition.
3. King, Karen E. *Blood Transfusion Therapy, A Physician's Handbook*, 9th Edition, 2008.

All Revision Dates

12/12/2023, 6/5/2020, 12/1/2016, 9/1/2009

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	12/12/2023
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	12/12/2023
Laboratory Services Department	Erlinda Roxas: Director Laboratory Services	4/22/2023

Status **Active** PolicyStat ID **11916400**

Origination	11/30/2011
Last Approved	1/11/2024
Effective	1/11/2024
Last Revised	1/11/2024
Next Review	1/10/2026
Owner	Erlinda Roxas: Director, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.78 Blood Bank Correlation of Methods

PRINCIPLE:

There are many standard approaches to antibody detection. The protocols that laboratories choose will affect what they subsequently detect and, thus, what they need to investigate. Currently there are three main ways to investigate antibodies: test tube, gel, and solid-phase testing.

Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH) Blood Bank routinely perform antibody detection or identification using the Ortho MTS IgG gel card methodology. No single method is optimal for detecting all antibodies. The blood bank may employ tube testing using Ortho Antibody Enhancement Solution technique as an alternative approach for use in special circumstances or as a backup for troubleshooting. PeG and Albumin enhancements are used for investigation and don't require method correlation.

Correlation will be performed for all primary methods. Santa Paula Hospital primary methods, include tube ABO/Rh, manual gel, and tube antibody screen using Ortho Antibody Enhancement Solution. Ventura County Medical Center primary methods include, ProVue, manual gel, tube ABO/Rh, and tube antibody screen using Ortho Antibody Enhancement Reagent.

SPECIMEN COLLECTION:

1. Patient samples collected in EDTA (K2) pink top tubes.
2. Patient specimens do not require blood bank wristbands.
3. Patient specimens (2) – Antibody screen positive by ProVue or manual gel.
4. Patient specimens (2) – Antibody screen negative by ProVue or manual gel.
5. Patient specimens (8) - One for each ABO/Rh blood type.
6. Red blood cell Unit segments (8) – One for each ABO/Rh blood type.

7. Patient specimen (1) – Antibody identified by MTS IgG gel card method.

REAGENTS/SUPPLIES AND MATERIALS

1. MTS IgG Gel Cards
2. Ortho Antibody Enhancement Solution.
3. 3% Surgiscreen Cells.
4. 0.8% Surgiscreen Cells.
5. MTS ABD & Reverse Gel Cards.
6. MTS A/B/D grouping Gel Cards
7. Anti-A reagent
8. Anti-B reagent
9. Anti-D reagent
10. Anti-Rh reagent
11. A1 Cells, 2-5% cell suspension.
12. B Cells, 2-5% cell suspension.
13. A1 Cells, 0.8% cell suspension.
14. B Cells, 0.8% cell suspension.
15. Test Tubes 12x75 mm.
16. Physiological saline.
17. Pipets: 50 uL, 25 uL.
18. Disposable Blood Bank pipets.
19. Panel A- 3%.
20. Panel A – 0.8%
21. Panel B – 0.8%
22. Methods Correlation Worksheet.

PROCEDURE:

SANTA PAULA HOSPITAL CORRELATIONS – ANTIBODY SCREENS

1. Obtain four patient samples that have had antibody screens performed using manual MTS IgG gel card method. Include at least two positive screens and two negative screens.
2. Perform antibody screens on the four samples using the following tube method:
    a. Ortho Antibody Enhancement Solution.
3. Record all testing results and interpretations on the Correlation of Methods worksheet.

VENTURA COUNTY MEDICAL CENTER

CORRELATIONS

ANTIBODY SCREENS:

1. Obtain four patient samples that have had antibody screens performed on the ProVue automated instrument. Include at least two positive screens and two negative screens.
2. Perform antibody screens on the four samples using the manual MTS IgG gel card method.
3. Perform antibody screens on the four samples using the following tube method:
    a. Ortho Antibody Enhancement Solution.
4. Record all testing results and interpretations on the Correlation of Methods worksheet.

ABO/RH TYPING:

1. Obtain eight (8) patient specimens that have had ABO/Rh typing performed on the ProVue. Choose one to represent each of the following blood groups:
    a. O Negative
    b. O Positive
    c. A Positive
    d. A Negative
    e. B Positive
    f. B Negative
    g. AB Positive
    h. AB Negative
2. Perform ABO/Rh typing by tube method on the eight specimens.
3. Record all testing results and interpretations on the Correlation of Methods worksheet.

ABO/RH UNIT CONFIRMATION:

1. Obtain eight (8) red blood cell unit segments from the stock inventory. Choose one to represent each of the following blood groups:
    a. O Negative
    b. O Positive
    c. A Positive
    d. A Negative
    e. B Positive
    f. B Negative
    g. AB Positive
    h. AB Negative

2. Perform an ABO/Rh type for each segment on the ProVue using the MTS A/B/D Grouping Card.
3. Perform an ABO/Rh type for each segment using the tube method.
4. Record all testing results and interpretations on the Correlation of Methods worksheet.

ANTIBODY IDENTIFICATION

5. Obtain one patient that had an antibody identification performed using the MTS IgG gel card methodology.
6. Perform an antibody identification using 3% Panel A using a tube method with Ortho Antibody Enhancement Solution.
7. Record all testing results and interpretations on the Correlation of Methods worksheet.

CALIBRATION:

N/A

CALCULATIONS:

N/A

QUALITY CONTROL:

See policy *L.BB.96 Quality Control of Blood Bank Reagents*.

RESULTS:

Compare the final interpretations of the antibody screens and observe the differences in grading strengths between the enhancement reagent method and the Ortho MTS IgG gel methods. It is not unexpected to have variation in strengths of reactions because all antibodies will react differently in different enhancement mediums. The gel methodology is generally the most sensitive and may produce the strongest reactions.
Compare the final interpretation of antibody identifications for the different methods performed. The various phases of antibody reactions can be seen with tube methods whereas the gel method only allows for one phase of reaction.

Compare the final interpretations for the patient ABO/Rh types and the ABO/Rh unit confirmation testing performed by gel and by tube. All interpretations should correlate. Tube testing reactions may not be as sensitive as the gel method but should closely correlate in reaction strength.

LIMITATIONS:

1. No single method is optimal for detecting all antibodies.
2. The laboratory that performs antibody detection or identification should have routine methods, as well as access to some alternative approaches. The use of enhancement techniques may be helpful.

3. Each enhancement reagent has specific characteristics that may be beneficial in the identification of some antibodies while being less than helpful in the identification of others. As such they are used to provide additional information in the solution to complex problems.
4. The general stock inventory does not routinely include B Negative, AB Positive, and AB Negative red blood cells. If these blood types are not available for correlation indicate this on the Correlation of Methods worksheet.

REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: American Association of Blood Banks. Current Edition.
2. Roback, John D. Technical Manual. Bethesda, MD: American Association of Blood Banks. Current Edition.

All Revision Dates

1/11/2024, 12/1/2016, 11/1/2015

Attachments

Correlation of Methods for Antibody Screens in the Blood Bank

ProVue A/B/D Monoclonal Grouping Card™ and Tube Testing with Ortho Reagents

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	1/11/2024
Laboratory Services Department	Brad Adler, MD	8/30/2022
Laboratory Services Department	Erlinda Roxas: Director Laboratory Services	8/14/2022

Status **Active** PolicyStat ID **12799390**

VENTURA COUNTY HEALTH CARE AGENCY

Origination	11/1/1997
Last Approved	1/18/2024
Effective	1/18/2024
Last Revised	1/18/2024
Next Review	1/17/2026
Owner	Erlinda Roxas: Director, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.96 Quality Control of Blood Bank Reagents

POLICY:

The purpose of daily quality assurance in the Blood Bank is to confirm the reliability of the test system. The test system includes reagents, test procedures, and equipment. Testing known samples is an accepted method of quality control. If expected test results are observed, procedures are being performed accurately and reagents and equipment are performing properly. The Laboratory must perform this quality control on each day of use. The Ventura County Medical Center daily quality control program utilizes the ORTHO Diagnostics Confidence System.

PROCEDURE:

The procedures used with these reagents are based on the principle of agglutination. The antibody and cell samples provided in the ORTHO Confidence System will confirm the reactivity of the reagents used for ABO and Rh determinations, the MTS Anti-IgG Card, the anti-IgG component of AHG, as well as reverse grouping cells and reagent red blood cells used in antibody detection tests. For the ORTHO Vision Blood Bank analyzer quality control information, see the ORTHO Vision procedure manual.

REAGENTS:

1. Ortho Confidence System, containing:
    - Cell I – A1B rr (dce/dce) human red blood cells, pooled, 3%.
        - Provides the positive control for ABO Blood Grouping Reagents and a negative control for Anti-D.
    - Cell II – O R1r (Dce/dce) human red blood cells, pooled, 3%.
        - Provides the positive control for Anti-D
    - Confidence Antibody- Anti-A, Anti-B, Anti-D and Anit-c that react when tested by the indirect anti-globulin technique.

- Store at 2-8°C. Allow to come to room temperature before using.

2. Anti-A, Anti-B, Anti-A,B, Anti-D, Rh Control, A1 Cells, and B Cells. Stored at 2-8°C and allowed to come to room temperature before using.
3. MTS Anti-IgG Card, Anti-IgG (rabbit) suspended in gel. Store at 18-25°C.
4. Antibody Screening cells comprised of three vials of human red blood cells as: 0.8%, ready for use in MTS Anti-IgG Gel testing; and 3% to perform tube method antibody screen tests, or to be modified to 0.8% in-house for use in MTS Anti-IgG testing. Store at 2-8°C. Allow reagents to come to room temperature before using.
5. Plasma from an O positive patient with a negative antibody screen using the MTS Gel card. Store at 2-8°C. Use for 7 days.
6. Ortho 7% BSA – an aqueous solution of bovine serum, inorganic salts, and preservatives. Storage and Stability

Reagent	Storage Condition	Stability
Unopened	Frozen ≤ 18 °C	Until expiration date
	Refrigerated 2-8 ° C	Until expiration date
Opened	Refrigerated 2-8 ° C	≤ 28 days if tightly stoppered

EQUIPMENT AND MATERIALS

1. Laboratory Information System (LIS)
2. Daily Quality Control Form BB 8.2 (Computer Down Form
3. 12x75mm glass tubes.
4. MTS Incubator/Centrifuge

PROCEDURE

Visual Inspection of reagents:

- Before mixing the reagent vials, inspect the red cells for hemolysis or contamination. If hemolysis is moderate, use a new set of cells and note the action taken in the comment section of Quality Control Result Entry (see Appendix A). If any other reagent appears cloudy, has particulate matter or is possibly contaminated, discard and note action taken.
- Document the performance and acceptance of reagent visual inspection by indicating "Satisfactory" in the visual inspection column in the Health-e-Connect System or placing a (√) under the appropriate day on the Daily Quality Control Form used when the computer is down.

Tube Quality Control (see Blood Bank QC Matrix)

1. Label 13 12x75 mm test tubes 1 through 13.
2. Add 1 drop of Anti-A to tubes 1 and 9.
3. Add 1 drop of Anti-B to tubes 2 and 10.
4. Add 1 drop of Anti-A,B to tubes 3 and 11.
5. Add 1 drop of Anti-D to tubes 4 and 5.

6. Add 2 drops of Ortho Confidence antibody reagent to tubes 6 and 7.
7. Add 1 drop of Rh Control to tube 8.
8. Add 2 drop of 7% BSA to tubes 12 and 13.
9. Add 1 drop of Confidence Cell 1 to tubes 1, 2, 3, and 4.
10. Add 1 drop of Confidence Cell 2 to tubes 5, 8, 9, 10, and 11.
11. Add 1 drop of A1 Cells to tube 6 and 12.
12. Add 1 drop of B Cells to tube 7 and 13.
13. Mix tubes gently and centrifuge for the calibrated time in the Blood Bank serofuge.
14. Examine for hemolysis and then gently re-suspend the cell button. Using the agglutination viewer, examine for macroscopic agglutination.
15. Grade the reactions and record the results.
16. Incubate tube 4 for 15 minutes at 37 degrees.
17. At the end of the incubation time, spin tube 4 for 15 seconds. Examine the tube for hemolysis and gently re-suspend while examining for agglutination. Record the results.
18. Wash tube 4 four times. Add two drops of IgG to the tube and spin for 15 seconds.
19. Examine tube for hemolysis and gently re-suspend while examining for agglutination. Record the results.
20. Add one drop of Coombs Control cells to tube 4 and spin for 15 seconds. Gently re-suspend while examining for agglutination. Record the results prior to disposing of the tubes.

Manual MTS IgG Gel Card QC (see Blood Bank QC Matrix)

21. Label the first 3 columns of an MTS Gel Card 1, 2, 3. Label columns 4-6 with 01, 02, and 03.
22. Add 50 µl of the appropriate 0.8% Screening Cell to the MTS Gel Card columns marked 1, 2, and 3.
23. Add 50 µl of the appropriate 0.8% Screening Cell to the MTS Gel Card column marked 01, 02, and 03.
24. Add 25 µl of the Confidence Antibody Reagent to the MTS Gel Card the columns marked 1, 2, and 3.
25. Add 25 µl of the negative patient control to the MTS Gel Card column position marked 01, 02, and 03.
26. Incubate MTS gel card for 15 minutes.
27. Centrifuge for 10 minutes.
28. Read and record results.

CALIBRATION:

See Laboratory Blood Bank policy L.BB.97, *Verification of Functional Calibration of Serologic Centrifuges,* for calibration of serological centrifuges.

CALCULATIONS:

N/A

EXPECTED RESULTS:

Reagent	Control	Phase	Expected Result
Anti-A	Confidence Cell 1	IS	2+, 3+, 4+
Anti-B	Confidence Cell 1	IS	2+, 3+, 4+
Anti-A,B	Confidence Cell 1	IS	2+, 3+, 4+
Anti-D	Confidence Cell 1	IS	0
Anti-D	Confidence Cell 1	37	0
Anti-D	Confidence Cell 1	AHG	0
Anti-D	Confidence Cell 1	CC	1+, 2+, 3+, 4+
Anti-D	Confidence Cell 2	IS	1+, 2+, 3+, 4+
A1 Cells	Confidence Antibody	IS	2+, 3+, 4+
B Cells	Confidence Antibody	IS	2+, 3+, 4+
D Con (Rh Control)	Confidence Cell 2	IS	0
Anti-A Neg Ctr	Confidence Cell 2	IS	0
Anti-B Neg Ctr	Confidence Cell 2	IS	0
Anti-AB Neg Ctr	Confidence Cell 2	IS	0
SC1	Confidence Antibody	AHG – Gel	1+, 2+, 3+, 4+
SC2	Confidence Antibody	AHG – Gel	1+, 2+, 3+, 4+
SC3	Confidence Antibody	AHG – Gel	1+, 2+, 3+, 4+
SC1 Neg Control	Patient Control	AHG – Gel	0, NT
SC2 Neg Control	Patient Control	AHG – Gel	0, NT
SC3 Neg Control	Patient Control	AHG – Gel	0, NT
A1 Cell Neg Ctr	7% BSA	IS	0
B Cell Neg Ctr	7% BSA	IS	0

PROCEDURE NOTES:

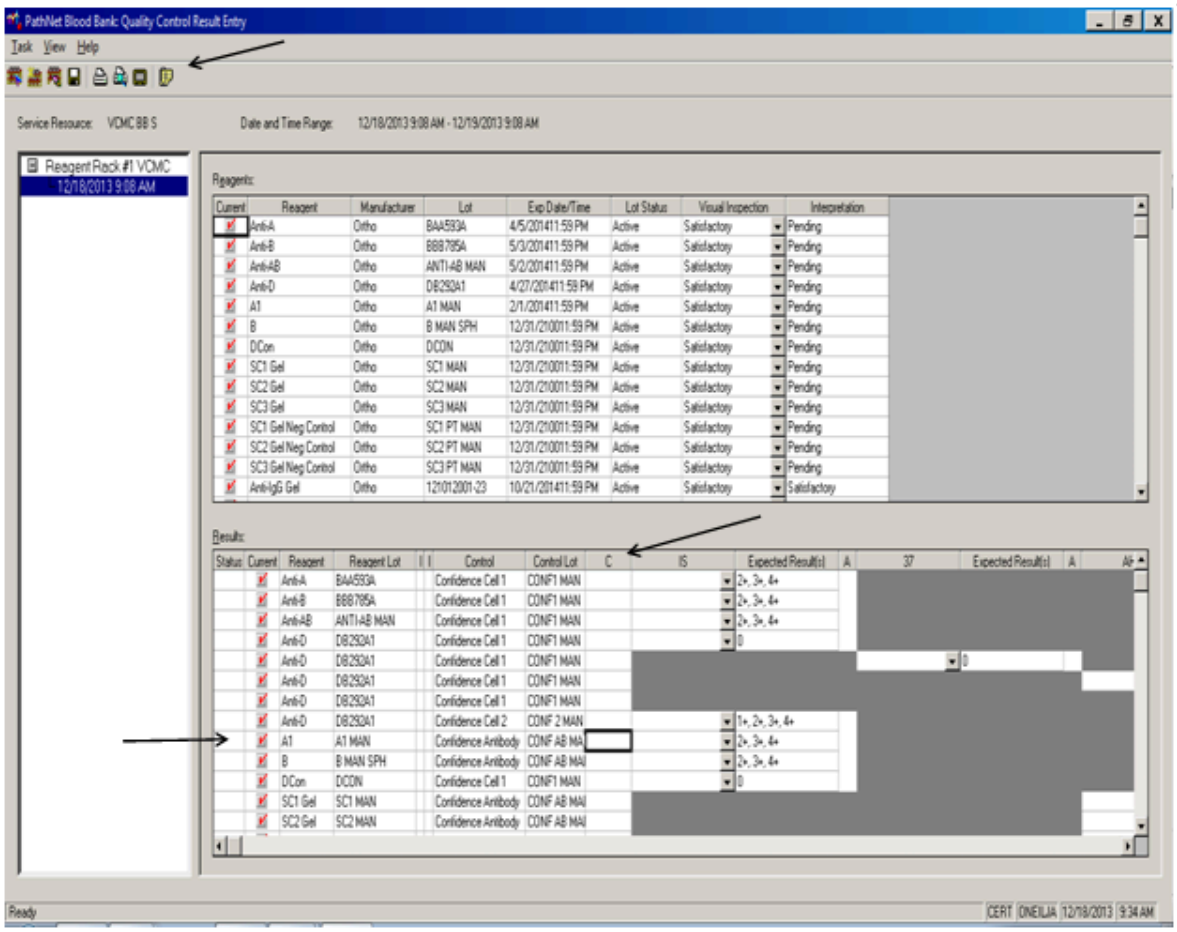
1. Quality Control results are entered concurrently with performance in the Health-e-Connect system. Follow procedure as outlined in Laboratory Blood Bank policy *Quality Control Scheduling and Result Entry*.
2. Manual bench quality control reagent racks are chosen in the Blood Bank Subsection indicated as VCMC Blood Bank/SPH Blood Bank.
3. ORTHO Vision automated quality control reagent racks are chosen in the Blood Bank Subsection indicated as VCMC Vision.
4. Appendix A gives directions on entering QC comments in the Health-e-Connect system.

REFERENCES:

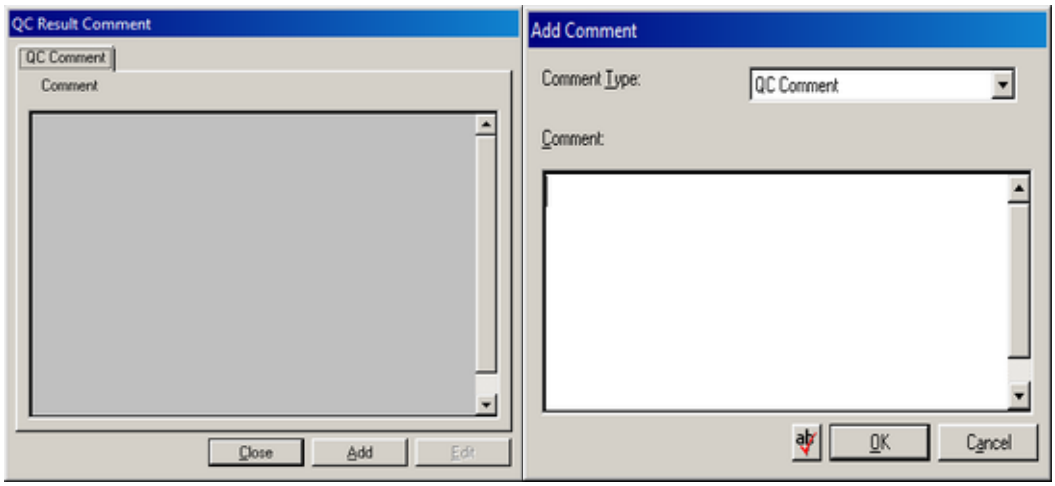
1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: American Association of Blood Banks, Current Edition.
2. Fung, Mark K MD, PhD. Technical Manual. Bethesda, MD: American Association of Blood Banks, Current Edition.
3. Current Manufacturer's package inserts.

APPENDIX A: Entering a QC Comment

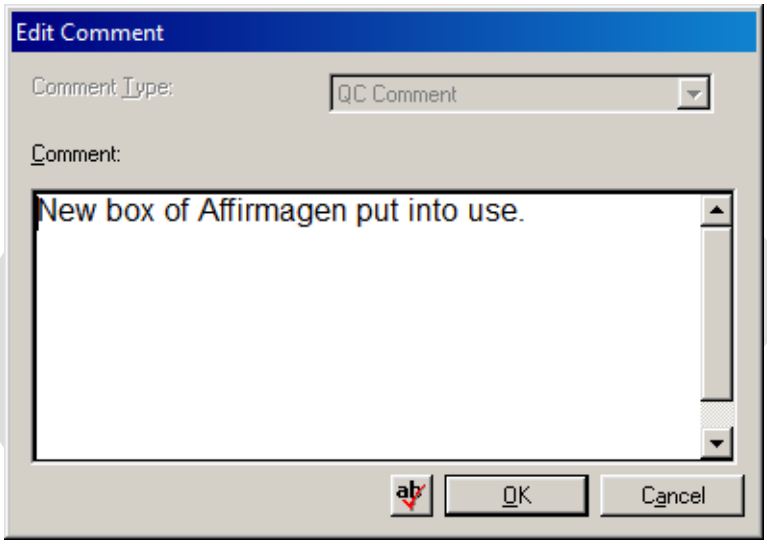
1. In the Results section, select the appropriate Reagent and then move through the row to the "C" column and place the cursor at this box.
2. Click on "Comment" icon.



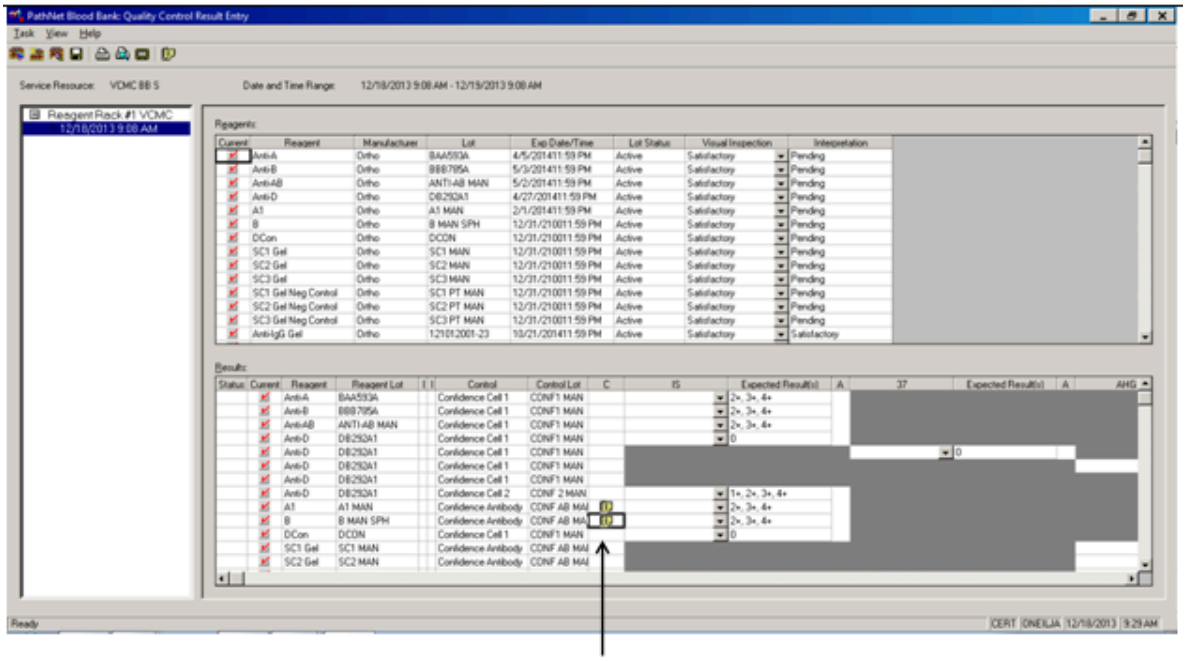
3. Click "Add" to enter a QC Comment.



4. Enter desired QC comment and click <OK>.



5. Comment icon will now appear in "C" column in Results section in the appropriate reagent row.



All Revision Dates

1/18/2024, 2/19/2021, 3/1/2017, 12/1/2016, 11/1/2015, 7/1/2013

Attachments

Blood Bank QC Matrix

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	1/18/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	1/18/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/11/2024

Status **Active** PolicyStat ID **11421612**

Origination	12/28/2011
Last Approved	12/12/2023
Effective	12/12/2023
Last Revised	12/12/2023
Next Review	12/11/2025
Owner	Erlinda Roxas: Director, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.100 Critical Supplies and Services

PRINCIPLE:

Critical equipment, supplies, and services are defined as equipment, supplies and services that have the potential to impact the quality, safety, efficacy, or purity of products or services. Critical equipment must be approved, validated, calibrated, maintained and monitored per manufacturer's instructions and in accordance with Food and Drug Administration (FDA) and American Association of Blood Bank (AABB) standards. Blood suppliers, reference laboratories and primary reagent suppliers must be approved (qualified) prior to use. Incoming reagents and critical supplies must be received, inspected and tested as necessary before acceptance or use. All materials shall be stored and used in accordance with the manufacturer's written instructions and shall meet specified requirements.

This procedure provides:

- A list of critical supplies, services and vendors for the Blood Bank/Transfusion Services department, approved by Ventura County Medical Center/Santa Paula Hospital management and it's purchasing group.
- Requirements and expectations set by the Blood Bank/Transfusion Services supervisor to help determine the ongoing ability of suppliers of products or services to meet the Blood Bank needs.

This procedure provides instruction for:

- Documentation of inspection of incoming critical materials.
- Corrective actions that prevent use of unacceptable supplies or services.
- Proper storage of incoming supplies.

POLICY:

The blood bank/transfusion service evaluates the ability of suppliers of critical materials, equipment, and services to consistently meet agreed upon requirements.

1. **Supplier Qualification**:

   The Blood Bank/Transfusion Services department will use test methods, equipment, reagents, and materials that provide accurate, reliable test results, test records and reports.

   The Blood Bank/Transfusion Services department will provide blood components and derivatives for transfusion or injection that are collected, labeled, stored, processed and transported per standards defined by AABB, FDA, and State agencies.

   The Blood Bank/Transfusion Services evaluates and participates in the selection of suppliers.

   a. Tests and services are performed in laboratories that are:
      - Accredited by the AABB or equivalent accrediting body, and
      - Certified by the Centers for Medicare and Medicaid Services (CMS), and
      - Registered by the Food and Drug Administration (FDA).

2. **Agreements**:

   a. Contracts and agreements between Ventura County Medical Center/Santa Paula Hospital and its suppliers will define each party's expectations and be reviewed and signed periodically as determined by the parties involved.

3. **Failure to Meet Requirements**:

   a. The Blood Bank/Transfusion Services department has defined criteria for acceptability of critical supplies and services. Failure of products, or vendors, to meet these requirements will be documented (***see Attachment A, Suppliers Problem Evaluation Form***) and corrective action taken immediately. Recurrent problems with products or services will be reported by the Blood Bank/Transfusion Services supervisor to the Laboratory Manager.

PROCEDURE:

I. **NEW PRODUCT EVALUATION**

   A. Administrative policy 107.038, ***New Product Evaluation*** should be followed for the submission of new products to the Product Evaluation Committee for evaluation and approval prior to purchase.

II. **CRITICAL SERVICES AND VENDORS**

   A. **VCMC/SPH BIOMEDICAL ENGINEERING DEPARTMENT**

      1. **Services Provided:**
         - Helps evaluate, inspect, and install new equipment.

- Assigns unique identifiers to Blood Bank equipment.
- Performs inspections, calibrations, and required maintenance on equipment per manufacturer's instructions, AABB and FDA standards.
- Repairs equipment.

2. **Blood Bank Department's Criteria for Acceptable Service.**
    - Timely scheduled maintenance or repairs to ensure proper performance of equipment and to prevent delays in testing.
    - Complete documentation of all inspections and maintenance performed.
    - Mechanism to identify and track all critical equipment, including a list of critical equipment and a schedule for performing maintenance.

3. **Evaluation of Services/ Corrective Action.**
    - Equipment problems that require repair by Biomedical Engineering will be documented on the ***Preventative Maintenance and Corrective Action Log (see Attachment B)*** by the Blood Bank technologist identifying the problem. This should include the date Biomedical Engineering is notified. A Biomedical Engineering ***Broken Equipment Form (VCMC-540-002)*** will be completed and left with the instrument. Timeliness of repair will be evaluated.
    - Quarterly/Semi-Annual/Annual inspections and maintenance will be documented and any contracted service. Completed forms will be submitted to the Laboratory Manager and reviewed by the Blood Bank/Transfusion Services supervisor.
    - The Blood Bank/Transfusion Services supervisor will review the ***Equipment Preventative Maintenance Book*** and the ***Preventative Maintenance and Corrective Action Log (Attachment B)***. Any delays or problems with repairs or maintenance will be investigated. Recurrent problems will be addressed by the Blood Bank/Transfusion Services Supervisor and the head of the Biomedical Engineering Department. The Laboratory Manager will be notified of recurrent problems.

B. **VCMC/SPH MAINTENANCE DEPARTMENT**

1. **Services/Products Provided (Refrigerators and Freezers)**
    - Helps evaluate, inspect, and install new refrigerators and freezers.
    - Assigns unique identifiers to Blood Bank refrigerators and freezers.
    - Performs inspections, repairs and required maintenance on all

refrigerators and freezers as required by the manufacturer's instructions, AABB and FDA standards.

- Retains and has available all documentation of preventative maintenance and repairs.

2. **Blood Bank's Criteria for Acceptable Service.**
    - Timely scheduled maintenance or repairs to ensure proper performance of equipment and to prevent delays in testing.
    - Complete documentation of all inspections and maintenance performed.
    - Mechanism to track all critical equipment, including a list of critical equipment and a schedule for performing maintenance.
3. **Evaluation of Service / Corrective Action.**
    - Refrigerator and/or freezer equipment problems that require repair by Maintenance will be documented on the ***Preventative Maintenance and Corrective Action Log (Attachment B)*** by the Blood Bank Technologist identifying the problem. This should include the date and time the Maintenance Department is notified. Timeliness of the response will be evaluated. Maintenance should respond immediately to any page from the blood bank regarding refrigerator and/or freezer equipment problems.
    - Preventative maintenance will be performed and documented and the records readily available.
    - Any delays or problems with repairs or maintenance will be investigated. Recurrent problems will be communicated by the Blood Bank supervisor to the Laboratory Manager.

C. **VITALANT**

1. **Services/Products Provided.**
    - Blood and components, including:
        - Red blood cells
        - Whole Blood
        - Frozen Plasma
        - Liquid plasma
        - Platelets
        - Cryoprecipitate
    - Product testing and preparation, including:
        - ABO/Rh and unexpected antibody identification
        - Infectious disease testing

        - CMV testing.
        - Hgb S testing.
        - Antigen screening.
        - HLA-matching.
        - Irradiation.
        - Leuko-reduction.
        - Sterile docking.
    - Reference laboratory for Immunohematology investigation and consultation.
    - Blood component delivery service.
    - Education Seminars.

2. **Blood Bank's Criteria for Acceptable Service.**
    - FDA/CBER-licensed/Meet FDA requirements
    - AABB-accredited/Meet AABB requirements
    - Have a quality system in place
    - Meets state requirements
    - Provide adequate stocking levels based on annual usage. Provide adequate restocking based on daily transfusions/ traumas/critical levels.
    - Timely notification of Vitalant Services stocking levels, including shortages, and critical levels.
    - Blood products are properly packaged to maintain appropriate temperatures during transportation to Ventura County Medical Center/Santa Paula Hospital from Vitalant Services.
    - Delivery services from Vitalant that are cost-effective, reliable, and frequent enough.
    - Competitive pricing that is comparable to alternate blood suppliers. Accurate and timely billing and credit.
    - Timely notification of changes affecting the safety of blood components are discovered, including look-back and recall.
    - Reference Laboratory providing Stat service. Timely verbal, faxed, and final reports. Competent staff who are willing to advise Ventura County Medical Center/Santa Paula Hospital Blood Bankers.

3. **Evaluation of Service / Corrective Action.**
    - Quality of the product
        - Units properly labeled

        - Acceptable visual inspection
        - Sufficient number of segments
        - Number of units recalled/questions of disposition
    - Availability of products
        - Full range of products available
        - Adequate supply different ABO/Rh types available for all products
    - Quality of service
        - Correct/Incorrect order
        - Shipment arrives on time
        - Product arrives in satisfactory condition
        - Consultation service responsiveness
        - Timely resolution of problem
        - Supplies required antigen-negative blood, timely manner
        - Billing problems/discrepancies

III. CRITICAL SUPPLIES AND VENDORS

A. List of critical supplies:

1. Supplies and vendors critical to the daily operations of the Blood Bank department have been identified. Refer to SOP L.BB.99, ***Reagent/Supply Ordering, Receipt, Rejection, and Storage*** for all materials, forms, labels, reagents and vendors.
2. Blood components have been addressed in SOP L.BB.76, entitled ***Ordering, Storage, and Return of Blood Components*.**

B. SUPPLIERS OF REAGENTS AND DERIVATIVES

1. **Services / Products Provided**
    - Reagents for testing
    - Filters for the administration of blood components
2. **Blood Bank's Criteria for Acceptable Service**
    - Provide materials that meet applicable FDA requirements
    - Be able to supply products at a level that meets our needs.
    - Products are shipped appropriately
    - Supply training and support as needed
    - Suppliers of reagents and derivatives must provide written instructions for use of products.
    - Suppliers of reagents and derivatives must provide directions for

handling and storage of products

- Provide Safety Data Sheets (SDS) where applicable
- Supplier should be facility-approved with a contract when feasible

3. **Evaluation of Service / Corrective Action**
    - Quality of product
        - Consistent satisfactory reagent quality control
        - Number of recalls
        - Red cell reagents not hemolyzed
    - Availability of reagents
        - Frequency of back-orders
        - Frequency of partial shipments
    - Frequency of problems with orders/ordering
    - Shipping problems
        - Reagents arrive on time and in good condition
    - Response to questions and problems
    - Knowledge of the sales representative
    - Courtesy and availability of the sales representative
    - Competitive pricing

IV. INVENTORY MANAGEMENT OF CRITICAL SUPPLIES

A. Ordering supplies:

1. Standing Orders.
    - Will be created by written contract between the supplier and Ventura County Medical Center/Santa Paula Hospital purchasing department.
    - Quantities will be determined by the Blood Bank/Transfusion Services supervisor based on monthly usage but may be increased or decreased based on changes in workload.
    - Delivery dates and frequency of delivery will be determined by the supplier based on manufacturing dates and expiration dates of the products ordered.

B. Supplies ordered as needed.

1. The Blood Bank/Transfusion Services supervisor will determine stocking levels based on workload.
2. The Blood Bank/Transfusion Services supervisor will manage the inventory supplies by review of:

- Quantities of supplies in stock
- Expiration dates of supplies in stock.

3. All blood bank technologists are responsible for alerting the Blood Bank/ Transfusion Services supervisor (or laboratory manager when the Blood Bank/Transfusion Services supervisor is not available) if any supply requires ordering due to spills or breakage, becomes contaminated during storage or use, is recalled by the manufacturer, or is adversely affected by equipment malfunction.

C. **Receipt, Inspection, and evaluating acceptability for use of Incoming Supplies**

1. Supplies will be delivered to the laboratory with packing slips. After reconciliation, the packing slip will be given to the Laboratory Manager for approval. Blood Bank technologists accepting delivery of supplies shall:
    - Verify all blood bank supplies received with the packing slips.
    - Alert the Blood Bank/Transfusion Services Supervisor, or the Laboratory Manager, to any unacceptable deliveries.
    - Follow SOP L.BB.99, ***Reagent/Supply Ordering, Receipt, Rejection, and Storage*** for receiving, inspecting, rejecting, and storing of all incoming supplies.
    - Date all supplies upon receipt.
    - Blood Bank labels, forms and red identification bands must be verified as the most current version in use. Follow the ***Label Control*** procedure in the **Label Control Manual** for receipt and acceptance of all blood bank labels.

V. MANUFACTURER'S PRODUCT RECALL

In the event that the Blood Bank/Transfusion Services Department receives a Product Recall from a manufacturer:

- Remove from inventory and quarantine any of the reagents, supplies or blood components listed in the recall letter sent by the manufacturer or supplier.
- Bring any recall notification letter to the attention of the Blood Bank/Transfusion Services supervisor or the Laboratory Manager when the Blood Bank supervisor is unavailable.
- Document all required information about the disposition of the recalled products on the ***Disposition of Rejected Reagent/Supply Log (see SOP L.BB.99, Attachment B).***
- Refer to the Lookback procedure when a blood component is recalled by Vitalant. Any blood component that has been transfused requires additional investigation by the Blood Bank Department and notification of the patient's physician.
- Bring all lookback / product recall notification to the attention of the Laboratory Medical Director.
- Complete any documentation required by the manufacturer.

REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: American Association of Blood Banks, Current Edition.
2. Roback, John D. Technical Manual. Bethesda, MD: American Association of Blood Banks, Current Edition.

All Revision Dates

12/12/2023, 6/5/2020, 12/1/2016, 11/1/2015

Attachments

A: Suppliers Problem Evaluation Form

B: Preventative Maintenance and Corrective Action Log

C: Broken Equipment Form

D: Current Reagent / Blood Supplier Assessment / Re-Qualification

E: Disposition of Rejected Reagent/Supply Log

F: New Reagent / Blood Supplier Assessment / Qualification

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	12/12/2023
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	12/12/2023
Laboratory Services Department	Erlinda Roxas: Director Laboratory Services	11/4/2023

Status **Active** PolicyStat ID **14998718**

Origination	1/28/2013
Last Approved	1/18/2024
Effective	1/28/2013
Last Revised	1/18/2024
Next Review	1/17/2026
Owner	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services
Policy Area	Laboratory Services - Chemistry

L.CHEM 1.11 Beta Human Chorionic Gonadotropin (BHCG)

Policy

Beta Human Chorionic Gonadotropin (BHCG)

Intended Use: The BHCG method is an in vitro diagnostic assay for the quantitative measurement of total Beta (ß) human chorionic gonadotropin: both the intact hCG dimer and the free ß subunit of human chorionic gonadotropin hormone in human serum and plasma on the Dimension Vista® System. Measurements of ß human chorionic gonadotropin are used for the early detection of pregnancy.

Summary: Human chorionic gonadotropin (hCG) is a heterodimeric (α plus ß) sialoglycoprotein hormone produced by the placenta soon after a fertilized ovum implants into the uterine wall.[1] Presence of hCG in serum shortly after conception, followed by a rapid rise in concentration, makes it an excellent marker to confirm and monitor a pregnancy. Physiologically, hCG appears to maintain the corpus luteum and support the endometrium. Serum and plasma hCG concentrations peak during the first trimester, then decrease and plateau during the remainder of pregnancy, circulating as the intact heterodimer in the blood of healthy women who have an uncomplicated pregnancy.[2]

Principles of Procedure

The BHCG method is a homogeneous, sandwich chemiluminescent immunoassay based on LOCI® technology. The LOCI® reagents include two synthetic bead reagents and a biotinylated anti–ßhCG monoclonal antibody fragment. The first bead reagent (Sensibeads) is coated with streptavidin and contains photosensitizer dye. The second bead reagent (Chemibeads) is coated with a second anti–ßhCG monoclonal antibody and contains chemiluminescent dye. Sample is

incubated with Chemibeads and biotinylated antibody to form a bead–ßhCG–biotinylated antibody sandwich. Sensibeads are added and bind to the biotin to form bead–pair immunocomplexes. Illumination of the complex at 680 nm generates singlet oxygen from Sensibeads which diffuses to the Chemibeads and triggers a chemiluminescent reaction. The resulting chemiluminescent signal is measured at 612 nm and is directly proportional to the free and intact, nicked and non–nicked ß human chorionic gonadotropin concentration in the sample.[3,4,5]

Reagents

Wells[a]	Form	Ingredient	Concentration[b]	Source
1–4	Liquid	ß human chorionic gonadotropin Chemibeadsc	300 µg/mL	Mouse monoclonal
5–8	Liquid	Biotinylated Antibodyc	7 µg/mL	Mouse monoclonal
9–12	Liquid	Streptavidin Sensibeadsc	240 µg/mL	Recombinant E. coli

a. Wells are numbered consecutively from the wide end of the cartridge.
b. Nominal value per well in a cartridge.
c. Antibody titer and conjugate activity may vary from lot to lot.

Risk and Safety

Irritant. Contains a mixture of 5–chloro–2–methyl–2H–isothiazol–3–one and 2–methyl–2H–isothiazol–3:1.

R43: May cause sensitization by skin contact.

S24: Avoid contact with skin.

S37: Wear suitable gloves.

Safety data sheets (MSDS/SDS) available on www.siemens.com/diagnostics

Precautions: Used reaction vessels contain human body fluids; handle with appropriate care to avoid skin contact or ingestion.

For *in vitro* diagnostic use.

Reagent Preparation: All reagents are liquid and ready to use.

Store at: 2–8 °C

Expiration: Refer to carton for expiration date of individual unopened reagent cartridges. Sealed wells on the instrument are stable for 30 days.

Open Well Stability: 5 days for wells 1–12

Specimen Collection and Handling

- **Recommended specimen types**: Serum or plasma samples (lithium heparin).
- **Samples and controls stabilized with azide cannot be used**.
- Serum and plasma can be collected using recommended procedures for collection of diagnostic blood specimens by venipuncture.[6]
- Follow the instructions provided with your specimen collection device for use and processing.[7]
- Complete clot formation should take place before centrifugation. Serum should be physically separated from cells as soon as possible with a maximum limit of 24 hours from the time of collection.[8,9]
- Samples should be kept at 4 °C and analyzed within 7 days. For longer storage, samples may be frozen at -20 °C or colder.[10]
- Ensure that patient samples, calibrators, and controls are equilibrated at ambient temperature (22–28 °C) before testing. Samples containing precipitates must be centrifuged before performing the assay.

Procedure

Materials

Materials Provided

BHCG Flex® reagent cartridge, Cat. No. K6430

Materials Required But Not Provided

BHCG CAL, Cat. No. KC632

Quality control materials

Test Steps

Sampling, reagent delivery, mixing, and processing are automatically performed by the Dimension Vista® System. For details of this processing, refer to your Dimension Vista® Operator's Guide.

Test Conditions

Sample Volume (delivered to the reaction vessel)	2 µL
Reagent 1 Volume	25 µL
Reagent 2 Volume	25 µL
Reagent 3 Volume	100 µL
Temperature	37.0 ºC

Reaction time	10 minutes
Wavelengths	Illumination 680 nm, Emission 612 nm
Type of Measurement	Chemiluminescence

Calibration

Calibration Material	BHCG CAL, Cat. No. KC632
Calibration Scheme	6 levels, n=3
Units	mIU/mL [IU/L][d]
Typical Calibration Levels	Level 1 (CAL A): 0 mIU/mL [IU/L]
	Level 2 (CAL B): 14 mIU/mL [IU/L]
	Level 3 (CAL C): 28 mIU/mL [IU/L]
	Level 4 (CAL D): 160 mIU/mL [IU/L]
	Level 5 (CAL E): 550 mIU/mL [IU/L]
	Level 6 (CAL F): 1100 mIU/mL [IU/L]
Calibration Frequency	Every 30 days for any one lot.
	Calibration interval may be extended based on acceptable
	verification of calibration.
A new calibration is required:	• For each new lot of Flex® reagent cartridges
	• After major maintenance or service, if indicated by
	quality control results
	• As indicated in laboratory quality control procedures
	• When required by government regulations

d. Système International d'Unités [SI units] are in brackets.

Quality Control

At least once each day of use, analyze two levels of a quality control (QC) material with known BHCG concentrations. Follow your laboratory internal QC procedures if the results obtained are outside acceptable limits.

Results

The instrument calculates the concentrations of BHCG in mIU/mL [IU/L] using the calculation scheme described in your Dimension Vista® Operator's Guide.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

AMR

Analytical Measurement Range (AMR): 1–1000 mIU/mL [IU/L]

This is the range of analyte values that can be measured directly from the specimen without any dilution or pretreatment that is not part of the usual analytical process and is equivalent to the assay range.

Dilution

- Samples with results in excess of 1000 mIU/mL [IU/L] should be repeated on dilution. **Manual Dilution**: Dilute with Reagent grade water to obtain results within reportable range. Enter dilution factor on the instrument. Reassay. Resulting readout is corrected for dilution. **Autodilution (AD)**: Instrument does a 1: 200 dilution in the aliquot tray and the normal 2 µL sample is still used for overrange samples. Refer to your Dimension Vista® Operator's Guide.
- Samples with results less than 1 mIU/mL [IU/L] will be reported as "less than 1 mIU/mL [IU/L]" by the instrument.

Limitations of Procedure

This test is not intended to be used for aiding in the diagnosis of cancer, or for monitoring the treatment of cancer patients.

Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. This assay has been designed to minimize interference from heterophilic antibodies. Nevertheless, complete elimination of this interference from all patient specimens cannot be guaranteed. A test result that is inconsistent with the clinical picture and patient history should be interpreted with caution.[11,12]

The instrument reporting system contains flags and comments to provide the user with information regarding instrument processing errors, instrument status information and potential errors in BHCG results. Refer to your Dimension Vista® Operator's Guide for the meaning of report flags and comments. Any report containing flags and/or comments should be addressed according to your laboratory's procedure manual and not reported.

Expected Values

Non–pregnant females, ages 18–62	1 – 3 mIU/mL [IU/L]	n=123
Adult males, ages 19–67	≤ 1 mIU/mL [IU/L]	n=130

The reference interval was calculated non–parametrically and represents the central 95% of results determined from a population of healthy adults. Each laboratory should establish its own expected values for BHCG as performed on the Dimension Vista® System.

The concentration of human chorionic gonadotropin rises rapidly during the first weeks of pregnancy, approximately doubling every two days. Low level BHCG values > 25 mIU/mL [IU/L] may be indicative of early pregnancy, but these results should always be evaluated in the context of the clinical situation: date

of last menstrual period, pelvic examination and other clinical findings. When borderline results are encountered, patient samples should be redrawn 48 hours later.[13,14]

Elevated hCG levels have also been associated with trophoblastic disease and non–trophoblastic neoplasms. The possibility of having these diseases should be considered before a diagnosis of pregnancy is made.[2]

A maximum level of 5000 to 200,000 mIU/mL [IU/L] for a single fetus is reached at 10–12 weeks, followed by a slow decline to levels of 1000 to 50000 mIU/mL [IU/L] during the third trimester.1,2 A reduced or declining hCG level may indicate an abnormal pregnancy and additional follow–up testing and clinical evaluations should occur. Throughout the entire pregnancy, hCG levels may vary with different gestational ages. See table below.

Levels with Gestational Age

hCG levels with Gestational Age:[15]

Gestational Age	hCG mIU/mL [IU/L]
0.2–1 week	5–50
1–2 weeks	50–500
2–3 weeks	100–5000
3–4 weeks	500–10000
4–5 weeks	1000–50000
5–6 weeks	10000–100,000
6–8 weeks	15000–200,000
2–3 months	10000–100,000

Hook Effect

One step sandwich immunoassays are susceptible to a high–dose "hook effect", where an excess of antigen prevents simultaneous binding of the capture and detection antibodies to a single analyte molecule.[19] Such samples must be diluted and reassayed prior to reporting the results. The BHCG method shows no hook effect up to 1 million mIU/mL [IU/L] of human chorionic gonadotropin.

Analytical Sensitivity

Analytical Sensitivity: 1 mIU/mL [IU/L]

The analytical sensitivity represents the lowest concentration of BHCG that can be distinguished from zero. This sensitivity is defined as the mean value (n=20) plus two standard deviations of the Level A (0 mIU/mL [IU/L]) BHCG Calibrator.

References

1. Williams MA, Hickok DE, Zingheim RW, Zebelman AM, Mittendorf R, Luthy DA. A longitudinal study of maternal serum human chorionic gonadotropin levels during pregnancy. Gynecol Obstet Invest. 1995;40(3): 158-61.
2. Ashwood ER, Knight GJ. Clinical Chemistry of Pregnancy: Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Ed. Burtis CA, Ashwood ER, and Bruns DE, eds. St. Louis, MO: Elsevier Saunders Co, 2006, pp.2179-82.
3. Ullman EF, Kirakossian H, Switchenko AC, Ishkanian J, et al. Luminescent oxygen channeling assay (LOCI): sensitive, broadly applicable homogenous immunoassay method. Clin Chem 1996;42(9): 1518-1526.
4. Ullman EF, Kirakossian H, Sharat S, Ping Wu Z, Irvin BR, et al. Luminescent oxygen channeling immunoassay: measurement of particle binding kinetics by chemiluminescence. Proc Nat Acad Sci USA, Biochem 1994; 91:5426-5430.
5. Ullman, EF. Homogenous Immunoassays: The Immunoassay Handbook, 2nd Ed. David Wild, ed. New York, NY:Nature Publishing Group, 2001, pp.192-194.
6. Clinical and Laboratory Standards Institute/NCCLS. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard-Fifth Edition. CLSI/NCCLS document H3-A5 (ISBN 1-56238-515-1). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087, 2003.
7. Clinical and Laboratory Standards Institute /NCCLS. Tubes and Additives for Venous Blood Specimen Collection; Approved Standard—Fifth Edition. CLSI /NCCLS document H1-A5 [ISBN 1-56238-519-4]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2003.
8. Clinical and Laboratory Standards Institute/NCCLS. Procedures for the Handling and Processing of Blood Specimens Approved Guideline-3rd Ed. CLSI/NCCLS document H18-A3 (ISBN 1-56238-555-0). CLSI, 940 West Valley Road, Suite1400, Wayne, PA 19087, 2004.
9. Zhang DJ, Elswick RK, Miller WG, and Bailey JL. Effect of serum-clot contact time on clinical chemistry laboratory results. Clin Chem 1998;44:1325-1333.
10. Wu AHB. Clinical Guide to Laboratory Tests, 4th Ed. St. Louis, MO: Elsevier Saunders Co, 2006, p 254.
11. Vaidya HC, Beatty BG. Eliminating interference from heterophilic antibodies in a two-site immunoassay for creatine kinase MB by using F(ab')2 conjugate and polyclonal mouse IgG. Clin Chem 1992;38:1737-1742.
12. Kricka LJ. Human anti-animal antibody interference in immunological assays. Clin Chem 1999;45(7): 942-956.
13. Lenton EA, Neal LM, Sulaiman R. Plasma concentration of human chorionic gonadotropin from the time of implantation until the second week of pregnancy. Fertil Steril 1982;37:773-778.
14. Faix JD, Sokolove PJ. Agreement of intact and beta chain-specific HCG assays in abnormal pregnancy. J Clin Immunoassay 1991;14-196.
15. Clinical Chemistry Theory, Analysis, and Correlation, 3rd Ed. Kaplan LA, Pesce AJ, eds. Philadelphia, PA: Mosby Co, 1996, pp. 816-817.

16. Clinical and Laboratory Standards Institute/NCCLS. Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition. CLSI/NCCLS Document EP5-A2 (ISBN 1-56238-542-9) CLSI, 940 West Valley Road, Suite 1400, Wayne, PA, 19087, 2004.
17. Clinical and Laboratory Standards Institute/NCCLS. Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition. CLSI/NCCLS Document EP9-A2 (ISBN 1- 56238-472-4) CLSI, 940 West Valley Road, Suite 1400, Wayne, PA, 19087, 2002.
18. Clinical and Laboratory Standards Institute/NCCLS. Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition.. CLSI/NCCLS document EP7-A2 (ISBN 1-56238-584-4). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087, 2005.
19. Fernando SA, Wilson GS. Studies of the 'hook' effect in the one-step sandwich immunoassay. J Immunol Methods. 1992;151(1-2):47-66.

All Revision Dates

1/18/2024

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	1/18/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	1/18/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/15/2024
Laboratory Services Department	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services	1/14/2024

Status **Active** PolicyStat ID **15005221**

Origination	5/20/2013
Last Approved	1/18/2024
Effective	5/20/2013
Last Revised	1/18/2024
Next Review	1/17/2026
Owner	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services
Policy Area	Laboratory Services - Chemistry

L.CHEM 1.14 C3 Complement (C3)

Policy

C3 Complement (C3)

Intended Use: The C3 method is an *in vitro* diagnostic test for the quantitative measurement of C3 complement in human serum and heparinized plasma on the Dimension Vista® System. Measurements of C3 are used as an aid in the diagnosis of immunologic disorders associated with
C3 complement protein.

Summary: The complement system is an integral part of the antigen-nonspecific immune defense. It can be activated via two reaction pathways, the classical pathway which is triggered primarily by cell-bound immune complexes, and the alternative pathway which is activated primarily by foreign bodies such as microorganisms. The complement component C3 is a key protein in both reaction pathways. Complement activation is associated with consumption of component C3 so that a reduction in this concentration can allow diagnostic conclusions to be reached. Diminished serum concentrations of C3 are observed primarily in active systemic lupus erythematosus (SLE), in forms of membrane proliferative glomerulonephritis and in immune complex diseases (serum sickness). In SLE the serum concentrations of the complement factors reflect the activity of the disease. Diminished C3 values occur in acute glomerulonephritis and in membrane proliferative glomerulonephritis. The complement components react as acute-phase proteins and may therefore show elevated serum concentrations in patients with inflammatory diseases. Hereditary deficiency states of this complement factor have been reported[1,2,3].

Principles of Procedure

Proteins contained in human body fluids form immune complexes in an immunochemical

reaction with specific antibodies. These complexes scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the respective protein in the sample. The result is evaluated by comparison with a standard of known concentration.

Reagents

Wells[a,b]	Form	Ingredient	Concentration[c]	Source
1 - 8	Liquid	Reaction Buffer: Phosphate buffer; Polyethylene Glycol	56 g/L	
9 - 12	Liquid	Antiserum to human C3c	984 g/L	Rabbit

a. Wells are numbered consecutively from the wide end of the cartridge.
b. Contain preservatives.
c. Nominal value per well in a cartridge.

Precautions

Contains sodium azide (< 0.1 %) as a preservative. Sodium azide can react with copper or lead pipes in drain lines to form explosive compounds. Dispose of properly in accordance with local regulations.

Used cuvettes contain human body fluids; handle with appropriate care to avoid skin contact or ingestion.

For in vitro diagnostic use.

Reagent Preparation

All reagents are liquid and ready to use.

Store at: 2 - 8 °C.

Expiration: Refer to carton for expiration date of individual unopened reagent cartridges. Sealed wells on the instrument are stable for 90 days.

Open well stability: 21 days for wells 1 - 12.

Specimen Collection and Handling

Recommended specimen types: serum, lithium heparinized plasma or sodium heparinized plasma.

Serum and plasma can be collected using recommended procedures for collection of diagnostic blood specimens by venipuncture[4].

Follow the instructions provided with your specimen collection device for use and processing[5].

For serum, complete clot formation should take place before centrifugation. Serum or plasma

should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection[6].

The antiserum is directed against the C3c fragment of the C3 molecule. The extent of fragmentation of C3 to the C3c fragment varies depending on the age of the sample and storage conditions. For fresh samples the C3 values obtained in the immunonephelometric assay have been observed to be up to 30 % lower than those obtained for stored samples, depending on the extent to which fragmentation has advanced[7].

Samples should be as fresh as possible (stored for no more than seven days at 2 - 8 °C) or stored frozen. Samples can be stored at below -20 °C for up to three months12. During storage serum or heparinized plasma specimens may increase in C3c concentration up to 17 %. Therefore, complement protein results for stored samples need to be assessed against reference intervals determined under similar conditions. Lipemic or frozen samples which become turbid after thawing must be clarified by centrifugation (10 minutes at approximately 15,000 x g) prior to testing.

Specimens should be free of particulate matter.

Procedure

Materials

Materials Provided

C3 Flex® reagent cartridge, Cat. No. K7026

Materials Required But Not Provided

PROT1 CAL, Cat. No. KC710

System Diluent, Cat. No. KS804

N Diluent, Cat. No. OUMT05

Quality Control Material, such as:

PROT1 CON L, Cat. No. KC715

PROT1 CON M, Cat. No. KC716

PROT1 CON H, Cat. No. KC717

Test Steps

Sampling, reagent delivery, mixing, and processing are automatically performed by the Dimension Vista® System. For details of this processing, refer to your Dimension Vista® Operator's Guide.

Test Conditions	

Initial Sample Dilution	1:20
	Cuvette
Diluted Sample Volume (delivered to the cuvette)	13.7 µL
Reaction Buffer	65.8 µL
Chase Volume	43.8 µL
Antiserum to human C3c	27.4 µL
Temperature	37.0 °C
Reaction time	6 minutes
Wavelength	840 nm
Type of Measurement	Nephelometric

Calibration

Calibration Material	PROT1 CAL, Cat. No. KC710
Calibration Scheme	6 levels, n = 3
Units Typical Calibration Levels	mg/dL [g/L]d (mg/dL x 0.01) = [g/L] 0.6, 1.4, 2.8, 6.4, 13.0, 28.0 mg/dL [0.006, 0.014, 0.028, 0.064, 0.13, 0.28 g/L] Multiply calibrator levels by the sample dilution to obtain the analytical measurement range. To obtain calibrator levels that span the measuring range, PROT1 CAL is diluted automatically with System Diluent by the instrument to the following dilutions:
	Level 1: 1:200 dilution
	Level 2: 1:94 dilution
	Level 3: 1:45 dilution
	Level 4: 1:20 dilution
	Level 5: 1:10 dilution
	Level 6: 1:4.5 dilution
Calibration Frequency	Every 30 days for any one lot Calibration interval may be extended based on acceptable verification of calibration.
A new calibration is required:	• For each new lot of Flex® reagent cartridges • After major maintenance or service, if indicated by quality control results • As indicated in laboratory quality control procedures • When required by government regulations

Quality Control

Follow government regulations or accreditation requirements for quality control frequency. If not

otherwise specified, analyze a minimum of two levels of a Quality Control (QC) material with known C3 complement concentrations at least once each day of use.

Follow your laboratory internal QC procedures if the results obtained are outside acceptable limits.

Results

The instrument calculates the concentration of C3 complement in mg/dL [g/L] using the calculation scheme described in your Dimension Vista® Operator's Guide.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

AMR

Analytical Measurement Range (AMR): 16.0 - 410 mg/dL [0.16 - 4.10 g/L]

This is the measuring range for the initial 1:20 dilution of samples that are automatically processed by the instrument. If the readings obtained are outside the initial measuring range, the method can be repeated using a lower or higher dilution of the sample.

Refer to your Dimension Vista® Operator's Guide for information on repeat measurements using other dilutions.

Dilution

- Samples with results in excess of 410 mg/dL [4.10 g/L] can be repeated on a higher dilution (1:200).
- Samples with results less than 16.0 mg/dL [0.16 g/L] can be repeated on a lower dilution (1:5).
- Samples with results less than 4.00 mg/dL [0.04 g/L] will be reported as "less than 4.00 mg/dL" by the instrument.

Limitations of Procedure

Turbidity and particles in the samples may interfere with the determination. Therefore, samples containing particles must be centrifuged prior to testing. Lipemic or turbid samples, which cannot be clarified by centrifugation (10 minutes at approximately 15,000 x g), must not be used.

Due to matrix effects, inter-laboratory survey samples and control samples may yield results that differ from those obtained with other methods. It may therefore be necessary to assess these results in relation to method-specific target values.

The instrument reporting system contains flags and comments to provide the user with information regarding instrument processing errors, instrument status information and potential errors in C3 complement results. Refer to your Dimension Vista® Operator's Guide for the meaning of report flags and comments. Any report containing flags and/or comments should be addressed according to your laboratory's procedure manual and not reported.

If a result exceeds the upper limit of the extended measuring range, it can be repeated by manual dilution.

Manual Dilution:	Dilute with N Diluent to obtain results within the analytical measuring range. Enter dilution factor on the instrument. Reassay. Results are multiplied by the dilution factor.

Expected Values

Expected Values: 90.0 - 180 mg/dL [0.90 - 1.80 g/L]

The reference interval applies for serum and plasma samples from healthy adults[8].

Reference intervals for C3 may vary with the population studied and depend on sample age and storage (refer to "Specimen Collection and Handling" section). Fresh samples can be expected to have lower C3 concentrations.

Each laboratory should establish its own expected values for C3 complement as performed on the Dimension Vista® System.

Specificity

HIL Interference

The C3 method was evaluated for interference according to CLSI EP7-A211. Bias is the difference in the results between the control sample (without the interferent) and the test sample (contains the interferent) expressed in percent. Bias exceeding 10 % is considered interference.

Substance Tested	Substance Concentration	C3 mg/dL [g/L]	Bias* %
Hemoglobin (hemolysate)	1000 mg/dL [0.155 mmol/L]	176 [1.76]	±0
Bilirubin (unconjugated)	60 mg/dL [1026 µmol/L]	180 [1.80]	-2
Bilirubin (conjugated)	60 mg/dL [1026 µmol/L]	180 [1.80]	-2
Lipemia	Refer to "Specimen Collection and Handling" section		

*** Analyte results should not be corrected based on this bias.**

Linearity

The assay was determined to be linear over the defined measuring range.

References

1. Thomas L. The complement system. In: Thomas L, ed. Clinical Laboratory Diagnostics. Frankfurt: TH-Books Verlagsgesellschaft, 1998:794-806.
2. Hebert LA, Cosio FG, Neff JC. Diagnostic significance of hypocomplementemia. Kidney Int 1991;39:811-21.
3. West CD. The complement profile in clinical medicine. Inherited and acquired conditions

lowering the serum concentrations of complement component and control proteins. Complement Inflamm 1989;6:49-64.

4. Clinical and Laboratory Standards Institute (CLSI). Procedures for the collection of diagnostic blood specimens by venipuncture; Approved Standard-Sixth Edition. CLSI document H3-A6 (ISBN 1-56238-650-6). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2007.
5. Clinical and Laboratory Standards Institute (CLSI). Tubes and additives for venous and capillary blood specimen collection; Approved Standard-Sixth Edition. CLSI document H1-A6 (ISBN 1-56238-740-5). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2010.
6. Clinical and Laboratory Standards Institute (CLSI). Procedures for the handling and processing of blood specimens for common laboratory tests; Approved Guideline-Fourth Edition. CLSI document H18-A4 (ISBN 1- 56238-724-3). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2010.
7. Okumura N, Nomura M, Tada T, et al. Effects of sample storage on serum C3 assay by immunonephelometry. Clin Lab Sci 1990;3:54-57.
8. Dati F, Schumann G, Thomas L, et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference ranges for 14 proteins in serum based on the standardization against the IFCC/BCR/CAP Reference Material (CRM 470). International Federation of Clinical Chemistry. Community Bureau of Reference of the Commission of the European Communities. College of American Pathologists. Eur J Clin Chem Clin Biochem 1996;34:517-20.
9. Clinical and Laboratory Standards Institute (CLSI). Evaluation of precision performance of quantitative measurement methods; Approved Guideline-Second Edition. CLSI document EP5-A2 (ISBN 1-56238-542-9). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2004.
10. Clinical and Laboratory Standards Institute (CLSI). Method comparison and bias estimation using patient samples; Approved Guideline-Second Edition. CLSI document EP9-A2 (ISBN 1-56238-472-4). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2002.
11. Clinical and Laboratory Standards Institute (CLSI). Interference testing in clinical chemistry; Approved Guideline-Second Edition. CLSI document EP7-A2 (ISBN 1-56238-584-4). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2005.
12. Schreiber W, Rausch S, Lammers M. Choice of specimen for immunonephelometric protein assays. Clin Chim Acta 2005;355:S407.

All Revision Dates

1/18/2024

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	1/18/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	1/18/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/15/2024
Laboratory Services Department	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services	1/14/2024

Status **Active** PolicyStat ID **15005710**

Origination	5/20/2013
Last Approved	1/18/2024
Effective	5/20/2013
Last Revised	1/18/2024
Next Review	1/17/2026
Owner	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services
Policy Area	Laboratory Services - Chemistry

L.CHEM 1.15 C4 Complement (C4)

Policy

C4 Complement (C4)

Intended Use: The C4 method is an *in vitro* diagnostic test for the quantitative measurement of C4 complement in human serum and heparinized plasma on the Dimension Vista® System. Measurements of C4 are used as an aid in the diagnosis of immunologic disorders associated with
C4 complement protein.

Summary: The complement system is an integral part of the antigen-nonspecific immune defense. It can be activated via two reaction pathways, the classical pathway which is triggered primarily by cell-bound immune complexes, and the alternative pathway which is activated primarily by foreign bodies such as microorganisms. The complement component C4 belongs to the classical pathway of complement activation. Complement activation is associated with consumption of component C4 so that a reduction in this concentration can allow diagnostic conclusions to be reached. Diminished serum concentrations of C4 are observed primarily in active systemic lupus erythematosus (SLE), in forms of membrane proliferative glomerulonephritis and in immune complex diseases (serum sickness). In SLE the serum concentrations of the complement factors reflect the activity of the disease. Isolated diminished levels of C4 can occur in hereditary angioedema (HAE) and in cases of autoimmune hemolytic anemia. The complement components react as acute-phase proteins and may therefore show elevated serum concentrations in patients with inflammatory diseases. Hereditary deficiency states of this complement factor have been reported[1,2,3].

Principles of Procedure

Proteins contained in human body fluids form immune complexes in an immunochemical reaction with specific antibodies. These complexes scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the respective protein in the sample. The result is evaluated by comparison with a standard of known concentration.

Reagents

Wells[a,b]	Form	Ingredient	Concentration[c]	Source
1 - 8	Liquid	Reaction Buffer: Phosphate buffer; Polyethylene glycol	56 g/L	
9 - 12	Liquid	Antiserum to human C4	984 g/L	Rabbit

a. Wells are numbered consecutively from the wide end of the cartridge.
b. Contain preservatives.
c. Nominal value per well in a cartridge.

Precautions

Contains sodium azide (< 0.1 %) as a preservative. Sodium azide can react with copper or lead pipes in drain lines to form explosive compounds. Dispose of properly in accordance with local regulations.
Used cuvettes contain human body fluids; handle with appropriate care to avoid skin contact or ingestion.
For *in vitro* diagnostic use.

Reagent Preparation:
All reagents are liquid and ready to use.
Store at: 2 - 8 °C.
Expiration: Refer to carton for expiration date of individual unopened reagent cartridges. Sealed wells on the instrument are stable for 90 days.
Open well stability: 21 days for wells 1 - 12.

Specimen Collection and Handling

Recommended specimen types: serum, lithium heparinized plasma or sodium heparinized plasma.
Serum and plasma can be collected using recommended procedures for collection of diagnostic blood specimens by venipuncture[4].

Follow the instructions provided with your specimen collection device for use and processing[5].
For serum, complete clot formation should take place before centrifugation. Serum or plasma

should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection[6].
Fragmentation of C4 to the more stable C4c fragment may occur during storage of the sample. C4 values have been observed to increase in relation to the period of storage.

Samples should be as fresh as possible (stored for no more than seven days at 2 - 8 °C) or stored frozen. Samples can be stored at below -20 °C for up to three months11. During storage serum or heparinized plasma specimens may increase in C4c concentration up to 8 %. Therefore, complement protein results for stored samples need to be assessed against reference intervals determined under similar conditions. Lipemic or frozen samples which become turbid after thawing must be clarified by centrifugation (10 minutes at approximately 15,000 x g) prior to testing.
Specimens should be free of particulate matter.

Procedure

Materials

Materials Provided

- C4 Flex® reagent cartridge, Cat. No. K7028

Materials Required But Not Provided

- PROT1 CAL, Cat. No. KC710
- System Diluent, Cat. No. KS804
- N Diluent, Cat. No. OUMT05
- Quality Control Material, such as:
- PROT1 CON L, Cat. No. KC715
- PROT1 CON M, Cat. No. KC716
- PROT1 CON H, Cat. No. KC717

Test Steps

Sampling, reagent delivery, mixing, and processing are automatically performed by the Dimension Vista® System. For details of this processing, refer to your Dimension Vista® Operator's Guide.

Test Conditions

Initial Sample Dilution	1:10
	Cuvette
Diluted Sample Volume (delivered to the cuvette)	25 µL
Reaction Buffer	63 µL
Chase Volume	42 µL

Antiserum to human C4	20 µL
Temperature	37.0 °C
Reaction time	6 minutes
Wavelength	840 nm
Type of Measurement	Nephelometric

Calibration

Calibration Material	PROT1 CAL, Cat. No. KC710
Calibration Scheme	6 levels, n = 3
Units Typical Calibration Levels	mg/dL [g/L]d (mg/dL x 0.01) = [g/L] 0.48, 0.96, 2.4, 4.8, 9.6, 24.0 mg/dL [0.0048, 0.0096, 0.024, 0.048, 0.096, 0.24 g/L] Multiply calibrator levels by the sample dilution to obtain the analytical measurement range. To obtain calibrator levels that span the measuring range, PROT1 CAL is diluted automatically with System Diluent by the instrument to the following dilutions:
	Level 1: 1:50 dilution
	Level 2: 1:25 dilution
	Level 3: 1:10 dilution
	Level 4: 1:5 dilution
	Level 5: 1:2.5 dilution
	Level 6: 1:1 dilution
Calibration Frequency	Every 30 days for any one lot Calibration interval may be extended based on acceptable verification of calibration.
A new calibration is required:	• For each new lot of Flex® reagent cartridges • After major maintenance or service, if indicated by quality control results • As indicated in laboratory quality control procedures • When required by government regulations

a. Système International d'Unités [SI Units] are in brackets.

Quality Control

Follow government regulations or accreditation requirements for quality control frequency. If not otherwise specified, analyze a minimum of two levels of a Quality Control (QC) material with known C4 complement concentrations at least once each day of use.

Follow your laboratory internal QC procedures if the results obtained are outside acceptable limits.

Results

The instrument calculates the concentration of C4 complement in mg/dL [g/L] using the calculation scheme described in your Dimension Vista® Operator's Guide.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

AMR

Analytical Measurement Range (AMR): 6.00 – 160 mg/dL [0.06 - 1.60 g/L]

This is the measuring range for the initial 1:10 dilution of samples that are automatically processed by the instrument. If the readings obtained are outside the initial measuring range, the method can be repeated using a lower or higher dilution of the sample.

Dilution

Refer to your Dimension Vista® Operator's Guide for information on repeat measurements using other dilutions.

- Samples with results in excess of 160 mg/dL [1.60 g/L] can be repeated on a higher dilution (1:100).
- Samples with results less than 6.00 mg/dL [0.06 g/L] can be repeated on a lower dilution (1:2.5).
- Samples with results less than 1.50 mg/dL [0.015 g/L] will be reported as "less than 1.50 mg/dL" by the instrument.

Limitations of Procedure

Turbidity and particles in the samples may interfere with the determination. Therefore, samples containing particles must be centrifuged prior to testing. Lipemic or turbid samples, which cannot be clarified by centrifugation (10 minutes at approximately 15,000 x g), must not be used.

Due to matrix effects, inter-laboratory survey samples and control samples may yield results that differ from those obtained with other methods. It may therefore be necessary to assess these results in relation to method-specific target values.

The instrument reporting system contains flags and comments to provide the user with information regarding instrument processing errors, instrument status information and potential errors in C4 complement results. Refer to your Dimension Vista® Operator's Guide for the meaning of report flags and comments. Any report containing flags and/or comments should be addressed according to your laboratory's procedure manual and not reported.

If a result exceeds the upper limit of the extended measuring range, it can be repeated by manual dilution.

Manual	Dilute with N Diluent to obtain results within the analytical measuring range.

Dilution:	Enter dilution factor on the instrument. Reassay. Results are multiplied by the dilution factor.

Expected Values

Expected Values: 10.0 – 40.0 mg/dL [0.10 - 0.40 g/L]

The reference interval applies for serum and plasma samples from healthy adults7.

Reference intervals for C4 may vary with the population studied and depend on sample age and storage (refer to "Specimen Collection and Handling" section).

Each laboratory should establish its own expected values for C4 as performed on the Dimension Vista® System.

Specificity

HIL Interference

The C4 method was evaluated for interference according to CLSI EP7-A210. Bias is the difference in the results between the control sample (without the interferent) and the test sample (contains the interferent) expressed in percent. Bias exceeding 10 % is considered interference.

Substance Tested	Substance Concentration	C4 mg/dL [g/L]	Bias* %
Hemoglobin (hemolysate)	1000 mg/dL [0.155 mmol/L]	40.0 [0.40]	±0
Bilirubin (unconjugated)	60 mg/dL [1026 µmol/L]	36.0 [0.36]	+1
Bilirubin (conjugated)	60 mg/dL [1026 µmol/L]	36.0 [0.36]	+5
Lipemia	Refer to "Specimen Collection and Handling" section		

*** Analyte results should not be corrected based on this bias.**

Linearity

The assay was determined to be linear over the defined measuring range.

References

1. Thomas L. The complement system. In: Thomas L, ed. Clinical Laboratory Diagnostics. Frankfurt: TH-Books Verlagsgesellschaft, 1998:794-806.
2. Hebert LA, Cosio FG, Neff JC. Diagnostic significance of hypocomplementemia. Kidney Int 1991; 39:811-21.
3. West CD. The complement profile in clinical medicine. Inherited and acquired conditions lowering the serum concentrations of complement component and control proteins. Complement Inflamm 1989;6:49-64.
4. Clinical and Laboratory Standards Institute (CLSI). Procedures for the collection of diagnostic blood specimens by venipuncture; Approved Standard-Sixth Edition. CLSI document H3-A6 (ISBN 1-56238-650-6). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA,

2007.

5. Clinical and Laboratory Standards Institute (CLSI). Tubes and additives for venous and capillary blood specimen collection; Approved Standard-Sixth Edition. CLSI document H1-A6 (ISBN 1-56238-740-5). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2010.
6. Clinical and Laboratory Standards Institute (CLSI). Procedures for the handling and processing of blood specimens for common laboratory tests; Approved Guideline-Fourth Edition. CLSI document H18-A4 (ISBN 1- 56238-724-3). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2010.
7. Dati F, Schumann G, Thomas L, et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference ranges for 14 proteins in serum based on the standardization against the IFCC/BCR/CAP Reference Material (CRM 470). International Federation of Clinical Chemistry. Community Bureau of Reference of the Commission of the European Communities. College of American Pathologists. Eur J Clin Chem Clin Biochem 1996; 34:517-20.
8. Clinical and Laboratory Standards Institute (CLSI). Evaluation of precision performance of quantitative measurement methods; Approved Guideline-Second Edition. CLSI document EP5-A2 (ISBN 1-56238-542-9). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2004.
9. Clinical and Laboratory Standards Institute (CLSI). Method comparison and bias estimation using patient samples; Approved Guideline-Second Edition. CLSI document EP9-A2 (ISBN 1-56238-472-4). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2002.
10. Clinical and Laboratory Standards Institute (CLSI). Interference testing in clinical chemistry; Approved Guideline-Second Edition. CLSI document EP7-A2 (ISBN 1-56238-584-4). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2005.
11. Schreiber W, Rausch S, Lammers M. Choice of specimen for immunonephelometric protein assays. Clin Chim Acta 2005;355:S407.

All Revision Dates

1/18/2024

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	1/18/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	1/18/2024

Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/15/2024
Laboratory Services Department	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services	1/14/2024

Status **Active** PolicyStat ID **15039959**

Origination	1/28/2013	Owner	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services
Last Approved	1/18/2024		
Effective	1/28/2013		
Last Revised	1/18/2024	Policy Area	Laboratory Services - Chemistry
Next Review	1/7/2026		

L.CHEM 1.23 C- Reactive Protein (CRP)

Policy

C- Reactive Protein (CRP)

Intended Use: The CRP method is an *in vitro* diagnostic test for the quantitative measurement of C-reactive protein (CRP) in human serum and heparinized plasma on the Dimension Vista® System. In acute phase response, increased levels of a number of plasma proteins, including C-reactive protein, are observed. Measurement of CRP is useful for the detection and evaluation of infection, tissue
injury and inflammatory disorders.

Summary: CRP is one of the 'acute-phase' proteins, whose serum or plasma levels rise during general, nonspecific response to infectious and non-infectious inflammatory processes. CRP is synthesized in the liver and is normally present as a trace constituent of serum or plasma.
In various disease states resulting in tissue injury, infection or acute inflammation, CRP values may rise to 20 to 500 mg/L[1]. As elevated CRP values are always associated with pathological changes, the CRP method provides useful information for the diagnosis, therapy and monitoring of inflammatory processes and associated diseases[2,3,4]. Increases in CRP values are non-specific and should
not be interpreted without a complete clinical history.

Principles of Procedure

Polystyrene particles coated with monoclonal antibodies specific to human CRP are aggregated when mixed with samples containing CRP. These aggregates scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the

concentration of the respective protein in the sample. The result is evaluated by comparison with a standard of known concentration.

Reagents

Reagents

Wells[a,b]	Form	Ingredient	Concentration[c]	Source
1 - 8	Liquid	CRP Supplement Reagent: Phosphate buffer; Polidocanol	 1.9 g/L	
9 - 12	Liquid	CRP Reagent: Polystyrene particles; Monoclonal antibodies	 1 g/L 13 mg/L	 Mouse

a) Wells are numbered consecutively from the wide end of the cartridge.
b) Contain preservatives.
c) Nominal value per well in a cartridge.

Precautions

- Contains sodium azide (< 0.1 %) as a preservative. Sodium azide can react with copper or lead pipes in drain lines to form explosive compounds. Dispose of properly in accordance with local regulations.
- Contains human source material.
- Each donor or donor unit was tested and found to be negative for human immunodeficiency virus (HIV) 1 and 2, hepatitis B virus (HBV) and hepatitis C virus (HCV) using either tests found to be in conformance with the In Vitro Diagnostic Directive in the EU or FDA approved tests. Because no known test can offer complete assurance of the absence of infectious agents, all human derived products should be handled with appropriate caution.
- Used cuvettes contain human body fluids; handle with appropriate care to avoid skin contact or ingestion.
- For *in vitro* diagnostic use.

Reagent Preparation:
All reagents are liquid and ready to use.
Store at: 2 - 8 °C.
Expiration: Refer to carton for expiration date of individual unopened reagent cartridges. Sealed wells on the instrument are stable for 90 days.
Open well stability: 21 days for wells 1 - 12.

Specimen Collection and Handling

- Recommended specimen types: serum or heparinized plasma.
- Serum and plasma can be collected using recommended procedures for collection of

diagnostic blood specimens by venipuncture[5].

- Follow the instructions provided with your specimen collection device for use and processing[6].
- For serum, complete clot formation should take place before centrifugation. Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection[7].
- Samples should be as fresh as possible (stored for no more than seven days at 2 - 8 °C) or stored frozen. Samples can be stored at below -20 °C for up to eight months[14], if they are frozen within 24 hours after collection and if repeated freeze-thaw cycles are avoided. **Lipemic or frozen samples, which become turbid after thawing, must be clarified by centrifugation (10 minutes at approximately 15,000 x g) prior to testing. Specimens should be free of particulate matter.**

Procedure

Materials

Materials Provided

- CRP Flex® reagent cartridge, Cat. No. K7032

Materials Required But Not Provided

- PROT2 CAL, Cat. No. KC780
- System Diluent, Cat. No. KS804
- N Diluent, Cat. No. OUMT05
- Quality Control Material, such as:
- PROT2 CON L, Cat. No. KC785
- PROT2 CON H, Cat. No. KC787

Test Steps

Sampling, reagent delivery, mixing, and processing are automatically performed by the Dimension Vista® System. For details of this processing, refer to your Dimension Vista® Operator's Guide.

Test Conditions

Initial Sample Dilution	1:20
	Cuvette
Diluted Sample Volume (delivered to the cuvette)	1.37µL
Diluent Volume	118 µL
CRP Reagent	27.3 µL
Temperature	37.0 °C
Reaction time	5 minutes 50 seconds

Wavelength	840 nm
Type of Measurement	Nephelometric

Calibration

Calibration Material	PROT2 CAL, Cat. No. KC780
Calibration Scheme	7 levels, n = 3
Units	mg/dL [mg/L][d] (mg/dL x 10) = [mg/L]
Typical Calibration Levels	0.012, 0.025, 0.056, 0.111, 0.222, 0.50, 1.0 mg/dL [0.12, 0.25, 0.56, 1.11, 2.22, 5.0, 10.0 mg/L] Multiply calibrator levels by the sample dilution to obtain the analytical measurement range. To obtain calibrator levels that span the measuring range, PROT2 CAL is diluted automatically with System Diluent by the instrument to the following dilutions: Level 1: 1:162 dilution Level 2: 1:81 dilution Level 3: 1:36 dilution Level 4: 1:18 dilution Level 5: 1:9 dilution Level 6: 1:4 dilution Level 7: 1:2 dilution
Calibration Frequency	Every 45 days for any one lot Calibration interval may be extended based on acceptable verification of calibration.
A new calibration is required:	• For each new lot of Flex® reagent cartridges • After major maintenance or service, if indicated by quality control results As indicated in laboratory quality control procedures • As indicated in laboratory quality control procedures • When required by government regulations

d) Système International d'Unités [SI Units] are in brackets.

Quality Control

Follow government regulations or accreditation requirements for quality control frequency. If not otherwise specified, analyze a minimum of two levels of a Quality Control (QC) material with known C-reactive protein concentrations, e. g., PROT2 CON L or H at least once each day of use. Follow your laboratory internal QC procedures if the results obtained are outside acceptable limits.

Results

The instrument calculates the concentration of C-reactive protein in mg/dL [mg/L] using the calculation scheme described in your Dimension Vista® Operator's Guide.
Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

AMR

Analytical Measurement Range (AMR): 0.29 - 19 mg/dL [2.90 - 190 mg/L]
This is the measuring range for the initial 1:20 dilution of samples that are automatically processed by the instrument. If the readings obtained are outside the initial measuring range, the method can be repeated using a higher dilution of the sample.

Dilution

Refer to your Dimension Vista® Operator's Guide for information on repeat measurements using other dilutions.

- Samples with results in excess of 19.0 mg/dL [190 mg/L] can be repeated on a higher dilution.
- Samples with results less than 0.29 mg/dL [2.90 mg/L] will be reported as "less than 0.29 mg/dL" by the instrument.

Limitations of Procedure

Turbidity and particles in the samples may interfere with the determination. Therefore, samples containing particles must be centrifuged prior to testing. Lipemic or turbid samples, which cannot be clarified by centrifugation (10 minutes at approximately 15,000 x g), must not be used.
Due to matrix effects, inter-laboratory survey samples and control samples may yield results that differ from those obtained with other methods. It may therefore be necessary to assess these results in relation to method-specific target values.
The instrument reporting system contains flags and comments to provide the user with information regarding instrument processing errors, instrument status information and potential errors in Creactive protein results. Refer to your Dimension Vista® Operator's Guide for the meaning of report flags and comments. Any report containing flags and/or comments should be addressed according to your laboratory's procedure manual and not reported.
Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. This method has been designed to minimize interference from heterophilic antibodies8. Nevertheless, complete elimination of this interference from all patient specimens cannot be guaranteed. A test result that is inconsistent with the clinical picture and patient history should be interpreted with caution.
If a result exceeds the upper limit of the extended measuring range, it can be repeated by

manual dilution.
Manual Dilution: Dilute with N Diluent to obtain results within the analytical measurement range.
Enter dilution factor on the instrument. Reassay. Results are multiplied by the dilution factor.

Expected Values

Expected Values: less than 0.30 mg/dL [3.00 mg/L]

This reference interval applies to serum samples from healthy adults [9,10]. As CRP is a nonspecific marker for a wide range of disease processes, different reference ranges apply depending on the clinical indication. Furthermore, reference intervals are affected by many factors that may differ for each population studied. Each laboratory should establish its own expected values for CRP as performed on the Dimension Vista® System.

Maximum Observed Repeatability

- The expected maximum observed standard deviations (SD) for repeatability (within-run precision) using n = 5 replicates at the following nominal CRP concentrations are:

CRP Concentration	Acceptable SD Maximum
1.25 mg/dL [12.50 mg/L]	0.239 mg/dL [2.39 mg/L]
5.00 mg/dL [50.00 mg/L]	0.768 mg/dL [7.68 mg/L]

A system malfunction may exist if the acceptable SD maximum is exceeded.

Specific Performance Characteristics

The following data represent typical performance for the Dimension Vista® System.

Precision[11,e]

Material	Mean		Standard Deviation mg/dL [mg/L] (% CV)					
	mg/dL	[mg/L]	Repeatability			Within-Lab		
PROT2 CON L	1.191	[11.91]	0.057	[0.57]	(4.8)	0.072	[0.72]	(6.0)
PROT2 CON H	4.947	[49.47]	0.183	[1.83]	(3.7)	0.214	[2.14]	(4.3)
Serum pool	0.569	[5.69]	0.030	[0.30]	(5.3)	0.038	[0.38]	(6.7)
Serum pool	4.479	[44.79]	0.217	[2.17]	(4.9)	0.232	[2.32]	(5.2)
Serum pool	17.67	[176.7]	0.65	[6.5]	(3.7)	0.68	[6.8]	(3.8)

e) CLSI EP5-A2 was used. During each day of testing, two separate runs, with two test samples, for each test material, were analyzed for 20 days.

Method Comparison[12]

Comparative Method	Regression Statistics[f]			
	Slope	Intercept mg/dL [mg/L]	Correlation Coefficient	n
CRP on the BN ProSpec® System	0.985	-0.0353 [-0.353]	0.997	140[g]

f) CLSI EP9-A2 was used. The method used to fit the linear regression line was Passing Bablok.
g) The range of CRP values in the correlation study was 0.336 mg/dL to 18.276 mg/dL [3.36 mg/L to 182.76 mg/L].

Specificity

HIL Interference

The CRP method was evaluated for interference according to CLSI EP7-A2[13]. Bias is the difference in the results between the control sample (without the interferent) and the test sample (contains the interferent) expressed in percent. Bias exceeding 10 % is considered interference.

Substance Tested	Substance Concentration		CRP mg/dL [mg/L]	Bias* %
Hemoglobin (hemolysate)	1000 mg/dL	[0.155 mmol/L]	1.368 [13.68]	-1
Bilirubin (unconjugated)	60 mg/dL	[1026 µmol/L]	1.370 [13.70]	-6
Bilirubin (conjugated)	60 mg/dL	[1026 µmol/L]	1.370 [13.70]	-1
Lipemia	Refer to „Specimen Collection and Handling" section			

* **Analyte results should not be corrected based on this bias.**

Non Interfering Substances

The following substances do not interfere with the CRP method when present in serum and plasma at the concentrations indicated. Inaccuracies (biases) due to these substances are less than 10 % at CRP concentration of 0.309 mg/dL to 11.239 mg/dL [3.09 mg/L to 112.39 mg/L].

Substance	Test Concentration	SI Units
Acetaminophen	0.025 mg/dL	1.66 µmol/L
Amikacin	15 mg/dL	256 µmol/L
Ammonium heparin	3 U/mL	3000 U/L
Ampicillin	5.3 mg/dL	152 µmol/L
Ascorbic acid	5 mg/dL	227 µmol/L
Caffeine	6 mg/dL	308 µmol/L
Carbamazepine	3 mg/dL	127 µmol/L
Chloramphenicol	5 mg/dL	155 µmol/L
Chlordiazepoxide	1 mg/dL	33.3 µmol/L
Chlorpromazine	0.2 mg/dL	6.27 µmol/L
Cholesterol	500 mg/dL	12.9 mmol/L
Cimetidine	2 mg/dL	79.2 µmol/L
Creatinine	30 mg/dL	2652 µmol/L
Dextran 40	6000 mg/dL	1500 µmol/L
Diazepam	0.5 mg/dL	17.6 µmol/L
Digoxin	5 ng/mL	6.15 nmol/L
Erythromycin	6 mg/dL	81.6 µmol/L
Ethanol	400 mg/dL	86.8 mmol/L
Ethosuximide	25 mg/dL	1770 µmol/L
Substance	**Test Concentration**	**SI Units**
Furosemide	6 mg/dL	181 µmol/L
Gentamicin	12 mg/dL	251 µmol/L
Ibuprofen	50 mg/dL	2425 µmol/L
Immunoglobulin G (IgG)	5 g/dL	50 g/L
Lidocaine	1.2 mg/dL	51.2 µmol/L
Lithium chloride	2.3 mg/dL	3.2 mmol/L
Lithium heparin	3 U/mL	3000 U/L
Nicotine	0.1 mg/dL	6.2 µmol/L
Penicillin G	25 U/mL	25000 U/L
Pentobarbital	8 mg/dL	354 µmol/L
Phenobarbital	10 mg/dL	431 µmol/L
Phenytoin	5 mg/dL	198 µmol/L
Primidone	4 mg/dL	183 µmol/L
Propoxyphene	0.2 mg/dL	4.91 µmol/L
Protein, Albumin	6 g/dL	60 g/L
Rheumatoid Factors	500 IU/mL	500 IU/mL
Salicylic acid	60 mg/dL	4.34 mmol/L
Sodium heparin	3 U/mL	3000 U/L
Theophylline	4 mg/dL	222 µmol/L
Urea	500 mg/dL	83.3 mmol/L
Uric acid	20 mg/dL	1190 µmol/L
Valproic acid	50 mg/dL	3467 µmol/L

Hook Effect

The CRP method shows no hook effect up to 134.79 mg/dL [1347.9 mg/L].

Recovery

Recovery of protein reference material ERM®-DA470 (CRM 470) ranged from 90.7 - 96.5 % with a mean recovery of 94.1 %.

Limit of Quantitation: 0.29 mg/dL [2.90 mg/L]

The limit of quantitation represents the lower limit of the reportable range for CRP.

References

1. Kushner I, Rzewnicki DL. The acute phase response: General aspects. Bailliere's Clinical Rheumatology 1994;8:513-530.
2. Dixon JS, Bird HA, Sitton NG et al. C-reactive protein in the serial assessment of disease activity in rheumatoid arthritis. Scand J Rheum 1984;13:39-44.
3. Hind CRK, Pepys MB. The role of serum C-reactive Protein (PCR) measurement in Clinical Practice. Int Med 1984;5:112-151.
4. Van Leeuwen M, van Rijswijk MH. Acute phase proteins in monitoring of inflammatory disorders. Bailliere's Clinical Rheumatology 1994;8:531-552.
5. Clinical and Laboratory Standards Institute (CLSI). Procedures for the collection of diagnostic blood specimens by venipuncture; Approved Standard-Sixth Edition. CLSI documents H3-A6 (ISBN 1-56238-650-6). CLSI, 940 West Valley Road, Suite 1400, Wayne PA 19087-1898 USA, 2007.
6. Clinical and Laboratory Standards Institute (CLSI).Tubes and Additives for venous and capillary blood specimen collection; Approved Standard-Sixth Edition. CLSI documents H3-A6 (ISBN 1-56238-740-5). CLSI, 940 West Valley Road, Suite 1400, Wayne PA 19087-1898 USA, 2010.
7. Clinical and Laboratory Standards Institute (CLSI).Procedures for the handling and processing of blood specimens for common laboratory tests; Approved Guideline-Fourth Edition. CLSI documents H18-A4 (ISBN 1-56238-724-3). CLSI, 940 West Valley Road, Suite 1400, Wayne PA 19087-1898 USA, 2010.
8. Kricka LJ. Human anti-animal antibody interference in immunological assays. Clin Chem 1999; 45:942-956.
9. Tracy RP, Lemaitre RN, Psaty BM, Ives DG, Evans RW, Cushman M, Meilahn EN, Kuller LH. Relationship of C-reactive protein to risk of cardiovascular disease in the elderly: results from the Cardiovascular Health Study and the Rural Health Promotion Project. Arterioscler Thromb Vasc Biol. 1997; 17:1121-1127.
10. Macy EM, Hayes TE, Tracy RP. Variability in the measurement of C-reactive protein in healthy subjects: implications for reference interval and epidemiological applications. Clin Chem 1997; 43:52-58.
11. Clinical and Laboratory Standards Institute (CLSI).Evaluation of precision performance of quantitative measurement methods; Approved Guideline- Second Edition. CLSI documents EP5-A2 (ISBN 1-56238-472-4). CLSI, 940 West Valley Road, Suite 1400, Wayne PA 19087-1898 USA, 2002.
12. Clinical and Laboratory Standards Institute (CLSI).Method comparison and bias

estimation using patient samples; Approved Guideline- Second Edition. CLSI documents EP9-A2 (ISBN 1-56238-472-4). CLSI, 940 West Valley Road, Suite 1400, Wayne PA 19087-1898 USA, 2002.

13. Clinical and Laboratory Standards Institute (CLSI).Interference testing in clinical chemistry; Approved Guideline- Second Edition. CLSI documents EP7-A2 (ISBN 1-56238-584-4). CLSI, 940 West Valley Road, Suite 1400, Wayne PA 19087-1898 USA, 2005.
14. Schreiber W, Rausch S, Lammers M. Choice of specimen for immunonephelometric protein assays. Clin Chem ACTA 2005;355:S407.

All Revision Dates

1/18/2024

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	1/18/2024
Laboratory Services Department	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services	1/18/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	1/18/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/15/2024

Status **Active** PolicyStat ID **15039969**

Origination	1/28/2013
Last Approved	1/18/2024
Effective	1/28/2013
Last Revised	1/18/2024
Next Review	1/17/2026
Owner	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services
Policy Area	Laboratory Services - Chemistry

L.CHEM 1.25 Direct Bilirubin (DBIL)

Policy

Direct Bilirubin (DBIL)

Intended Use: The DBIL method is an *in vitro* diagnostic test for the quantitative measurement of direct (conjugated) bilirubin in human serum and plasma on the Dimension Vista® System. Measurements of direct bilirubin are used in the diagnosis and treatment of liver, hemolytic, hematological and metabolic disorders, including hepatitis and gall bladder disease.

Summary: There are at least four distinct bilirubin species in serum. The direct reacting species are mono-and diconjugated bilirubin (β- and γ-bilirubin) and the delta fraction (δ-bilirubin), which is tightly bound to albumin. Unconjugated bilirubin (α-bilirubin) is water-insoluble and reacts only after addition of an accelerator such as caffeine.[1] The DBIL method is a modification of the Doumas reference method, which is a modification of the diazo method described by Jendrassik and Grof in 1938.[1]

Principles of Procedure

Diazotized sulfanilic acid is formed by combining sodium nitrite and sulfanilic acid at low pH. The sample is diluted in 0.5M HCl. A sample blank reading is taken to eliminate interference from non-bilirubin pigments. Upon addition of the diazotized sulfanilic acid, the conjugated bilirubin is converted to diazo-bilirubin, a red chromophore which absorbs at 540 nm and is measured using a bichromatic (540, 700 nm) endpoint technique.

Reagents

Wells[a]	Form	Ingredient	Concentration[b]
5–6	Liquid	Hydrochloric acid	500 mM
7–8	Liquid	Sodium nitrite	72.5 mM
9–12	Liquid	Sulfanilic acid	25.9 mM
		Hydrochloric acid	132 mM

a. Wells are numbered consecutively from the wide end of the cartridge.

b. Nominal value per well in a cartridge.

Precautions

- Used cuvettes contain human body fluids; handle with appropriate care to avoid skin contact or ingestion.
- For *in vitro* diagnostic use.

Reagent Preparation: All reagents are liquid and ready to use.

Diazotized sulfanilic acid is prepared automatically by the instrument in wells 1–4 with the addition of sodium nitrite from wells 7–8 and sulfanilic acid/HCl from wells 9–12.

Store at: 2–8 °C

Expiration: Refer to carton for expiration date of individual unopened reagent cartridges. Sealed wells on the instrument are stable for 30 days.

Open Well Stability: 2 days for wells 1–4 (diazotized sulfanilic acid)

30 days for wells 5–6

8 days for wells 7–8

Sulfanilic acid in wells 9–12 is used immediately to prepare the diazo reagent in wells 1–4.

Specimen Collection and Handling

- Recommended specimen types: serum and plasma (lithium heparin and EDTA).
- Serum and plasma can be collected using recommended procedures for collection of diagnostic blood specimens by venipuncture.[2]
- Follow the instructions provided with your specimen collection device for use and processing.[6]
- Complete clot formation should take place before centrifugation. Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection.[3] Specimens should be free of particulate matter.

- Bilirubin is extremely photosensitive. Care should be taken to protect sample from both daylight and fluorescent light to avoid photodegradation.
- Samples should be stored at 4 °C and analyzed within 5 days. For longer storage, samples may be frozen at -20 °C or colder for up to 3 months.[4, 5]

Procedure

Materials

Materials Provided

- DBIL Flex® reagent cartridge, Cat. No. K2125

Materials Required But Not Provided

- BILI CAL, Cat. No. KC210
- Quality Control Materials

Test Steps

Sampling, reagent delivery, mixing, and processing are automatically performed by the Dimension Vista® System. For details of this processing, refer to your Dimension Vista® Operator's Guide.

Test Conditions

Sample Volume (delivered to the cuvette)	5 µL
Reagent 1 Volume	12.5 µL
Reagent 2 Volume	25 µL
Temperature	37.0 °C
Reaction time	4.9 minutes
Wavelength	540 and 700 nm
Type of Measurement	Bichromatic endpoint

Calibration

Calibration Material	BILI CAL, Cat. No. KC210
Calibration Scheme	2 levels (n=5)
Units	mg/dL [µmol/L][c] (mg/dL x 17.1)=[µmol/L]
Typical Calibration Levels	Level 1 (System water): 0.0 mg/dL [0 µmol/L] Level 2 (Calibrator A): 19.3 mg/dL [330 µmol/L]
Calibration Frequency:	Every 90 days for any one lot Calibration interval may be extended based on acceptable verification of calibration.

A new calibration is required:	• For each new lot of Flex® reagent cartridges • After major maintenance or service, if indicated by quality control results • As indicated in laboratory quality control procedures • When required by government regulations

c.Système International d'Unités [SI units] are in brackets.

Quality Control

At least once each day of use, analyze two levels of a Quality Control (QC) material with known direct bilirubin concentrations. Follow your laboratory internal QC procedures if the results obtained are outside acceptable limits.

Results

The instrument calculates the concentration of direct bilirubin in mg/dL [µmol/L] using the calculation scheme described in your Dimension Vista® Operator's Guide.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

AMR

Analytical Measurement Range (AMR): 0.05–16.0 mg/dL [1–274 µmol/L]

This is the range of analyte values that can be measured directly from the specimen without any dilution or pretreatment that is not part of the usual analytical process and is equivalent to the assay range.

Dilution

- Samples with results in excess of 16.0 mg/dL [274 µmol/L] should be repeated on dilution.
- **Manual Dilution:** Dilute with Reagent grade water to obtain results within reportable range. Enter dilution factor on the instrument. Reassay. Resulting readout is corrected for dilution.
- **Autodilution (AD):** The autodilute sample volume is 13 µL (dilution factor = 4) for serum/plasma. Refer to your Dimension Vista® Operator's Guide.
- Samples with results less than 0.05 mg/dL [1 µmol/L] will be reported as "less than 0.05 mg/dL [1 µmol/L]"by the instrument.

Limitations of Procedure

The instrument reporting system contains flags and comments to provide the user with information regarding instrument processing errors, instrument status information and potential errors in direct bilirubin results. Refer to your Dimension Vista® Operator's Guide for the meaning of report flags and comments. Any report containing flags and/or comments should be addressed according to your laboratory's procedure manual and not reported.

Interfering Substances

The DBIL method was evaluated for interference according to CLSI/NCCLS EP7-A2.[7] Bias is the difference in the results between the control sample (without the interferent) and the test sample (contains the interferent). Bias exceeding 10% is considered interference.

Substance Tested	Substance Concentration	Direct Bilirubin mg/dL [µmol/L]	Bias* %
Immunoglobulin G (IgG)	5 g/dL [50 g/L]	0.4 [7]	-29
Triglycerides	3000 mg/dL [33.9 mmol/L]	0.3 [5]	-22
Hemoglobin	Hemoglobin (monomer)		
(Hemolysate)	10 mg/dL [0.01 mmol/L]	0.4 [7]	-25.0
	10 mg/dL [0.01 mmol/L]	4.0 [68]	-2.4
	10 mg/dL [0.01 mmol/L]	15.8 [270]	-2.5
	25 mg/dL [0.02 mmol/L]	0.4 [7]	-33
	25 mg/dL [0.02 mmol/L]	4.2 [72]	-16.7
	25 mg/dL [0.02 mmol/L]	15.9 [272]	-8.2
	50 mg/dL [0.03 mmol/L]	0.3 [6]	-66.7
	50 mg/dL [0.03 mmol/L]	4.2 [72]	-20.9
	50 mg/dL [0.03 mmol/L]	15.6 [267]	-8.3

***Analyte results should not be corrected based on this bias.**

Expected Values

- **Expected Values: 0–0.2 mg/dL [0–3 µmol/L][8]**
- The reference interval was verified using 31 serum samples. Each laboratory should establish its own expected values for DBIL as performed on the Dimension Vista® System.
- The assay performance has not been established/tested for neonate/pediatric population.

Specificity

HIL Interference

The DBIL method was evaluated for interference according to CLSI/NCCLS EP7-A2.[7] Bias is the difference in the results between the control sample (without the interferent) and the test sample (contains the interferent) expressed in percent. Bias exceeding 10% is considered interference.

Substance Tested	Substance Concentration	Direct Bilirubin mg/dL [µmol/L]	Bias* %
Hemoglobin (hemolysate)	Hemoglobin (monomer) ≥ 50 mg/dL [0.03 mmol/L]	≤ 16 [274]	i, j
Lipemia (Intralipid®)	1000 mg/dL [11.30 mmol/L]	0.4 [7]	<10

	3000 mg/dL [33.90 mmol/L]	0.4 [7]	50
	3000 mg/dL [33.90 mmol/L]	5.1 [87]	<10
	3000 mg/dL [33.90 mmol/L]	14.1 [241]	<10

Intralipid® is a registered trademark of Fresenius Kabi AG, Bad Homburg, Germany.

*** Analyte results should not be corrected based on this bias.**

i. Hemolyzed samples containing 50 mg/dL [0.03 mmol/L] or greater of hemoglobin will be reported with an "H Interference" comment. Refer to your Dimension Vista® Operator's Guide.

j. Refer to Interfering Substances section for hemoglobin interference at various DBIL levels.

Analytical Sensitivity

Analytical Sensitivity: 0.05 mg/dL [1 µmol/L]

The analytical sensitivity represents the lowest concentration of direct bilirubin that can be distinguished from zero. This sensitivity is defined as the mean value (n=20) plus two standard deviations of the level 1 (0 mg/dL [µmol/L]) calibrator (system water).

References

1. Burtis CA, Ashwood ER, Bruns DE,Tietz NW, Textbook of Clinical Chemistry and Molecular Diagnostics, 4th ed., Elsevier Saunders, 2006; pp 1165-1208.
2. Clinical and Laboratory Standards Institute/NCCLS. *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition*. CLSI/NCCLS document H3-A5 [ISBN 1-56238-515-1]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2003.
3. Clinical and Laboratory Standards Institute/NCCLS. *Procedures for the Handling and Processing of Blood Specimens; Approved Guideline—Third Edition*. CLSI/NCCLS document H18-A3 [ISBN 1-56238-555-0]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2004.
4. Burtis CA, Ashwood ER, Bruns DE, Tietz NW, Textbook of Clinical Chemistry and Molecular Diagnostics, 4th ed., Elsevier Saunders, 2006; pp 1165-1208.
5. Young DS, Effects of Preanalytical Variables on Clinical Laboratory Tests-2nd ed, 1997 AACC Press Washington , DC, pp 3-88, 4-492.
6. Clinical and Laboratory Standards Institute /NCCLS. *Tubes and Additives for Venous Blood Specimen Collection; Approved Standard—Fifth Edition.* CLSI/NCCLS document H1-A5 [ISBN 1-56238-519-4]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2003.
7. Clinical and Laboratory Standards Institute/NCCLS. *Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition.* CLSI/NCCLS document EP7-A2 [ISBN 1-56238-584-4]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2005
8. Kaplan LA, Pesce AJ. Clinical Chemistry: Theory, Analysis, and Correlation, 3rd ed. St. Louis, MO: Mosby, Inc, 1996: p. 712.

9. Clinical and Laboratory Standards Institute /NCCLS. *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition.* CLSI/NCCLS document EP5-A2 [ISBN 1-56238-542-9]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2004.
10. Clinical and Laboratory Standards Institute/NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition*. CLSI/NCCLS document EP9-A2 [ISBN 1-56238-472-4]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2002. Dimension Vista®, Dimension® and Flex® are registered trademarks of Siemens Healthcare Diagnostics Inc.

All Revision Dates

1/18/2024

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	1/18/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	1/18/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/15/2024
Laboratory Services Department	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services	1/14/2024

Status Active PolicyStat ID 15039985

Origination	1/28/2013
Last Approved	1/18/2024
Effective	1/28/2013
Last Revised	1/18/2024
Next Review	1/17/2026
Owner	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services
Policy Area	Laboratory Services - Chemistry

L.CHEM 1.26 Digoxin (DIGXN)

Policy

Digoxin (DIGXN)

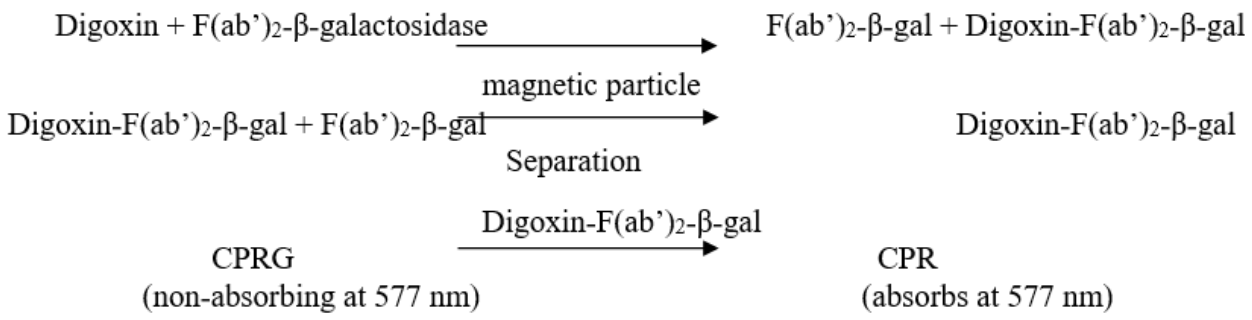
Intended Use: The DIG method is an *in vitro* diagnostic test for the quantitative measurement of digoxin in human serum and plasma on the Dimension Vista® System. Measurements of digoxin are used in the diagnosis and treatment of digoxin overdose and in monitoring levels of digoxin to ensure appropriate therapy.

Summary: Digoxin, a cardiac glycoside, is used as an antiarrhythmic agent, both alone and in conjunction with other drugs. Absorption from the gastrointestinal tract is variable: 60 – 80% of the administered dose is absorbed. Digoxin is excreted by the kidney almost entirely unchanged. Therefore the patient's renal function is an important consideration in determining dosage. In persons with normal kidney function the half-life is about 1.5 days. The most serious complications of digoxin toxicity are ventricular arrhythmias: ventricular tachycardia and ventricular fibrillation.[1,2]

Principles of Procedure

The digoxin method uses an immunoassay technique in which free and digoxin-bound antibody-enzyme species are separated using magnetic particles. The DIG chemistry is optimized for measurement of β-galactosidase activity. Magnesium acetate activates the enzyme and N-2-Hydroxyethylpiperazine-N'-1-ethanesulfonic acid (HEPES) buffer provides optimum pH. The methodology for DIG involves Antibody Conjugate reagent mixing with patient's serum or plasma. The Antibody Conjugate reagent utilizes the $F(ab')_2$ fragment of the antibody to eliminate interference from rheumatoid factor. Digoxin in the sample is bound by the $F(ab')_2$-β-galactosidase in the Antibody Conjugate reagent. Magnetic particles coated with the digoxin analog ouabain are added to bind free (unbound) antibody-enzyme conjugate. The reaction mixture is then separated magnetically. Following separation, the supernatant containing the digoxin-antibody-enzyme complex is transferred and mixed

with a substrate. The β-galactosidase (β-gal) portion of the Digoxin-F(ab')$_2$-β-galactosidase complex catalyzes the hydrolysis of chlorophenol-β-D-galactopyranoside (CPRG) to chlorophenol red (CPR). The change in absorbance at 577 nm due to the formation of CPR is directly proportional to β-galactosidase activity. Since β-galactosidase is not present in serum, its activity is directly proportional to digoxin in the patient's sample and is measured using a bichromatic (577, 700 nm) rate technique.



Reagents

Wells[a]	Form	Ingredient	Concentration[b]	Source
1, 2	Liquid	Antibody Conjugate Reagent and stabilizers	c	Rabbit, polyclonal
3, 4	Tablets	Ouabain Magnetic Particles	0.3%	
7, 8	Tablets	CPRG	7 mM	
11 – 12	Liquid	Substrate Diluent Buffer	100 mM	

a. Wells are numbered consecutively from the wide end of the cartridge.
b. Nominal value in hydrated cartridge.
c. Antibody titer and conjugate activity may vary from lot to lot.

Risk and Safety

- Irritant. Contains a mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1).
- May cause sensitization by skin contact.
- Avoid contact with skin.
- Wear suitable gloves.
- Safety data sheets (MSDS/SDS) available on www.siemens.com/diagnostics

Precautions: Used cuvettes contain human body fluids; handle with appropriate care to avoid skin contact or ingestion.
For *in vitro* diagnostic use.
Reagent Preparation: Hydrating, diluting and mixing are automatically performed by the

Dimension Vista® System.
Store at: 2 – 8 °C
Expiration: Refer to carton for expiration date of individual unopened reagent cartridges. Sealed wells on the instrument are stable for 30 days.
Open Well Stability: 3 days for wells 1 – 4, 7 – 8, 11 – 12

Specimen Collection and Handling

- Recommended specimen types: serum and plasma (sodium heparin).
- Serum and plasma can be collected using recommended procedures for collection of diagnostic blood specimens by venipuncture.[3]
- Follow the instructions provided with your specimen collection device for use and processing.[4]
- Blood specimens for digoxin levels should be collected between six and eight hours after the last oral dose. Each laboratory must determine its appropriate sample timing/collection protocol.
- Complete clot formation should take place before centrifugation. Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection.[5] Specimens should be free of particulate matter.
- Separated specimens are stable for 8 hours at 20 – 25 °C, 7 days at 2 – 8 °C. For longer storage, specimens may be frozen at-20 °C or colder for up to 6 months.[6]
- The purpose of specimen storage information is to provide guidance to users; however, users may validate their own procedures for storing patient samples.
- Repetitive freezing and thawing of specimens should be avoided. Ensure that patient samples, calibrators, and controls are equilibrated at ambient temperature (22 – 28 °C) before testing. Samples containing precipitates must be centrifuged before performing the assay.

Procedure

Materials

Materials Provided

- DIG Flex® reagent cartridge, Cat. No. K4035

Materials Required But Not Provided

- DRUG 1 Calibrator, Cat. No. KC410
- Quality Control Materials

Test Steps

Sampling, reagent delivery, mixing, and processing are automatically performed by the Dimension Vista® System. For details of this processing, refer to your Dimension Vista® Operator's Guide.
Test Conditions

Sample Volume (delivered to the cuvette)	10.00 µL
Antibody Conjugate Reagent Volume	33.33 µL

Ouabain Particle Volume	35.0 µL
CPRG	62.87 µL
Temperature	37.0 °C
Reaction time	10.7 minutes
Wavelength	577 and 700 nm
Type of Measurement	Bichromatic rate

Calibration

Calibration Material	DRUG 1 CAL, Cat. No. KC410
Calibration Scheme	5 levels, n = 2
Units	ng/mL [nmol/L][d] (ng/mL x 1.28) = [nmol/L]
Typical Calibration Levels	Level 1 (Calibrator A): 0.0 ng/mL [0.0 nmol/L] Intermediate levels automatically prepared by the instrument: 0.6, 1.2, 2.5 ng/mL [0.8, 1.5, 3.2 nmol/L] Level 5 (Calibrator B): 4.9 ng/mL [6.2 nmol/L]
Calibration Frequency	Every 30 days for any one lot Calibration interval may be extended based on acceptable verification of calibration.
A new calibration is required:	•For each new lot of Flex® reagent cartridges •After major maintenance or service, if indicated by quality control results •As indicated in laboratory quality control procedures •When required by government regulations

d. Système International d'Unités [SI units] are in brackets.

Quality Control

Follow government regulations or accreditation requirements for quality control frequency. At least once each day of use, analyze two levels of a Quality Control (QC) material with known digoxin concentrations. Follow your laboratory internal QC procedures if the results obtained are outside acceptable limits.

Results

The instrument calculates the concentration of digoxin in ng/mL [nmol/L] using the calculation scheme described in your Dimension Vista® Operator's Guide.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

AMR

Analytical Measurement Range (AMR): 0.1 – 5.0 ng/mL [0.1 – 6.4 nmol/L]

This is the range of analyte values that can be measured directly from the specimen without any dilution or

pretreatment that is not part of the usual analytical process and is equivalent to the assay range.

Dilution

- Samples with results in excess of 5.0 ng/mL [6.4 nmol/L] should be repeated on dilution. **Manual Dilution**: Dilute with digoxin-free serum to obtain results within reportable range. Enter dilution factor on the instrument. Reassay. Resulting readout is corrected for dilution.
- **Autodilution (AD)**: Not recommended
- Samples with results less than 0.1 ng/mL [0.1 nmol/L] will be reported as "less than 0.1 ng/mL [0.1 nmol/L]" by the instrument.

Limitations of Procedure

The instrument reporting system contains flags and comments to provide the user with information regarding instrument processing errors, instrument status information and potential errors in digoxin results. Refer to your Dimension Vista® Operator's Guide for the meaning of report flags and comments. Any report containing flags and/or comments should be addressed according to your laboratory's procedure manual and not reported.

Lower concentrations of 0.5 – 1.2 ng/mL [0.64 – 1.54 nmol/L] have been found to be more appropriate in certain populations such as chronic heart failure patients.[7,8] Digoxin toxicity is commonly associated with serum levels >2.0 ng/mL [2.6 nmol/L] but may occur with lower digoxin levels. Significant overlap of toxic and nontoxic values has been reported. Consequently, analysis of serum concentrations alone is not sufficient for optimization of digoxin therapy. Additional factors such as age, thyroid condition, electrolyte balance, hepatic and renal functions, and other clinical symptoms must be considered.[9]

Interfering Substances

- ‡ Endogenous, digoxin-like immunoreactive factors (DLIF) have been detected in the serum and plasma of neonates, pregnant women, and patients in renal and hepatic failure. Several studies have established that these factors can cause falsely elevated digoxin measurements when assayed by commercially available immunoassays.[10]
- ‡ Digoxin bound to Fab fragments of anti-digoxin antibodies, as found in serum and plasma of individuals being treated for digoxin toxicity, may result in misleading digoxin values.[11]
- Dextran 40 at a concentration of 6000 mg/dL [1500 µmol/L] decreases the DIG result by 21% at a DIG concentration of 1.0 ng/mL [1.3 nmol/L].

Therapeutic Range

- **Therapeutic Range: 0.9 – 2.0 ng/mL [1.2 – 2.6 nmol/L][12, 13]**
- Therapeutic digoxin concentrations vary significantly, depending on the individual. A range of 0.9 – 2.0 ng/mL [1.2 – 2.6 nmol/L] includes effective serum concentrations for many patients; however, some individuals are best treated at concentrations outside this range.
- Concentrations greater than 2.0 ng/mL [2.6 nmol/L] are often associated with toxic symptoms.[12, 13] Each laboratory should establish its own therapeutic range for digoxin as performed on the Dimension Vista® System.

Hemolysis, Icterus, Lipemia (HIL) Interference

DIG was evaluated for interference according to CLSI/NCCLS EP7-A2.[16] Bias is the difference in the results between the control sample (without the interferent) and the test sample (contains the interferent) expressed in percent. Bias exceeding 10% is considered interference.

Substance Tested	Substance Concentration	Digoxin ng/mL [nmol/L]	Bias* %
Hemoglobin (hemolysate)	Hemoglobin (monomer) 1000 mg/dL [0.62 mmol/L]	1.0 [1.0]	<10
Bilirubin (unconjugated)	40 mg/dL [684 µmol/L] 60 mg/dL [1026 µmol/L]	1.0 [1.0] 1.0 [1.0]	<10 12
Bilirubin (conjugated)	40 mg/dL [684 µmol/L] 60 mg/dL [1026 µmol/L]	1.0 [1.0] 1.0 [1.0]	<10 17
Lipemia (Intralipid®)	600 mg/dL [6.78 mmol/L] 800 mg/dL [9.04 mmol/L] 1000 mg/dL [11.3 mmol/L]	1.0 [1.0] 1.0 [1.0] 1.0 [1.0]	<10 -25 -13

Intralipid® is a registered trademark of Fresenius Kabi AG, Bad Homburg, Germany.

*** Analyte results should not be corrected based on this bias.**

Analytical Sensitivity

Analytical Sensitivity: 0.1 ng/mL [0.1 nmol/L]

The analytical sensitivity represents the lowest concentration of digoxin that can be distinguished from zero. This sensitivity is defined as the mean value (n=20) plus two standard deviations of the level 1 (0 ng/mL [0 nmol/L]) Drug 1 Calibrator.

References

1. Finn AL, Taylor WJ. Individualizing Drug Therapy, Practical Applications of Drug Monitoring. New York: Gross, Townsend, Frank, Inc., 1981: 2-6.
2. Burtis CA, Ashwood ER, Bruns DE. Tietz Textbook of Clinical Chemistry and Molecular Biology, Fourth Edition, Elsevier Saunders, St. Louis, MO; 2006, p. 1256
3. Clinical and Laboratory Standards Institute/NCCLS. *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition.* CLSI/NCCLS document H3-A5 [ISBN 1-56238-515-1]. CLSI,
   940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2003.
4. Clinical and Laboratory Standards Institute/NCCLS. *Tubes and Additives for Venous Blood Specimen Collection; Approved Standard—Fifth Edition*. CLSI/NCCLS document H1-A5 [ISBN 1-56238-519-4]. CLSI,
   940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2003.
5. Clinical and Laboratory Standards Institute/NCCLS. *Procedures for the Handling and Processing of Blood Specimens; Approved Guideline—Third Edition*. CLSI/NCCLS document H18-A3 [ISBN 1-56238-555-0]. CLSI,
   940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2004.

6. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests, 3rd ed. Washington, DC: AACC Press, 2007.
7. ESC Guidelines for diagnosis and treatment of patients with heart failure 2008. Eur. J Heart Failure 10: 933-989, 2008.
8. 2009 Focused Update Incorporated into the ACC/AHA 2005 Guidelines for the Diagnosis and Management of Heart Failure in Adults: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines: Developed in Collaboration With the International Society for Heart and Lung Transplantation, Circulation, 2009; 119: e391 – e479.
9. Dec, William G., Digoxin remains useful in the management of chronic heart failure, Med Clin N Am 87: 317-337, 2003.
10. Stone JA and Soldin SJ. Update On Digoxin, Clin Chem, 1989, Vol35, pp 1326-1331.
11. Reiney. Effects of Digoxin Immune Fab, American Journal of Clin Path, 1990, Vol 92, pp 779-786.
12. Evans WE, Schentag JJ, Jusko WJ. Applied Pharmacokinetics, Applied Therapeutics Inc., San Francisco, CA, 1980, p 330.
13. Huffman DH, Crow JW, Pentikainen P, Azarnoff DL. Association between clinical cardiac status, laboratory parameters and digoxin use, Amer Heart Journal 1976; 91:28–34.
14. Clinical and Laboratory Standards Institute/NCCLS. *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition.* CLSI/NCCLS document EP5-A2 [ISBN 1-56238-542-9]. CLSI,
940 West Valley Road, Suite 1400, Wayne, PA, 19087-1898 USA, 2004.
15. Clinical and Laboratory Standards Institute/NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition*. CLSI/NCCLS document EP9-A2 [ISBN 1-56238-472-4]. CLSI,
940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2002.
16. Clinical and Laboratory Standards Institute/NCCLS. I*nterference Testing in Clinical Chemistry; Approved Guideline—Second Edition*. CLSI/NCCLS document EP7-A2 [ISBN 1-56238-584-4]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2005.

All Revision Dates

1/18/2024

Approval Signatures

Step Description	Approver	Date

Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	1/18/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	1/18/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/15/2024
Laboratory Services Department	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services	1/14/2024

Status **Active** PolicyStat ID **15040012**

Origination	1/28/2013
Last Approved	1/18/2024
Effective	1/28/2013
Last Revised	1/18/2024
Next Review	1/17/2026
Owner	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services
Policy Area	Laboratory Services - Chemistry

L.CHEM 1.27 Alcohol (ETOH)

Policy

Alcohol (ETOH)

Intended Use: The Ethyl Alcohol (ETOH) method is an *in vitro* diagnostic test for the quantitative measurement of ethyl alcohol in human serum, plasma and urine on the Dimension Vista® System. Ethyl alcohol test results may be used in the diagnosis and treatment of alcohol intoxication and poisoning.

Summary: Ethanol (ethyl alcohol, alcohol) is the most common toxic substance encountered. Ethanol's deleterious effects have been linked with birth defects (fetal alcohol syndrome), cardiac conditions, high blood pressure, liver disease and mental deterioration.

The rate of ethanol absorption is dependent on the emptying time of the stomach. Since ethanol distributes evenly throughout the body water, its concentration in blood following a known dose may be estimated indirectly by measuring concentrations in serum, plasma or urine. Ethanol is rapidly metabolized so that a moderate dose will clear from the blood in approximately one hour.[1,2,3,4]

Principles of Procedure

The ETOH method is based on an enzymatic reaction. Reagent 1 contains the buffering system. Reagent 2 contains alcohol dehydrogenase (ADH), the coenzyme nicotinamide adenine dinucleotide (NAD), buffer, preservatives, and stabilizers. The ADH catalyzes the oxidation of ethyl alcohol to acetaldehyde. During this reaction, NAD is reduced to NADH. The absorbance due to NADH (and thus the alcohol concentration) is determined using a two-filter (340–383 nm) bichromatic rate technique.

$$\text{Ethyl alcohol} + NAD^{+} \xrightleftharpoons{ADH} \text{acetaldehyde} + NADH$$

(absorbs at 340 nm)

Reagents

Wells[a]	Form	Ingredient	Concentration[b]	Source
1–5 Reagent 2	Liquid	ADH	525 U/mL	Yeast
		NAD	18 mM	
		Tris Buffer		
8–12 Reagent 1	Liquid	Buffer Reagent		

a. Wells are numbered consecutively from the wide end of the cartridge.

b. Nominal value per well in a cartridge.

Precautions

For *in vitro* diagnostic use.
Reagent Preparation: All reagents are liquid and ready to use.
Store at: 2–8 °C
Expiration: Refer to carton for expiration date of individual unopened reagent cartridges.Sealed wells on the instrument are stable for 30 days.
Open Well Stability: 5 days for wells 1–5, 8–12

Specimen Collection and Handling

- Recommended specimen type: serum, plasma (sodium heparin, lithium heparin, EDTA, sodium fluoride/potassium oxalate), urine.
- Follow the instructions provided with your specimen collection device for use and processing.[8]
- Use non-alcohol germicidal solution to cleanse the skin. If reusable containers, syringes, and needles are employed, they must not be cleaned or stored with alcohol or other volatile solvents. The specimen tube should be completely filled and stored under refrigeration until analyzed.[5,6,7] To minimize the losses of alcohol in a sample due to evaporation, open and process samples in STAT mode. If not analyzed immediately, specimens may be stored tightly closed and refrigerated at 2–8 °C for up to 3 days following collection. After 3 days, specimens should be stored frozen. Repeated freeze-thaw cycles should be avoided.
- The purpose of specimen storage information is to provide guidance to users; however, users may validate their own procedures for storing patient samples.
- Urine specimens within the pH range of 3.0–11.0 do not require prior adjustment of pH.

Procedure

Materials

Materials Provided

- ETOH Flex® reagent cartridge, Cat. No. K5022

Materials Required But Not Provided

- CHEM 3 CAL, Cat. No. KC130
- Quality Control Material

Test Steps

Sampling, reagent delivery, mixing, and processing are automatically performed by the Dimension Vista® System. For details of this processing, refer to your Dimension Vista® Operator's Guide.

Test Conditions

Sample Volume (delivered to the cuvette)	4 µL
Reagent 1 Volume	98 µL
Reagent 2 Volume	55 µL
Temperature	37.0 °C
Reaction time	4 minutes
Wavelength	340–383 nm
Type of Measurement	Bichromatic Rate

Calibration

Calibration Material	CHEM 3 CAL, Cat. No. KC130
Calibration Scheme	2 levels, n = 3
Units	(mg/dL x 0.217) = [mmol/L][c]
Typical Calibration Levels	Level 1 (Calibrator A): 0 mg/dL [0.0 mmol/L] Level 2 (Calibrator B): 303 mg/dL [65.8 mmol/L]
Calibration Frequency	Every 30 days for any one lot Calibration interval may be extended based on acceptable verification of calibration.
A new calibration is required:	• For each new lot of Flex® reagent cartridges • After major maintenance or service, if indicated by quality control results • As indicated in laboratory quality control procedures • When required by government regulations

c. Système International d'Unités [SI units] are in brackets

Quality Control

Follow government regulations or accreditation requirements for quality control frequency. At least once each day of use, analyze two levels of a Quality Control (QC) material with known ethyl alcohol concentrations. Follow your laboratory internal QC procedures if the results obtained are outside acceptable limits.

Results

The instrument calculates the concentration of ethyl alcohol in mg/dL [mmol/L] using the calculation

scheme described in your Dimension Vista® Operator's Guide.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

AMR

Analytical Measurement Range (AMR): 3–300 mg/dL [0.7–65.1 mmol/L]

This is the range of analyte values that can be measured directly from the specimen without any dilution or pretreatment that is not part of the usual analytical process and is equivalent to the assay range.

Dilution

- Samples with results in excess of 300 mg/dL [65.1 mmol/L] should be repeated on dilution. **Manual Dilution**: Dilute with Reagent grade water to obtain results within reportable range. Enter dilution factor on the instrument. Reassay. Resulting readout is corrected for dilution.
- **Autodilution (AD)**: The autodilute sample volume is 50 µL (dilution factor = 4) for serum/plasma and urine. Refer to your Dimension Vista™ Operator's Guide.
- Samples with results less than 3 mg/dL [0.7 mmol/L] will be reported as "less than 3 mg/dL [0.7 mmol/L]" by the instrument.

Limitations of Procedure

The instrument reporting system contains flags and comments to provide the user with information regarding instrument processing errors, instrument status information and potential errors in ethyl alcohol results. Refer to your Dimension Vista® Operator's Guide for the meaning of report flags and comments. Any report containing flags and/or comments should be addressed according to your laboratory's procedure manual and not reported.

Environmental ethanol contamination may result in elevated ethanol results and has been shown to effect open well stability.

Expected Values

The pharmacological response to blood alcohol levels may vary from individual to individual. The fatal concentration has been reported to be greater than 400 mg/dL [86.8 mmol/L].[9]

- **Critical Values: greater than 400 mg/dL [86.8 mmol/L]**

Specificity

Hemolysis, Icterus, Lipemia (HIL) Interference

The ETOH method was evaluated for interference according to CLSI/NCCLS EP7-A2.[12] Bias is the difference in the results between the control sample (without the interferent) and the test sample (contains the interferent) expressed in percent. Bias exceeding 10% is considered interference.

Substance Tested	Substance Concentration	Ethyl Alcohol mg/dL [mmol/L]	Bias* %

Hemoglobin (hemolysate)	Hemoglobin (monomer) 1000 mg/dL [0.62 mmol/L]	92 [20.0]	<10
Bilirubin (unconjugated)	80 mg/dL [1368 µmol/L]	96 [20.8]	<10
Bilirubin (conjugated)	80 mg/dL [1368 µmol/L]	95 [20.7]	<10
Lipemia (Intralipid®)	3000 mg/dL [33.9 mmol/L]	101 [21.9]	<10

Intralipid® is a registered trademark of Fresenius Kabi AG, Bad Homburg, Germany.

*** Analyte results should not be corrected based on this bias.**

Non Interfering Substances

The following substances do not interfere with the ETOH method when present in serum at the concentrations indicated. Inaccuracies (biases) due to these substances are less than 10% at ethanol concentrations of 100 mg/dL [21.7 mmol/L].

Substance	Test Concentration	SI Units
Acetaminophen	20.0 mg/dL	1324 µmol/L
Amikacin	8.0 mg/dL	137 µmol/L
Ampicillin	5.3 mg/dL	152 µmol/L
Ascorbic Acid	6.0 mg/dL	342 µmol/L
Caffeine	6.0 mg/dL	308 µmol/L
Carbamezepine	3.0 mg/dL	127 µmol/L
Chloramphenicol	5.0 mg/dL	155 µmol/L
Chlordiazepoxide	1.0 mg/dL	33.3 µmol/L
Chlorpromazine	0.20 mg/dL	6.27 µmol/L
Cholesterol	503 mg/dL	13 mmol/L
Cimetidine	2.0 mg/dL	79.2 µmol/L
Creatinine	30 mg/dL	2.7 mmol/L
Dextran 40	6000 mg/dL	1500 µmol/L
Diazepam	0.51 mg/dL	18.0 µmol/L
Digoxin	6.1 ng/mL	7.8 nmol/L
Erythromycin	6.0 mg/dL	81.6 µmol/L
Ethosuximide	25.0 mg/dL	1770 µmol/L
Furosemide	6.0 mg/dL	181 µmol/L
Gentamicin	1.0 mg/dL	21 µmol/L
Heparin	3.0 U/mL	3000 U/L
Ibuprofen	50 mg/dL	2425 µmol/L
Immunoglobulin G (IgG)	5.0 g/dL	50 g/L
Lactate Dehydrogenase	237,500 U/L	237,500 U/L
Lactate	901 mg/dL	100 mmol/L
Lidocaine	1.2 mg/dL	51.2 µmol/L
Lithium	2.2 mg/dL	3.2 mmol/L
Mannitol	500 mg/dL	27.4 mmol/L
Nicotine	0.10 mg/dL	6.2 µmol/L
Penicillin G	25 U/mL	25000 U/L
Pentobarbital	8.0 mg/dL	354 µmol/L
Phenobarbital	10.0 mg/dL	431 µmol/L
Phenytoin	5.0 mg/dL	198 µmol/L
Primidone	4.0 mg/dL	183 µmol/L
Propoxyphene	0.16 mg/dL	4.91 µmol/L
Protein (Albumin)	6.0 g/dL	60 g/L
Protein (Total)	12.0 g/dL	120 g/L
Salicylic Acid	60 mg/dL	4.34 mmol/L
Theophylline	4.0 mg/dL	222 µmol/L
Triglycerides	3000 mg/dL	33.9 mmol/L
Urea	500 mg/dL	83 mmol/L
Uric acid	20 mg/dL	1.2 mmol/L
Valproic Acid	50 mg/dL	3467 µmol/L

Urine

The following substances do not interfere with the ETOH method when present in urine at the concentrations indicated. Inaccuracies (biases) due to these substances are less than 10% at ethanol concentrations of 100 mg/dL [21.7 mmol/L].

Substance	Test Concentration	SI Units
Acetone	1.0 g/dL	172.2 mmol/L
Ascorbic acid	1.5 g/dL	85.2 mmol/L
Bilirubin	2.0 mg/dL	34.2 µmol/L
Creatinine	0.5 g/dL	44.2 mmol/L
Gamma globulin	0.5 g/dL	5.0 g/L
Glucose	2 g/dL	0.11 mol/L
Hemoglobin	115 mg/dL	1.15 g/L
Human serum albumin	0.5 g/dL	5.0 g/L
Oxalic acid	0.1 g/dL	11.1 mmol/L
Riboflavin	7.5 mg/dL	199.3 µmol/L
Sodium chloride	6.0 g/dL	1.03 mol/L
Urea	6.0 g/dL	1.00 mol/L
Boric acid	1% w/v	162 mmol/L
Sodium azide	1% w/v	154 mmol/L
Sodium fluoride	1% w/v	238 mmol/L

Cross-reactivity

The following substances were evaluated for cross-reactivity with the ETOH method when present in serum containing 100 mg/dL [21.7 mmol/L] of ethanol in the amounts indicated. The percent cross-reactivity was calculated as follows:

$$\% \text{ Cross-reactivity} = \frac{[\text{measured analyte}] - [\text{control analyte}]}{[\text{substance added}]} \times 100$$

Substance	mg/dL [mmol/L]	% Cross-reactivity
Acetaldehyde	2000 [454]	0.1
Acetone	2000 [344]	0.1
n-Butanol	500 [67.5]	1.9
Ethylene Glycol	2000 [322]	0.0
Isopropanol	2000 [332]	0.4
Methanol	2000 [624]	0.0
n-Propanol	47 [7.8]	17.3
Propylene Glycol	2000 [263]	0.0

Analytical Sensitivity

Analytical Sensitivity: 3 mg/dL [0.7 mmol/L]

The analytical sensitivity represents the lowest concentration of ethanol that can be distinguished from zero. This sensitivity is defined as the mean value (n=20) plus two standard deviations of the level 1(0 mg/dL [0 mmol/L]) CHEM 3 CAL.

References

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 3rd ed. Chicago, IL: Year Book Medical Publishers Inc; 1989:322–324.
2. Ellenhorn MJ, Barceloux DG. Medical Toxicology. New York, NY: Elsevier Science Publishing Company, Inc; 1988:525–526, 782–796.
3. Wyngaarden JB, Smith LH Jr. Cecil Textbook of Medicine. Philadelphia, PA: WB Saunders Co; 1988:48–52.
4. Tietz NW. Textbook of Clinical Chemistry. Philadelphia, PA: WB Saunders Co; 1986:1704–1706, 1692–1694.
5. Tietz NW. Textbook of Clinical Chemistry, W.B. Saunders Co., Philadelphia, PA 1986, pp 52–53 (techniques and procedures to minimize laboratory infections) and p 1706 (specimen collection and storage recommendations).
6. Henry JB. Clinical Diagnosis and Management by Laboratory Methods, W.B.Saunders Co., Philadelphia, PA 1979, p 507.
7. Tietz NW. Clinical Guide to Laboratory Tests, Second Edition, W.B. Saunders Co., Philadelphia, PA 1990, p 207.
8. Clinical and Laboratory Standards Institute /NCCLS. *Tubes and Additives for Venous Blood Specimen Collection; Approved Standard—Fifth Edition*. CLSI/NCCLS document H1-A5 [ISBN 1-56238-519-4]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2003.
9. Sunshine I. Methodology for Analytical Toxicology, CRC Press, Inc, Cleveland, OH, 1975 pp 152-153.
10. Clinical and Laboratory Standards Institute /NCCLS. *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition*. CLSI/NCCLS document EP5-A2 [ISBN 1-56238-542-9]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2004.
11. Clinical and Laboratory Standards Institute/NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition*. CLSI/NCCLS document EP9-A2 [ISBN 1-56238-472-4]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2002.
12. Clinical and Laboratory Standards Institute/NCCLS. *Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition*. CLSI/NCCLS document EP7-A2 [ISBN 1-56238-584-4]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2005.

All Revision Dates

1/18/2024

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	1/18/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	1/18/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/15/2024
Laboratory Services Department	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services	1/14/2024

Status **Active** PolicyStat ID **15040121**

Origination	1/28/2013	Owner	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services
Last Approved	1/18/2024		
Effective	1/28/2013		
Last Revised	1/18/2024	Policy Area	Laboratory Services - Chemistry
Next Review	1/17/2026		

L.CHEM 1.28 Ferritin (FERR)

Policy

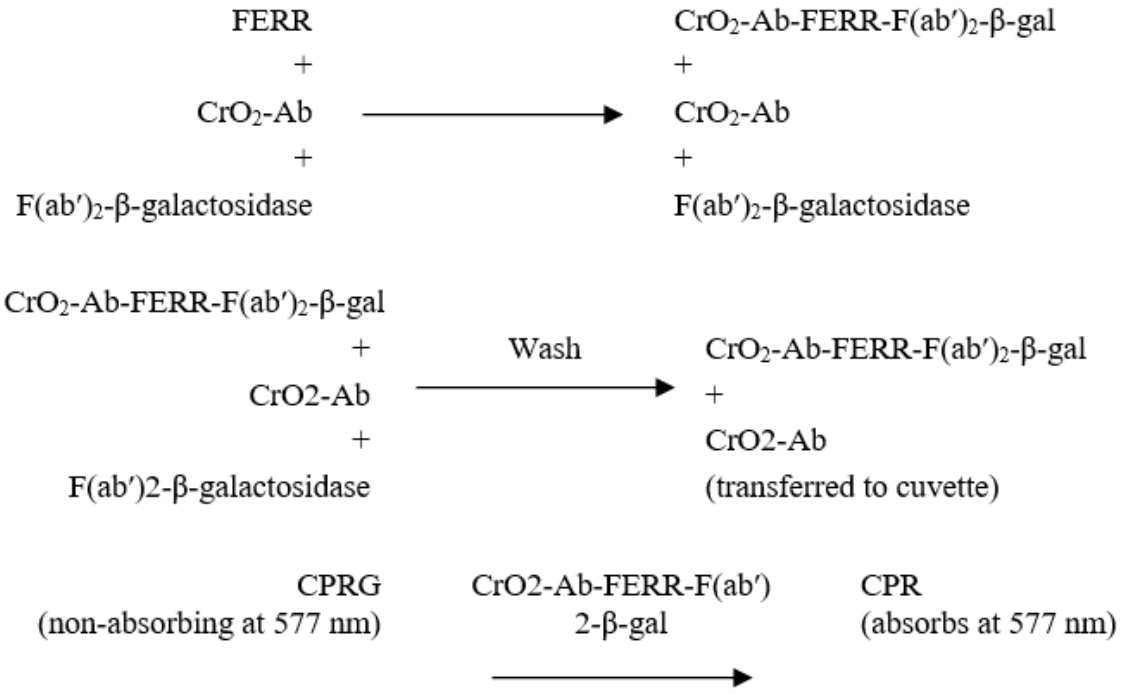
Ferritin (FERR)

Intended Use: The FERR method used on the Dimension® clinical chemistry system with the heterogeneous immunoassay module is an *in vitro* diagnostic test intended to quantitatively measure ferritin in human serum and heparinized plasma. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis and iron deficiency anemia.

Summary: Ferritin is a high-molecular weight protein (470 kDa) that functions as the primary iron storage compound in the body. Circulating ferritin levels accurately reflect iron stores in the body and are useful when either iron deficiency or iron overload is suspected.[1,2] The protein originates in the reticuloendothelial cells of the liver and spleen and in the erythroblasts of bone marrow. It consists of 24 subunits belonging to either the subtype H or L. The subunits form a ball shaped protein shell (apoferritin) containing iron in the center as hydroxidephosphate complexes.[3,4]
Iron deficiency anemia (IDA) is common among menstruating and reproductively active females, children,older adults, and vegetarians. A low ferritin level is an early indicator of IDA; occurring before serum iron is decreased and morphological abnormalities appear in red blood cells.[1,2]
Normal ferritin levels cannot be used to exclude IDA if a hepatic, malignant or inflammatory condition exists in the patient (anemia of chronic disease, ACD). Patients with ACD may show normal or slightly increased ferritin levels due to an increase in ferritin, caused by the acute phase response associated with chronic inflammation, which overrides the decrease in ferritin associated with IDA.[5]

Principles of Procedure

The FERR method for the Dimension® clinical chemistry system is a one-step enzyme immunoassay based on the "sandwich" principle.
Sample is incubated with chromium dioxide particles, coated with monoclonal antibodies specific for ferritin, and conjugate reagent (β-galactosidase labeled monoclonal antibodies specific for a second binding site on ferritin) to form a particle/ferritin/conjugate sandwich. Unbound conjugate and analyte are removed by magnetic separation and washing.
The sandwich bound β-galactosidase is combined with a chromogenic substrate chlorophenol red-β-d-galactopyranoside (CPRG). Hydrolysis of CPRG releases a chromophore (CPR). The concentration of FERR present in the patient sample is directly proportional to the rate of color change due to formation of CPR measured at 577/700 nm.



Reagents

Wells[a]	Form	Ingredient	Concentration[b]	Source
1	Liquid	FERR		
		Ab-b-galactosidase	c	Mouse/bacterial
3	Tablet[d]	Antibody-CrO_2	1.5 mg/mL[c]	Mouse
4, 5, 6	Tablets[d]	CPRG	23.6 mM	
7	Liquid	Substrate diluent, buffer	175 mM	

a. Wells are numbered consecutively from the wide end of the cartridge.

b. Nominal value in hydrated cartridge.
c. Antibody titer and conjugate activity vary from lot to lot.
d. Tablets contain excipients, buffers and stabilizers.

Risk and Safety

- Irritant. Contains mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1).
- May contain sensitization by skin contact.
- Avoid contact with skin.
- Wear suitable gloves.
- Safety data sheets (MSDS/SDS) available on www.siemens.com/diagnostics

Precautions: Used cuvettes contain human body fluids; handle with appropriate care to avoid skin contact or ingestion. Contains bovine serum albumin.
For *in vitro* diagnostic use
Reagent Preparation: Hydrating, diluting, and mixing are automatically performed by the Dimension® system.
Store at: 2 – 8 °C
Expiration: Refer to carton for expiration date of individual unopened reagent cartridges. Sealed or unhydrated cartridge wells on the instrument are stable for 30 days.
Open Well Stability: 10 days for wells 1, 3 & 7

3 days for wells 4 – 6

Specimen Collection and Handling

- Serum and plasma can be collected using recommended procedures for collection of diagnostic blood specimens by venipuncture.[6]
- Follow the instructions provided with your specimen collection device for use and processing.[7]
- Specimens should be free of particulate matter. To prevent the appearance of fibrin in serum samples, complete clot formation should take place before centrifugation.[8] If clotting time is increased due to thrombolytic or anticoagulant therapy, the use of plasma specimens will allow for faster sample processing and reduce the risk of particulate matter.
- Heparin anticoagulants do not interfere with the FERR method.
- Blood collected in the presence of oxalate potentially can cause clumping of the chrome particles and should not be used.
- Frozen plasma samples with insufficient anticoagulants potentially can cause clumping of chrome particles and should not be used.
- Separated specimens are stable for 8 hours at room temperature[9] and 7 days at 2 – 8 °C. For longer storage, specimens may be frozen at -20 °C for up to 6 months. Mix thoroughly after thawing. Avoid repeated freezing and thawing. Do not thaw specimens in a 37 °C water bath.

Violent mixing may denature ferritin.[8]

Procedure

Materials

Materials Provided

- FERR Flex® reagent cartridge, Cat. No. RF440

Materials Required But Not Provided

- FERR Calibrator, Cat. No. RC440
- Reaction Vessels, Cat. No. RXV1A
- Chemistry Wash, Cat. No. RD701
- Reagent Probe Cleaner, Cat. No. RD702
- Sample Diluent, Cat. No. 791092901
- Quality Control Materials

Test Steps

Sampling, reagent delivery, mixing, separation, processing and printing of results are automatically performed by the Dimension® system with the heterogeneous immunoassay module. For details of this processing, refer to your Dimension® Operator's Guide.

Test Conditions

Reaction Vessel	
Sample Volume	40 µL
Antibody-CrO_2	30 µL
Antibody-β-galactosidase	50 µL
Incubation Temperature	42 °C*
*Dimension® EXL™ with LOCI® Module: 37°C	
Reaction Cuvette	
Transfer Volume	20 µL
CPRG Reagent Volume	175 µL
Diluent Volume	195 µL
Temperature	37.0 °C
Wavelength	577 and 700 nm
Type of Measurement	Bichromatic rate

Calibration

Assay Range	1 – 2000 ng/mL [µg/L][e]
Calibration Material	FERR Calibrator, Cat. No. RC440
Calibration Scheme	Levels 1 and 5, n = 3
	Levels 2 – 4, n = 2
Units	ng/mL [µg/L]
Typical Calibration Levels	0, 25, 210, 1050, 2000 ng/mL [µg/L]
Calibration Frequency	Every 3 months for any lot
A new calibration is required	• For each new lot of Flex® reagent cartridges • After major maintenance or service, if indicated by quality control results • As indicated in laboratory quality control procedures • When required by government regulations
Assigned Coefficients	C_0 -50.0 C_1 7000 C_2 -1.0 C_3 8000 C_4 0.01

e. Système International d'Unités [SI Units] are in brackets.

Quality Control

- At least once each day of use, analyze two levels of a quality control material with known ferritin concentrations.
- Follow your laboratory internal QC procedures if the results obtained are outside acceptable limits.

Results

The instrument automatically calculates and prints the concentration of FERR result in ng/mL [µg/L].

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

AMR

Analytical Measurement Range (AMR): 1 – 2000 ng/mL [µg/L]

This is the range of analyte values that can be directly measured on the specimen without any dilution or pretreatment that is not part of the usual analytical process and is equivalent to the assay range.

Dilution

- Samples with results in excess of 2000 ng/mL [µg/L] are reported as "Above Assay Range" and should be repeated on dilution.
- **Manual Dilution**: Dilute with Laboratory Reagent grade water to obtain results within reportable range. Enter dilution factor on the instrument. Reassay. The resulting readout is corrected for dilution.
- **Autodilution (AD):** The recommended autodilute sample volume is 10 µL for serum/plasma (dilution factor = 20).
- Samples with results less than 0.5 ng/mL [µg/L] will be reported as "less than 0.5 ng/mL [µg/L]" by the instrument.

Limitations of Procedure

The instrument reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing such error messages should be held for follow-up. Refer to your Dimension® Operator's Guide.

Interfering Substances

Patient samples may contain human anti-mouse antibodies (HAMA) that could give falsely elevated or depressed results with assays that use mouse monoclonal antibodies. This assay has been designed to minimize interference from HAMA containing samples.

Expected Values

- **Expected Values:Female: 8 – 252 ng/mL [µg/L]**
- **Male: 26 – 388 ng/mL [µg/L]**
- **Combined: 8 – 388 ng/mL [µg/L]**

The reference interval was determined from a population of healthy adults. A total of 296 serum samples, comprised of 178 females and 118 males were tested. The reference intervals were calculated non parametrically and represent the central 95% of the population.

Each laboratory should establish its own reference intervals for FERR as performed on the Dimension® system.

HIL Interference

The following substances have less than 10% effect on the FERR method: hemolysis (hemoglobin 1000 mg/dL [0.62 mmol/L] monomer), icterus (bilirubin 60 mg/dL [1026 µmol/L]), or lipemia (triglyceride 3000 mg/dL [33.9 mmol/L]).

Hook Effect

One-step sandwich immunometric assays are susceptible to a high-dose "hook effect," where an

excess of antigen prevents simultaneous binding of the capture and detection antibodies to a single analyte molecule.[10] Such samples must be diluted and reassayed prior to reporting the results (see Manual Dilution Procedure).

The FERR method shows no hook effect up to at least 100,000 ng/mL [µg/L] ferritin.

Analytical Sensitivity

Analytical Sensitivity: 1 ng/mL [µg/L]

The analytical sensitivity represents the lowest concentration of FERR that can be distinguished from zero. This sensitivity is defined as the mean value (n = 20) plus two standard deviations of the Level 1 FERR Calibrator (0 ng/mL [µg/L]).

References

1. Bakerman's ABC's of Interpretive Laboratory Data, Fourth Edition. 2002; 243-244.
2. Sherwood RA, Pippard, MJ, Peters TJ. Iron Homeostasis and the Assessment of Iron Status. Ann Clin Biochem 1998; 35: 693-708.
3. Higgins T, Beutler E, Doumas BT. Hemoglobin, Iron and Bilirubin. Tietz Textbook of Clinical Chemistry and Molecular Diagnosis, Fourth Edition, 2006: 1186-1193.
4. Tietz N. Clinical Guide to Laboratory Tests, Fourth Edition, 2006: 392-393.
5. Van den Bosch G et al. Determination of Iron Metabolism-related Reference Values in a Healthy Adult Population. Clin Chem 2001; 47: 1465-1467.
6. Clinical and Laboratory Standards Institute/NCCLS. *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard – Fifth Edition.* CLSI/NCCLS document H3-A5 [ISBN 1-56238-515-1]. CLSI,
940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2003.
7. Clinical and Laboratory Standards Institute/NCCLS. *Tubes and Additives for Venous Blood Specimen Collection; Approved Standard – Fifth Edition.* CLSI/NCCLS document H1-A5 [ISBN 1-56238-519-4]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2003.
8. Clinical and Laboratory Standards Institute/NCCLS. *Procedures for the Handling and Processing of Blood Specimens; Approved Guideline – Third Edition.* CLSI/NCCLS document H18-A3 [ISBN 1-56238-555-0]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2004.
9. Tietz NW. Clinical Guide to Laboratory Tests. 4th ed., 2006, Saunders WB Co, Philadelphia, PA., pp 392.
10. Ryall RG, Story CJ, Turner DR. Reappraisal of the causes of the "hook effect" in two-site immunoradiometric assays. Anal Biochem 1982;127:308.

All Revision Dates

1/18/2024

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	1/18/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	1/18/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/15/2024
Laboratory Services Department	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services	1/14/2024

Status **Active** PolicyStat ID **15040142**

Origination	4/29/2013
Last Approved	1/18/2024
Effective	4/29/2013
Last Revised	1/18/2024
Next Review	1/17/2026
Owner	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services
Policy Area	Laboratory Services - Chemistry

L.CHEM 1.29 Folate (FOL)

Policy

Folate (FOL)

Intended Use: The LOCI FOL method is an *in vitro* diagnostic test for the quantitative measurement of folate in human serum and plasma on the Dimension Vista® System.

Summary: The terms folate and folic acid are often used interchangeably for a water-soluble B complex vitamin (B9) found in dark green leafy vegetables, fruits, dairy products and cereal. The main function of folate coenzymes in the body is the transfer of one-carbon units in a variety of reactions critical to the synthesis of DNA, RNA and amino acids. In nucleic acid metabolism, folic acid is involved in synthesis of DNA from its precursors and in the synthesis of methionine, which is required for the synthesis of S-adenosylmethionine (SAM), a methyl donor in many biological methylation reactions in DNA and RNA. Folic acid is also involved in amino acid metabolism. The synthesis of methionine from homocysteine requires both folate and vitamin B12 dependent enzymes. A folate deficiency can result in decreased synthesis of methionine and a buildup of homocysteine.[1, 2] Recent clinical studies indicate that a mild to moderate increase in homocysteine is associated with atherosclerotic vascular disease such as coronary artery disease and stroke.[3, 4, 5]

Macrocytic anemia is the major clinical manifestation of folate deficiency. It is characterized by abnormal maturation of red blood cell precursors in the bone marrow, the presence of megaloblasts and decreased red blood cell survival. Both folate and vitamin B12 deficiency can cause macrocytic anemia. Folate supplementation can mask B12 deficiency because the associated anemia responds to folate alone. Misdiagnosis delays treatment of the deficiency allowing irreversible neurological abnormalities to progress. Appropriate treatment depends on the differential diagnosis of the deficiency.[1, 2]

The main causes of folate deficiency are absence of intestinal microorganisms, poor intestinal absorption (surgical resection, celiac disease), increased demands (pregnancy, liver disease, and malignancies), insufficient dietary uptake (alcoholism), anti-folate drugs (methotrexate) and anticonvulsants (carbamazepine, phenobarbital, phenytoin, valproic acid). Although serum folate measurement provides an early index of folate status, red blood cell folate more closely reflects tissue stores and is considered the most reliable indicator of folate status.[1, 6]

Principles of Procedure

The LOCI Folate method is a homogeneous, competitive chemiluminescent immunoassay based on LOCI® technology. LOCI® reagents include two synthetic bead reagents and labeled folate binding protein (FBP). The first bead reagent (Chemibeads) is coated with a folic acid derivative and contains a chemiluminescent dye. The second bead reagent (Sensibeads) is coated with streptavidin and contains photosensitive dye. Before the immunological portion of the reaction is initiated, the patient sample is pretreated with Sodium Hydroxide (NaOH) and Dithioerythritol (DTE) to release serum folate from endogenous folate binding protein (FBP) and to maintain 5-methyltetrahydrofolate in its reduced form. After the sample pretreatment, chemibeads and labeled folate binding reagent are added sequentially to the reaction vessel. Folate from the patient sample competes with the folate-chemibead for a limited amount of labeled FBP. Sensibeads are then added and bind to the biotinylated portion of the labeled FBP to form bead pair immunocomplexes. Illumination of the complex by light at 680 nm generates singlet oxygen from the Sensibeads which diffuses to the Chemibeads triggering a chemiluminescent reaction. The resulting signal is measured at 612 nm and is an inverse function of the concentration of folate in the sample.[7, 8]

Reagents

Wells[a]	Form	Ingredient	Concentration[b]	Source
1–2		Empty		
3–4	Liquid	Sodium Hydroxide (NaOH)	0.5 N	
5–6	Tablet [c, d]	Dithioerythritol (DTE)	39 mg/mL	
7–8	Liquid	Folate Binding Protein (FBP)	0.225 µg/mL	Bovine
		Biotinylated antibody	1.8 µg/mL	Mouse monoclonal
9–10	Liquid	Folate Chemibeads	400 µg/mL	
11–12	Liquid	Streptavidin Sensibeads	500 µg/mL	Recombinant *E. coli*

a. Wells are numbered consecutively from the wide end of the cartridge.
b. Nominal value per well in a cartridge.
c. Tablets contain excipients, buffers, and stabilizers.
d. Nominal value in hydrated cartridge.
e. Tableted reagent not used for Folate measurement

Risk and Safety

- Irritant. Contains a mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1).
- Irritating to eyes and skin.
- May cause sensitization by skin contact.
- Avoid skin contact.
- Wear suitable gloves.
- Safety data sheets (MSDS/SDS) available on www.siemens.com/diagnostics

Precautions: Used LOCI® reaction vessels contain human body fluids; handle with appropriate care to avoid skin contact or ingestion.
For *in vitro* diagnostic use.
Reagent Preparation: Hydrating, diluting and mixing are automatically performed by the Dimension Vista® System.
Store at: 2 – 8 °C
Expiration: Refer to carton for expiration date of individual unopened reagent cartridges. Sealed wells on the instrument are stable for 30 days.
Open Well Stability: 3 days for wells 3 – 12

Specimen Collection and Handling

- Recommended specimen types: serum or plasma (sodium or lithium heparin).
- **Samples and controls stabilized with sodium azide cannot be used.**
- Serum and plasma can be collected using recommended procedures for collection of diagnostic blood specimens by venipuncture.[9]
- Samples may be stored refrigerated at 2 – 8 °C for up to 8 hours. If testing is delayed beyond 8 hours, samples should be frozen at -20 °C or colder. Protect samples from light. Avoid using hemolyzed samples.[10] Mix thoroughly after thawing. Avoid repeated freezing and thawing.[11]
- Follow the instructions provided with your specimen collection device for use and processing.[12] Complete clot formation should take place before centrifugation. Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection. Specimens should be free of particulate matter.[11]
- The purpose of specimen storage information is to provide guidance to users; however, users may validate their own procedures for storing patient samples.

Procedure

Materials

Materials Provided

- FOL Flex® reagent cartridge, Cat. No. K6444

Materials Required But Not Provided

- **LOCI 4 CAL, Cat. No. KC640 or KC640A**
- Quality Control Materials

Test Steps

Sampling, reagent delivery, mixing, and processing are automatically performed by the Dimension Vista® System. For details of this processing, refer to your Dimension Vista® Operator's Guide.

Test Conditions

Sample Volume (delivered to the vessel)	10 µL
DTE Reagent Volume	10 µL
Extractant Reagent Volume	10 µL
FBP/Bio-Mab Reagent Volume	30 µL
Chemibead Reagent Volume	20 µL
Sensibead Reagent Volume	30 µL
Temperature	37 °C
Reaction time	21 minutes
Wavelength	Illumination: 680 nm, emission: 612 nm
Type of Measurement	Chemiluminescence

Calibration

Calibration Material	LOCI 4 CAL, Cat. No. KC640 or KC640A
Calibration Scheme	5 levels, n = 3
Units	ng/mL [nmol/L][f] (ng/mL x 2.266) = [nmol/L]
Typical Calibration Levels	Level 1 (Calibrator A): 0.0 ng/mL [0.0 nmol/L] Level 2 (Calibrator B): 2.5 ng/mL [5.7 nmol/L] Level 3 (Calibrator C): 5.0 ng/mL [11.3 nmol/L] Level 4 (Calibrator D): 10.0 ng/mL [22.7 nmol/L] Level 5 (Calibrator E): 21.0 ng/mL [46.8 nmol/L]
Calibration Frequency	Every 30 days for any one lot Calibration interval may be extended based on acceptable verification of calibration.
A new calibration is required:	• For each new lot of Flex® reagent cartridges • After major maintenance or service, if indicated by quality control results • As indicated in laboratory quality control procedures

	• When required by government regulations

f. Système International d'Unités [SI units] are in brackets.

Quality Control

Follow government regulations or accreditation requirements for quality control frequency. At least once each day of use, analyze two levels of a Quality Control (QC) material with known folate concentrations. Follow your laboratory internal QC procedures if the results obtained are outside acceptable limits.

Results

The instrument calculates the concentration of folate in ng/mL [nmol/L] using the calculation scheme described in your Dimension Vista® Operator's Guide.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

AMR

Analytical Measurement Range (AMR)): 0.5 – 20 ng/mL [1.1 – 45.3 nmol/L]

This is the range of analyte values that can be measured directly from the specimen without any dilution or pretreatment that is not part of the usual analytical process and is equivalent to the assay range.

Dilution

- Samples with results in excess of 20 ng/mL [45.3 nmol/L] should be repeated on dilution.
- **Manual Dilution**: Dilute with Reagent grade water to obtain results within reportable range. Enter dilution factor on the instrument. Reassay. Resulting readout is corrected for dilution.
- **Autodilution (AD)**: The autodilute sample volume is 2 µL (dilution factor = 5) for serum/plasma. Refer to your Dimension Vista® Operator's Guide.
- Samples with results less than 0.5 ng/mL [1.1 nmol/L] will be reported as "less than 0.5 ng/mL [1.1 nmol/L]" by the instrument.

Limitations of Procedure

The instrument reporting system contains flags and comments to provide the user with information regarding instrument processing errors, instrument status information and potential errors in folate results. Refer to your Dimension Vista® Operator's Guide for the meaning of report flags and comments. Any report containing flags and/or comments should be addressed according to your laboratory's procedure manual and not reported.
Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. This assay has been designed to minimize interference from heterophilic antibodies. Nevertheless, complete elimination of this interference from all patient specimens cannot be guaranteed. A test result that is inconsistent with the clinical picture and patient history should be

interpreted with caution. [13,14]

- **Serum folate measurements cannot be made on hemolyzed specimens.**
- **Methotrexate and Leucovorin (folinic acid) interfere with the measurement of folate. These chemotherapeutic drugs cross-react with folate binding proteins in the folate assay. Therefore, patients receiving these drugs should not be tested for folate by this method.**

Expected Values

Expected Values: 3.1 - 17.5 ng/mL [7.0 – 39.7 nmol/L][16]

- These values were obtained in the US before cereal- grain products were fortified with folic acid (beginning in the mid 1990's).
- A more recent study performed in the US, a population typically supplemented with dietary folate, yielded a reference interval of 8.7 – 55.4 ng/mL [19.7 – 125.5 nmol/L]. This reference interval represents the central 95% of results determined non-parametrically from a population of 120 apparently healthy adults (60 males and 60 females, 24 – 67 years of age) and was performed in accordance with CLSI/NCCLS C28-A2.[17]
- Because folic acid levels are strongly influenced by diet and dietary supplementation, population- based reference intervals can show marked demographic differences. In the US, for example, fortification of enriched grain products, as required by the Food and Drug Administration (FDA) since the mid-1990s, has led to an estimated doubling of the mean plasma folate level among subjects not using vitamin supplements and a decrease in the prevalence of low folate levels, i.e. levels below 3 ng/mL (7 nmol/L).[18]
- Each laboratory should establish its own expected values for FOL as performed on the Dimension Vista® System.

Hemolysis, Icterus and Lipemia (HIL) Interference

The FOL method was evaluated for interference according to CLSI/NCCLS EP7-A2.[15] Bias is the difference in the results between the control sample (without the interferent) and the test sample (contains the interferent) expressed in percent. Bias exceeding 10% is considered interference.

Substance Tested	Substance Concentration	Folate ng/mL [nmol/L]	Bias* %
Hemoglobin (hemolysate)	Hemoglobin (monomer)	See Limitations	
Bilirubin (unconjugated)	20 mg/dL [342 µmol/L]	2.9 [6.6]	<10
Bilirubin (conjugated)	20 mg/dL [342 µmol/L]	2.9 [6.6]	<10
Lipemia (Intralipid®)	3000 mg/dL [33.9 mmol/L]	2.9 [6.6]	<10

Intralipid® is a registered trademark of Fresenius Kabi AG, Bad Homburg, Germany.

*** Analyte results should not be corrected based on this bias.**

Analytical Sensitivity

Analytical Sensitivity: 0.5 ng/mL [1.1 nmol/L]

The limit of blank (analytical sensitivity) represents the lowest concentration of FOL that can be distinguished from zero. This sensitivity is defined as the mean value (n=20) plus two standard deviations of the Level 1 (0 ng/mL [0 nmol/L]) LOCI 4 CAL.

References

1. Shenkin A, Baines M, Fell GS et al. Vitamins and Trace Elements in Tietz Textbook of Clinical Chemistry and Molecular Diagnosis. Fourth Edition, 2006; 1109 -1114.
2. Snow CF. *Laboratory Diagnosis of Vitamin B12 and Folate Deficiency.* Arch Intern Med 1999; 159:1289-1298.
3. Boushey CJ, Beresford SA, Omenn GS, Motulsky AG. *A Quantitative Assessment of Plasma Homocysteine as a Risk Factor for Vascular Disease. Probable Benefits of Increasing Folic Acid Intakes.* JAMA 1995; 274:1049-1057.
4. Bokhari SW, Bokhari ZW, Zell JA et al. *Plasma Homocysteine Levels and the Left Ventricular Systolic Function in Coronary Artery Disease Patients.* Coron Artery Dis 2005; 16:153-161.
5. Lee BJ, Lin PT, Liaw YP et al. *Homocysteine and Risk of Coronary Artery Disease: Folate is the Important Determinant of Plasma Homocysteine Concentration.* Nutrition 2003; 19: 577-583.
6. Tietz. Clinical Guide to Laboratory Tests, Fourth Edition, Alan H. B. Wu editor, 2006: 410-413.
7. Ullman EF, Kirakossian H, Switchenko AC, Ishkanian J, et. al. *Luminescent oxygen channeling assay (LOCI™): sensitive, broadly applicable homogeneous immunoassay method.* Clin Chem 1996; 42:9: 1518-1526.
8. Ullman EF, Kirakossian H, Sharat S, Ping Wu Z, Irvin BR, et. al. *Luminescent oxygen channeling immunoassay: Measurement of particle binding kinetics by chemiluminescence.* Proc.Natl.Acad.Sci. USA, 1994; 91: 5426-5430.
9. Clinical and Laboratory Standards Institute/NCCLS. *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition.* CLSI/NCCLS document H3-A5 [ISBN 1-56238-515-1]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2003.
10. Tietz Clinical Guide to Laboratory Tests. Fourth Edition. Alan H. B. Wu editor, 2006; 410-413, 1124-1127.
11. Clinical and Laboratory Standards Institute/NCCLS. *Procedures for the Handling and Processing of Blood Specimens; Approved Guideline – Third Edition.* CLSI/NCCLS document H18-A3 [ISBN 1-56238-555-0]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2004.
12. Clinical and Laboratory Standards Institute /NCCLS. *Tubes and Additives for Venous Blood Specimen Collection; Approved Standard—Fifth Edition.* CLSI/NCCLS document H1-A5 [ISBN 1-56238-519-4]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2003.

13. Kricka LJ. *Human anti-animal antibody interference in immunological assays*. Clin Chem. 1999;45: 7:942-956.
14. Vaidya HC, Beatty BG. Eliminating interference from heterophilic antibodies in a two-site immunoassay for creatine kinase MB by using $F(ab')_2$ conjugate and polymouse IgG. Clin Chem 1992; 38: 1737-1742.
15. Clinical and Laboratory Standards Institute/NCCLS. *Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition*. CLSI/NCCLS document EP7-A2 [ISBN 1-56238-584-4]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2005.
16. Kratz A., Lewandrowski K. B. MGH Case Records- Normal Reference Laboratory Values. N Engl J Med. 1998; 339:15:1063-1072.
17. Clinical and Laboratory Standards Institute/NCCLS. How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline — Second Edition. CLSI/NCCLS document C28-A2 [ISBN 1-56238-406-6]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2005.
18. Pfeiffer C, Johnson C, Jain R, et.al. Trends in blood folate and vitamin B-12 concentrations in the United States 1988-2004, American Journal of Clinical Nutrition, 2007; 86; 718-727
19. Clinical and Laboratory Standards Institute /NCCLS. Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition. CLSI/NCCLS document EP5-A2
[ISBN 1-56238-542-9]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2004.
20. Clinical and Laboratory Standards Institute/NCCLS. Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition. CLSI/NCCLS document EP9-A2 [ISBN 1-56238-472-4]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2002.

All Revision Dates

1/18/2024

Approval Signatures

Step Description	Approver	Date

Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	1/18/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	1/18/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/15/2024
Laboratory Services Department	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services	1/14/2024

Status Active PolicyStat ID 15040149

Origination	1/28/2013
Last Approved	1/18/2024
Effective	1/28/2013
Last Revised	1/18/2024
Next Review	1/17/2026
Owner	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services
Policy Area	Laboratory Services - Chemistry

L.CHEM 1.30 Free Prostate Specific Antigen (FPSA)

Policy

Free Prostate Specific Antigen (FPSA)

CAUTION: United States Federal law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to, by or on the order of a physician.
Warning: The concentration of PSA in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the PSA assay used. Values obtained with different assay methods cannot be used interchangeably. The FPSA method should only be used with the Dimension Vista® TPSA method to calculate the ratio of free PSA to total PSA (percent free PSA).

Intended Use: The FPSA method is an *in vitro* diagnostic test for the quantitative measurement of free prostate specific antigen (FPSA) in human serum and plasma on the Dimension Vista® System. Measurements of FPSA are used in conjunction with the total PSA (TPSA) method on the Dimension Vista® System to calculate the FPSA to TPSA ratio expressed as percent FPSA. The percent FPSA is used as an aid in distinguishing prostate cancer from benign prostate conditions in men 50 years or older with TPSA of 4.0 to 10.0 ng/mL [µg/L] and digital rectal examination (DRE) findings not suspicious for cancer.
Prostate biopsy is required for definitive diagnosis of cancer.

Summary: Prostate cancer is the most common type of cancer found in men in the United States and the second leading cause of male cancer mortality, accounting for more than 30000 deaths in 2008.[1] Prior to the use of PSA for early detection of prostate cancer, the traditional method of digital rectal examination (DRE) detected considerably fewer tumors.[1,2] The most sensitive

method for early detection of prostate cancer uses both DRE and PSA. The American Cancer Society and the American Urological Association (AUA) recommend that early detection of prostate cancer should be offered to asymptomatic men 50 years of age or older with an estimated life expectancy of more than 10 years.[1]
The specificity of PSA to prostate tissue makes it a significant marker in the early detection and management of prostate diseases.

Prostate specific antigen (PSA) is a serine protease of approximately 30000 Daltons produced by the epithelial cells of the prostate gland.[3,4] The level of PSA in serum and other tissues is normally very low. In malignant prostate disease (prostatic adenocarcinoma) and in non-malignant disorders such as benign prostate hypertrophy (BPH) and prostatitis, the serum level of PSA may become elevated.[2]

In serum, PSA exists primarily as three forms: complexed with either α1-antichymotrypsin (ACT) or α2-macroglobulin and free.[5,6] The PSA protein associated with α2-macroglobulin is encapsulated and unavailable for measurement by current immunoassay systems. The Dimension® FPSA assay measures the free components of serum PSA.

Measurement of free PSA helps to discriminate between prostate cancer and benign prostatic diseases. The percentage of free PSA has been shown to enhance the specificity of PSA testing for prostate cancer detection.[7,8] The percentage of free PSA is lower in patients with prostate cancer.

Principles of Procedure

The FPSA method is a homogeneous, sandwich chemiluminescent immunoassay based on LOCI® technology. The LOCI® reagents include two synthetic bead reagents and a biotinylated anti-FPSA monoclonal antibody $F(ab')_2$ fragment. The first bead reagent (Chemibeads) is coated with anti-TPSA monoclonal antibody and contains chemiluminescent dye; the second bead reagent (Sensibeads) is coated with streptavidin and contains a photosensitizer dye. Sample is incubated with biotinylated antibody and Chemibeads to form bead/FPSA/biotinylated antibody sandwiches. Sensibeads are then added and bind to the biotin to form bead pair immunocomplexes. When illuminated by light at 680 nm, Sensibeads convert dissolved oxygen in the reaction solution into singlet oxygen form ($^1O_2$). In the bead pairs, the singlet oxygen diffuses ("channels") into Chemibeads, triggering a chemiluminescent reaction. The resulting chemiluminescent signal is measured at 612 nm and is directly proportional the concentration of FPSA in the sample.[9,10]

Reagents

Wells[a]	Form	Ingredient	Concentration[b]	Source
1– 4	Liquid	FPSA biotinylated antibody	15 µg/mL	Mouse, monoclonal
5 – 8	Liquid	FPSA Chemibeads	200 µg/mL	Mouse, monoclonal
9 – 12	Liquid	Streptavidin Sensibeads	300 µg/mL	Recombinant *E. coli*

a. Wells are numbered consecutively from the wide end of the cartridge.

b. Nominal value per well in a cartridge.

Risk and Safety

- **Irritant. Contains a mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1).**
- May cause sensitization by skin contact.
- Avoid contact with skin.
- Wear suitable gloves.
- Safety data sheets (MSDS/SDS) available on www.siemens.com/diagnostics

Precautions: Used LOCI® reaction vessels contain human body fluids; handle with appropriate care to avoid skin contact or ingestion.
For *in vitro* diagnostic use.
Reagent Preparation: All reagents are liquid and ready to use.
Store at: 2 – 8 °C
Expiration: Refer to carton for expiration date of individual unopened reagent cartridges. Sealed wells on the instrument are stable for 30 days.
Open Well Stability: 5 days for wells 1 – 12

Specimen Collection and Handling

- Recommended specimen types: serum and plasma (lithium heparin)
- **Samples and controls stabilized with sodium azide cannot be used.**
- Serum and plasma can be collected using recommended procedures for collection of diagnostic blood specimens by venipuncture.[11]
- Follow the instructions provided with your specimen collection device for use and processing.[12]
- Serum and plasma specimens should be separated from cells and refrigerated within 3 – 4 hours after venipuncture.[13,14]
- Specimens should be free of particulate matter. To prevent the appearance of fibrin in serum samples, complete clot formation should take place before centrifugation.[15] Clotting time may be increased due to thrombolytic or anticoagulant therapy.
- Samples should be kept at 4 °C and analyzed within 8 hours. Samples held for longer times (up to 4 months) should be frozen at -20 °C or colder. Storage at -70 °C is preferred for long-term storage. Samples stored at room temperature show a significant loss of immunoreactivity within 4 hours.[13,14]
- The purpose of specimen storage information is to provide guidance to users; however, users may validate their own procedures for storing patient samples.

Procedure

Materials

Materials Provided

- FPSA Flex® reagent cartridge, Cat. No. K6452

Materials Required But Not Provided

- PSA Calibrator, Cat. No. KC602
- Quality Control Materials

Test Steps

Sampling, reagent delivery, mixing, and processing are automatically performed by the Dimension Vista® System. For details of this processing, refer to your Dimension Vista® Operator's Guide.

Test Conditions

Sample Volume (delivered to the reaction vessel)	3 µL
Biotinylated antibody Reagent Volume	20 µL
Chemibead Reagent Volume	20 µL
Streptavidin Sensibead Reagent Volume	100 µL
Temperature	37.0 °C
Reaction time	10 minutes
Wavelength	Illumination 680 nm, Emission 612 nm
Type of Measurement	Chemiluminescence

Calibration

Calibration Material	PSA CAL, Cat. No. KC602
Calibration Scheme	4 levels, n = 3
Units	ng/mL [µg/L][C] (ng/mL x 1) = [µg/L]
Typical Calibration Levels	Level 1 (CAL A): 0 ng/mL [µg/L] Level 2 (CAL B): 1.00 ng/mL [µg/L] Level 3 (CAL C): 4.00 ng/mL [µg/L] Level 4 (CAL D): 20.0 ng/mL [µg/L]
Calibration Frequency	Every 30 days for any one lot Calibration interval may be extended based on acceptable verification of calibration.
A new calibration is required:	•For each new lot of Flex® reagent cartridges •After major maintenance or service, if indicated by quality control

	results •As indicated in laboratory quality control procedures •When required by government regulations

c. Système International d'Unités [SI units] are in brackets.

Quality Control

Follow government regulations or accreditation requirements for quality control frequency. At least once each day of use, analyze two levels of a Quality Control (QC) material with known free prostate specific antigen concentrations. Unless addressed by your internal laboratory procedures, do not report patient results if Quality Control is outside acceptable limits.

Results

The instrument calculates the concentration of free prostate specific antigen in ng/mL [µg/L] using the calculation scheme described in your Dimension Vista® Operator's Guide.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

AMR

Analytical Measurement Range (Reportable Range): 0.015 – 20 ng/mL [µg/L]

This is the range of analyte values that can be measured directly on the specimen without any dilution or pretreatment that is not part of the usual analytical process and is equivalent to the assay range.

Dilution

- Samples with results in excess of 20 ng/mL [µg/L] should be repeated on dilution.
- **Manual Dilution**: Dilute with Clinical laboratory grade water to obtain results within reportable range. Enter dilution factor on the instrument. Reassay. Resulting readout is corrected for dilution.
- **Autodilution (AD)**: The autodilute sample volume is 10 µL for serum/plasma (dilution factor = 10). Refer to your Dimension Vista® Operator's Guide.
- Samples with results less than 0.015 ng/mL [µg/L] will be reported as "less than 0.015 ng/mL [µg/L]" by the instrument.

Limitations of Procedure

Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. This assay has been designed to minimize interference from heterophilic antibodies.[16] Nevertheless, complete elimination of this interference from all patient specimens cannot be guaranteed. A test result that is inconsistent with the clinical picture and patient history should be interpreted with caution.[17]

The instrument reporting system contains flags and comments to provide the user with information regarding instrument processing errors, instrument status information and potential errors in FPSA results. Refer to your Dimension Vista® Operator's Guide for the meaning of report flags and comments. Any report containing flags and/or comments should be held for follow-up and addressed according to your laboratory's procedure manual.

Expected Values

A multicenter prospective clinical study was conducted to evaluate the effectiveness of percent free PSA (FPSA/TPSA x 100) ratio as measured on the Dimension Vista® System.

The percent FPSA is used as an aid in distinguishing prostate cancer from benign prostate conditions in men 50 years or older with TPSA of 4.0 to 10.0 ng/mL [µg/L] by the Dimension Vista® System TPSA method and DRE findings not suspicious for cancer. The study consisted of 645 patients from 28 clinical sites referred to a urologist for evaluation of prostate cancer.

In order to conclusively establish prostate cancer versus benign disease, all patients underwent a transrectal prostate biopsy. Thus, the cohort included in the clinical study may not fully represent a population where free PSA would be used for detection of prostate cancer since the performance of free PSA in a population of men who do not undergo biopsy for detection of prostate cancer was not evaluated.

Ethnic composition of the population studied included 522 (80.9%) Caucasian, 60 (9.3%) African-American, 54 (8.3%) Hispanic or Mexican, 7 (1.1%) Asian, 1 (0.2%) Native American and 1 (0.2%) Filipino men. The median age for the prostate cancer group was 65.0 years, while the median age for the benign group was 63.0 years.

Hemolysis, Icterus, and Lipemia (HIL) Interference

The FPSA method was evaluated for interference according to CLSI/NCCLS EP7-A2[20] at a Free Prostate Specific Antigen concentration of approximately 2.0 and 5.0 ng/mL [µg/L]. Bias is the difference in the results between the control sample (without the interferent) and the test sample (contains the interferent) expressed in percent. Bias exceeding 10% is considered interference.

Substance Tested	Substance Concentration [SI Units]	Bias* %
Hemoglobin (hemolysate)	500 mg/dL [0.31 mmol/L] (monomer)	< 10
Bilirubin (unconjugated)	20 mg/dL [342 µmol/L]	< 10
Bilirubin (conjugated)	20 mg/dL [342 µmol/L]	< 10
Lipemia (Intralipid®)	3000 mg/dL [33.9 mmol/L]	< 10

Intralipid® is a registered trademark of Fresenius Kabi AG, Bad Homburg, Germany.

***Analyte results should not be corrected based on this bias.**

Analytical Sensitivity: 0.005 ng/mL [µg/L]

The analytical sensitivity represents the lowest concentration of FPSA that can be distinguished from zero. This sensitivity is defined as the mean value (n = 20) plus two standard deviations of the level 1 (0 ng/mL [µg/L]) PSA Calibrator.

Limit of Detection and Limit of Blank

- **Limit of Detection and Limit of Blank[22]**
- The Limit of Detection (LoD) for FPSA is 0.015 ng/mL [µg/L], determined consistent with CLSI guideline EP17-A and with proportions of false positives (α) less than 5% and false negatives (β) less than 5%; based on 60 determinations, with 5 blank and 5 low level samples.
- The Limit of Blank (LoB) is 0.005 ng/mL [µg/L].
- LoD is the lowest concentration of analyte that can be detected reliably.
- LoB is the highest concentration that is likely to be observed for a blank sample.
- Functional Sensitivity: ≤ 0.030 ng/mL [µg/L]
- The Functional sensitivity represents the lowest concentration with an observed 20% coefficient of variation.

References

1. www.cancer.org
2. Coley CM, Barry MJ, Fleming C, et al. Early detection of prostate cancer: I. Prior probability and effectiveness of tests. ANN Intern Med 1997; 126:394-406.
3. Lilja H. A kallikrein-like serine protease in prostatic fluid cleaves the predominant seminal vesicle protein. J. Clin Invest 1985;76:1899-903.
4. Watt KWK, Lee P-J, Timkulu T, Chan W-P, Loor R. Human prostate-specific antigen: structural and functional similarities with serine protease. Proc Natl Acad Sci. 1986; 83:3166-3170.
5. Stenman V-H, Leinonen J, Alfthan H, et al. A complex between prostate-specific antigen and α1-antichymotrypsin is the major form of prostate-specific antigen in serum of patients with prostate cancer: Assay of the complex improves clinical sensitivity for cancer. Cancer Res 1991;51:222-6.
6. Lilja H, Christensson A, Dahlen V, et al. Prostate-specific antigen in human serum occurs predominantly in complex with α1-antichymotrypsin. Clin Chem 1991;37:1618-25.
7. Catalona WJ, et al. Use of the Percentage of Free Prostate-Specific Antigen to Enhance Differentiation of Prostate Cancer from benign Prostatic Disease. JAMA 1998; 279: 1542-1547.
8. Potter SR, Partin AW. The clinical utility, benefits, and limitations of percent free PSA testing. Contemporary Urology 1999;15-27.
9. Ullman EF, Kirakossian H, Switchenko AC, Ishkanian J, et. al. Luminescent oxygen channeling assay (LOCI®): sensitive, broadly applicable homogenous immunoassay method. Clin Chem 42:9 1996, 1518-1526.

10. Ullman EF, Kirakossian H, Sharat S, Ping Wu Z, Irvin BR, et. al. Luminescent oxygen channeling immunoassay: Measurement of particle binding kinetics by chemiluminescence. Proc.Natl.Acad.Sci. USA, Vol 91, pp.5426-5430, June 1994 Biochemistry.
11. Tietz NW. Textbook of Clinical Chemistry, W.B. Saunders Co. Philadelphia, PA 1999: pp. 42-72.
12. Clinical and Laboratory Standards Institute/NCCLS. *Tubes and Additives for Venous Blood Specimen Collection; Approved Standard—Fifth Edition*. CLSI/NCCLS document H1-A5 (ISBN 1-56238-519-4). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2003.
13. Woodrum D, French C, Shamel LB. Stability of free Prostate-Specific Antigen in serum samples under a variety of sample collection and sample storage conditions. Urology 1996; 48(6A): 33-39.
14. Jung K, et al. Preanalytical Determinants of Total and Free Prostate-Specific Antigen and Their Ratio: Blood Collection and Storage Conditions. Clin Chem 1998; 44:685-688.
15. Clinical and Laboratory Standards Institute/NCCLS. *Procedures for the Handling and Processing of Blood Specimens; Approved Guideline—Third Edition*. CLSI/NCCLS document H18-A3 (ISBN 1-56238-555-0). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2004.
16. Kricka LJ. Human Anti-Animal Antibody Interferences in Immunological Assays. Clin Chem 1999; 45:7;942-956.
17. Vaidya HC, Beatty BG. Eliminating interference from heterophilic antibodies in a two-site immunoassay for creatine kinase MB by using $F(ab')_2$ conjugate and polyclonal mouse IgG. Clin Chem 1992; 38:1737-42.
18. Clinical and Laboratory Standards Institute/NCCLS. *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition*. CLSI/NCCLS document EP5-A2 [ISBN 1-56238-542-9]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2004.
19. Clinical and Laboratory Standards Institute/NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition*. CLSI/NCCLS document EP9-A2 [ISBN 1-56238-472-4]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2002.
20. Clinical and Laboratory Standards Institute/NCCLS. *Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition*. CLSI/NCCLS document EP7-A2 [ISBN 1-56238-584-4]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2005.
21. Ryall RG, Story CJ, and Turner DR. Reappraisal of the causes of the "hook" effect in two-site immunometric assays. Anal Biochem 1982; 127:308-15.
22. Clinical and Laboratory Standards Institute/NCCLS. *Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline*. CLSI/NCCLS document EP17-A [ISBN 1-56238-551-8]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2004.

All Revision Dates

1/18/2024

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	1/18/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	1/18/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/15/2024
Laboratory Services Department	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services	1/14/2024

Status **Active** PolicyStat ID **15040263**

Origination	1/28/2013	Owner	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services
Last Approved	1/18/2024		
Effective	1/28/2013		
Last Revised	1/18/2024	Policy Area	Laboratory Services - Chemistry
Next Review	1/17/2026		

L.CHEM 1.32 Gentamicin (GENT)

Policy

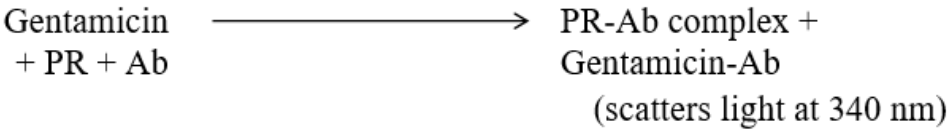
Gentamicin (GENT)

Intended Use: The GENT method is an *in vitro* diagnostic test for the quantitative measurement of gentamicin, an aminoglycoside antibiotic, in human serum and plasma on the Dimension Vista® System. Gentamicin measurements may be used in the diagnosis and treatment of gentamicin overdose and in monitoring levels of gentamicin to ensure appropriate therapy.

Summary: Gentamicin is an antibiotic effective against gram negative aerobic bacteria. It has a wide spectrum of antibiotic activity and relatively low toxicity. Gentamicin is a naturally occurring antibiotic produced by the organism Micromonospora purpurea. Gentamicin is administered either intramuscularly or intravenously. Peak concentrations are reached 60 minutes after intramuscular injection and after completion of intravenous injection.[1,2]

Principles of Procedure

The methodology for GENT is based on a homogeneous particle enhanced turbidimetric inhibition immunoassay (PETINIA) technique which uses a synthetic particle gentamicin conjugate (PR) and monoclonal gentamicin specific antibody (Ab). Gentamicin present in the sample competes with gentamicin on the particles for available antibody, thereby decreasing the rate of aggregation. Hence, the rate of aggregation is inversely proportional to the concentration of gentamicin in the sample. The rate of aggregation is measured using bichromatic turbidimetric readings at 340 nm and 700 nm.



Reagents

Wells[a]	Form	Ingredient	Concentration[b]	Source
1, 2	Liquid	Particle Reagent	3.3 g/L[c, d]	
3, 4	Liquid	Buffer	25.7 mM	
5, 6	Liquid	Antibody	0.027 g/L[c, d]	Mouse, monoclonal

a. Wells are numbered consecutively from the wide end of the cartridge.

b. Nominal value per well in a cartridge.

c. Antibody titer and conjugate activity may vary from lot to lot.

d. Contain buffers, stabilizers and preservatives.

Risk and safety

- Irritant. Contains a mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1).
- May cause sensitization by skin contact.
- Avoid contact with skin.
- Wear suitable gloves.
- Safety data sheets (MSDS/SDS) available on www.siemens.com/diagnostics

Precautions: Used cuvettes contain human body fluids; handle with appropriate care to avoid skin contact or ingestion.
For *in vitro* diagnostic use.
Reagent Preparation: All reagents are liquid and ready to use.
Store at: 2–8 °C
Expiration: Refer to carton for expiration date of individual unopened reagent cartridges. Sealed wells on the instrument are stable for 30 days.
Open Well Stability: 3 days for wells 1–6

Specimen Collection and Handling

- Recommended specimen types: serum or plasma (lithium heparin).
- Serum and plasma can be collected using recommended procedures for collection of diagnostic blood specimens by venipuncture.[3]
- Follow the instructions provided with your specimen collection device for use and processing.[5]

- Each laboratory must determine its appropriate sample timing/collection protocol.
- Complete clot formation should take place before centrifugation. Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection.[4] Specimens should be free of particulate matter.

Procedure

Materials

Materials Provided

- GENT Flex® reagent cartridge, Cat. No. K4012

Materials Required But Not Provided

- DRUG 2 CAL, Cat. No. KC420
- Quality Control Materials

Test Steps

Sampling, reagent delivery, mixing, and processing are automatically performed by the Dimension Vista® System. For details of this processing, refer to your Dimension Vista® Operator's Guide.

Test Conditions

Sample Volume (delivered to the cuvette)	1.31 µL
Buffer Volume	50.2 µL
Particle Reagent Volume	27.9 µL
Antibody Volume	27.9 µL
Temperature	37.0 °C
Reaction time	6.4 minutes
Wavelength	340 and 700 nm
Type of Measurement	Turbidimetric Rate

Calibration

Calibration Material	DRUG 2 CAL, Cat. No. KC420
Calibration Scheme	5 levels, n=4
Units	µg/mL [µmol/L][e] (µg/mL x 2.16)=[µmol/L]
Typical Calibration Levels	Level 1 (Calibrator A): 0 µg/mL [0.0 µmol/L] Intermediate level/Levels automatically prepared by the instrument: 1.5, 3.0, 6.0 µg/mL [3.24, 6.48, 12.96 µmol/L]

	Level 5 (Calibrator B): 12.0 µg/mL [25.92 µmol/L]
Calibration Frequency	Every 30 days for any one lot Calibration interval may be extended based on acceptable verification of calibration.
A new calibration is required:	• For each new lot of Flex® reagent cartridges • After major maintenance or service, if indicated by quality control results • As indicated in laboratory quality control procedures • When required by government regulations

e. Système International d'Unités [SI units] are in brackets.

Quality Control

- At least once each day of use, analyze two levels of a Quality Control (QC) material with known gentamicin concentrations. Follow your laboratory internal QC procedures if the results obtained are outside acceptable limits.

Results

The instrument calculates the concentration of gentamicin in µg/mL [µmol/L] using the calculation scheme described in your Dimension Vista® Operator's Guide.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

AMR

Analytical Measurement Range (AMR): 0.2–12.0 µg/mL [0.43–25.92 µmol/L]

This is the range of analyte values that can be measured directly on the specimen without any dilution or pretreatment that is not part of the usual analytical process and is equivalent to the assay range.

Dilution

- Samples with results in excess of 12.0 µg/mL [25.92 µmol/L] should be repeated on dilution.
- **Manual Dilution**: Dilute with Level 1 (0 µg/mL [0 µmol/L]) of Drug 2 Calibrator or drug-free serum to obtain results within reportable range. Enter dilution factor on the instrument. Reassay. Resulting readout is corrected for dilution.
- **Autodilution (AD):** The autodilute sample volume is 25 µL (dilution factor = 4) for serum/plasma. Refer to your
Dimension Vista® Operator's Guide.
- Samples with results less than 0.2 µg/mL [0.43 µmol/L] will be reported as "less than 0.2 µg/mL [0.43 µmol/L]" by the instrument.

Limitations of Procedure

The instrument reporting system contains flags and comments to provide the user with information regarding instrument processing errors, instrument status information and potential errors in gentamicin results. Refer to your Dimension Vista® Operator's Guide for the meaning of report flags and comments. Any report containing flags and/or comments should be addressed according to your laboratory's procedure manual and not reported.

Therapeutic Range

Therapeutic gentamicin concentrations vary significantly depending on the individual patient. A range of 4.0–8.0 µg/mL [8.64–17.28 µmol/L] for peak drug levels indicates effective plasma or serum levels for many patients; however, some individuals are best treated at concentrations outside this range. Although it has not yet been established exactly what specimen concentration is toxic, minimal values in excess of 2 µg/mL [4.32 µmol/L] for longer than 10 days have been associated with toxicity.[1,2] The physician must determine the most appropriate therapeutic range for each patient.

Interference

HIL Interference

GENT was evaluated for interference according to CLSI/NCCLS EP7-A2.[8] Bias is the difference in the results between the control sample (without the interferent) and the test sample (contains the interferent) expressed in percent. Bias exceeding 10% is considered interference.

Substance Tested	Substance Concentration	Gentamicin µg/mL [µmol/L]	Bias* %
Hemoglobin (hemolysate)	Hemoglobin (monomer) 1000 mg/dL [0.62 mmol/L]	8 [17.3]	<10
Bilirubin (unconjugated)	60 mg/dL [1026 µmol/L]	8 [17.3]	<10
Bilirubin (conjugated)	60 mg/dL [1026 µmol/L]	8 [17.3]	<10
Lipemia (Intralipid®)	1000 mg/dL [11.3 mmol/L] 3000 mg/dL [33.9 mmol/L]	8 [17.3]	<10 -22.5

Intralipid® is a registered trademark of Fresenius Kabi AG, Bad Homburg, Germany.

*** Analyte results should not be corrected based on this bias.**

Cross reactivity ‡

Aminoglycosides structurally similar to gentamicin (e.g. netilmicin, sagamicin, and sisomicin) may significantly cross-react with this method. Therefore, GENT cannot reliably be used for patients receiving these antibiotics separately or in combination with gentamicin.

Analytical Sensitivity

The analytical sensitivity is 0.2 µg/mL [0.43 µmol/L]. It represents the lowest concentration of gentamicin that can be distinguished from zero. This sensitivity is defined as the mean value (n=20) plus two standard deviations of the level 1

(0 µg/mL) [0 µmol/L] Drug 2 Calibrator.

References

1. Burtis CA, Ashwood ER, Bruns DE. Tietz Textbook of Clinical Chemistry and Molecular Biology, Fourth Edition, Elsevier Saunders, St. Louis, MO; pp. 1262 (clinical significance), pp. 2305 (reference values).
2. Finn AL, Taylor WJ. Individualizing Drug Therapy, Practical Applications of Drug Monitoring. New York: Gross, Townsend, Frank, Inc., 1981: 114-147.
3. Clinical and Laboratory Standards Institute/NCCLS. *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition.* CLSI/NCCLS document H3-A5 [ISBN 1-56238-515-1]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2003.
4. Clinical and Laboratory Standards Institute/NCCLS. *Procedures for the Handling and Processing of Blood Specimens; Approved Guideline—Third Edition.* CLSI/NCCLS document H18-A3 [ISBN 1-56238-555-0]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2004.
5. Clinical and Laboratory Standards Institute /NCCLS. *Tubes and Additives for Venous Blood Specimen Collection; Approved Standard—Fifth Edition.* CLSI/NCCLS document H1-A5 [ISBN 1-56238-519-4]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2003.
6. Clinical and Laboratory Standards Institute/NCCLS. *Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition.* CLSI/NCCLS document EP7-A2 [ISBN 1-56238-584-4]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2005.
7. Clinical and Laboratory Standards Institute /NCCLS. *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition.* CLSI/NCCLS document EP5-A2 [ISBN 1-56238-542-9]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2004.
8. Clinical and Laboratory Standards Institute/NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition.* CLSI/NCCLS document EP9-A2 [ISBN 1-56238-472-4]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2002. ©2008 Siemens Healthcare Diagnostics Inc.

All Revision Dates

1/18/2024

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	1/18/2024
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	1/18/2024
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/15/2024
Laboratory Services Department	Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services	1/14/2024

Status **Active** PolicyStat ID **12799432**

Origination	10/1/2012	Owner	Erlinda Roxas: Director, Laboratory Services
Last Approved	12/12/2023		
Effective	12/12/2023	Policy Area	Laboratory Services
Last Revised	12/12/2023		
Next Review	12/11/2025		

L.SPH.10 Amylase

POLICY:

The AMY method used on the EXL ® clinical chemistry system is an in vitro diagnostic test intended for the quantitative determination of amylase activity in **serum** , **plasma** and **urine** .
Clinical Significance

Amylases are secreted by the salivary and pancreatic glands into their respective juices, which enter the gastrointestinal tract. These enzymes are important for the digestion of ingested starches, but the amylase from the pancreas plays the major role, because the salivary amylase soon becomes inactive in the acidic condition prevailing in the stomach. Several isoenzymes of both pancreatic and salivary amylase exist. The amylase that is normally present in serum is derived from both pancreas and salivary glands. The activity of serum amylase rises after an obstruction to the flow of fluid from either the salivary or the pancreatic glands, but the elevation is usually much greater when the outflow from the pancreatic gland is blocked. Acute pancreatitis is caused by blockage of the pancreatic ducts, by direct injury to the pancreatic tissue by toxins, inflammation, or trauma, or by impaired blood flow to the pancreas. The inflammation and autodigestion by pancreatic enzymes that accompany pancreatic injury usually result in an obstruction to the flow of pancreatic juice into the intestine. High levels of amylase activity may be found in pleural fluid in some cases of pancreatitis.

Increased Activity

Serum amylase activity is raised considerably in acute pancreatitis and obstruction of the pancreatic ducts, and mildly in obstruction of the parotid (salivary) gland. The rise in serum amylase activity after compression of the common bile duct by a cancerous growth of the head of the pancreas is rapid and temporary. It usually reaches a maximum value, which may be from 6-10 times the upper limit of normal, in about 24 hours, with a return to normal in 2-3 days. The increase in serum amylase activity caused by a stone in the parotid duct or by the disease mumps usually is less the 4 times the upper limit of normal.

Because serum amylase is rapidly cleared by the kidney, measurement of urinary amylase is a valuable adjunct to the serum test. Some types of renal damage may be accompanied by a mildly elevated level of serum amylase because of impaired excretion.

Decreased Activity

A decreased concentration of serum amylase may be found in acute or chronic hepatocellular damage, but this is not a sensitive liver function test.

PROCEDURE:

The AMY method on the EXL ® system utilizes a chromogenic substrate, 2-chloro-4-nitrophenol linked with maltotriose. [1] The direct reaction of α-amylase with the substrate results in the formation of 2-chloro-4 nitrophenol, which is monitored spectrophotometrically. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis. The AMY method responds to both pancreatic and salivary amylase isoenzymes.

α-amylase (α-1, 4-glucan, 4-glucanohydrolase; EC 3.2.1.1) catalyzes the hydrolysis of a defined synthetic substrate, 2-chloro-4-nitrophenyl-α-D-maltotrioside (CNPG3), to yield 2-chloro-4-nitrophenol (CNP), 2-chloro-4-nitrophenyl-α-D-maltoside (CNPG2), maltotriose (G3) and glucose. After an incubation of 70 seconds at 37°C, the absorbance due to the formation of 2-chloro-4-nitrophenol (CNP) is measured using a bichromatic (405, 577 nm) rate technique.

$$\text{CNPG3} \xrightarrow{\text{Amylase}} \text{CNP} + \text{CNPG2} + \text{G3} + \text{GLUCOSE}$$

Reagents

See the EXL Amylase insert sheet for details of reagents used in this method. Reagents are stored at 2-8°C.

Refer to carton for expiration date of individual unopened reagent cartridges. Sealed or un-hydrated cartridge wells on the instrument are stable for 30 days. Once wells have been entered by the instrument, they are stable for 72 hours.

Specimen Collection

Normal procedures for collecting and storing, plasma (Lithium Heparin), body fluids may be used for samples to be analyzed for this method.

Known Interfering Substances

- Hemolysis, Icterus and Lipemia have minimal interference at moderate levels. See the insert sheet for details.
- Refer to the Amylase reagent insert sheet for a complete list of substances tested for interference.

Procedure

The AMY Flex™ reagent cartridge, Cat. No. DF17A, is required to perform the AMY test. This test is performed on the EXL ® clinical chemistry system after the method is verified (see Reference Material in Verification section).

Test Steps

Sampling, [d] reagent delivery, mixing, and processing and printing of results are automatically performed by the EXL ® system. For details of this processing, refer to the EXL ® system manual.

[d] The sample container (if not a primary tube) must contain sufficient quantity to accommodate the sample volume plus the dead volume; precise container filling is not required.

Test Conditions

• Sample Size:	14 µL
• Reagent Volume:	220 µL
• Diluent Volume:	166 µL
• Test Temperature:	37°C
• Wavelength:	405 and 577 nm
• Type of Measurement:	bichromatic rate

Procedure Notes

Verification

The general verification procedure is described in the EXL ® system manual (also see Appendix B). The following information should be considered when verifying the amylase method:

Assay Range (@37°C):	0-650 U/L
Reference Material:	Enzyme Verifier (Cat. No. DC19)
Suggested Verification Levels:	60, 400, 725 U/L
Verification Scheme:	Three levels in triplicate
Verification Frequency:	Every new reagent cartridge lot. Every 3 months for any one lot.
Verification Slope Range:	0.90-1.10

Assigned Coefficients:	C0=0.000 C1=5.400

Quality Control

Two levels of controls are run once every 24 hours. Currently used controls with means and standard deviations are posted in the computer and on the analyzer. See the Chemistry Policy Manual: Chemistry QC Program for details.

Results

The instrument automatically calculates and prints the activity of amylase in U/L using the calculation scheme illustrated in the EXL ® system manual. A change of 0.2 milli-absorbance units (mA) per minute corresponds to an α-amylase activity of 1 U/L at 37°C.

Limitations of Procedure

Results:	>650 U/L
Manual dilution:	**Serum/Plasma:** Make appropriate dilution with Enzyme Diluent (Cat No 790035901) or equivalent to obtain result within the assay range. Enter dilution factor. **Serum/Plasma/Urine: Reassay** . Resulting readout is corrected for dilution.
Autodilution (AD) (for serum, plasma):	Refer to the EXL ® system literature.
Automated Urine Dilution (AUD) (for urine):	Refer to the EXL ® system literature.

The instrument reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing such error messages should be held for follow up. Refer to the EXL ® system manual.

Reference Interval

Serum [6]	**25-115 U/L**

Note

Urine specimens will be sent to the Ventura County Medical Center Laboratory for processing and testing.

Bibliography

1. Chavez RG. U.S. Patent 4,963,479

2. Tietz NW. Textbook of Clinical Chemistry. Philadelphia: WB Saunders Co., 1986:52–53 (techniques and procedures to minimize laboratory infections), 478–497 (specimen collection and storage recommendations), 729 (amylase specimen).
3. Zakowski JJ, Bruns DE. Biochemistry of Human Alpha Amylase Isoenzymes. Crit Rev Clin Lab Sci, 1981;21:283-322.
4. Irie A, Hunaki M, Banda K, Kawai K. Activation of α-Amylase in Urine. Clin Chem Acta 1974;5:241-245.
5. Berger GMB, Liesching W. Interbatch Variability in Measurement of Urinary Amylase with a Commercial Kit. Clin Chem 1976;22:556.
6. Dicht JJ. Reference Intervals for Serum Amylase and Urine Creatinine on the aca ® discrete clinical analyzer. DuPont Company, Wilmington, DE (November, 1984).
7. Barger JD, Dicht JJ. Reference Interals for Urine on AML, CALCM, MG, Na/K and UP. DuPont Company, Wilmington, DE (October 1983).
8. Gadsden RH, Phelps CA. A Normal Range Study of Amylase in Urine and Serum on the aca ®, DuPont Company, Wilmington, DE (March 1978).
9. McCroskey R, Chang T, David H, Winn E. p-Nitrophenylglycosides as Substrates for Measurement of Amylase in Serum and Urine, Clin Chem 1982; 28:1787-1791.
10. Salt WB, Schenker S. Amylase—Its Clinical Significance: A Review of the Literature, *Medicine* , 1976; 55:269.

All Revision Dates

12/12/2023, 12/1/2016

Attachments

Image 02

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	12/12/2023
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	12/12/2023

Laboratory Services Department	Erlinda Roxas: Director Laboratory Services	7/16/2023

Status **Active** PolicyStat ID **14493237**

Origination	12/12/2023
Last Approved	12/12/2023
Effective	12/12/2023
Last Revised	12/12/2023
Next Review	12/11/2025
Owner	Erlinda Roxas: Director, Laboratory Services
Policy Area	Laboratory Services

L.SPH.29.1 DIMENSION LIPASE ASSAY

Principles of the Procedure

The Dimension LIP assay uses as a substrate 1,2-O-dilauryl-rac-glycero-3-glutaric acid- (6'-methylresorufin) ester. Lipase catalyzes the hydrolysis of this substrate in the presence of colipase, bile salt, and CaCl2 at alkaline pH. The hydrolysis produces 1,2-O-dilauryl-rac-glycerol and glutaric acid- 6'-methylresorufin ester. Glutaric acid-6'-methylresorufin ester is an unstable reaction intermediate and breaks down to yield chromogenic free methylresorufin in proportion to the activity of lipase in the sample. The rate of production of methylresorufin is measured by a bichromatic rate reaction at 577 and 700 nm.

1,2-O-dilauryl-rac-glycero-3-glutaric acid- (6'-methylresorufin) ester	→	1,2-O-dilauryl-rac-glycerol + H2O glutaric acid 6'-methylresorufin ester (unstable)
	Lipase	
1,2-O-dilauryl-rac-glycerol glutaric acid 6'-methylresorufin-ester (unstable)	→	glutaric acid + methylresorufin (absorbs at 577 nm)

Intended Use

The LIP assay is an in vitro diagnostic test for the quantitative determination of lipase in human serum and plasma on the Dimension® clinical chemistry system.

Specimen Types

Serum and Plasma

Specimen Stability

Specimen Type(s)	Storage Condition(s)	Storage Duration
Serum	2–8°C	7 days
	Frozen at ≤ -20°C	12 months
Lithium heparin plasma	2–8°C	7 days
	Frozen at ≤ -20°C	12 months

For separated specimens that are frozen:

- Avoid more than 3 freeze-thaw cycles.
- Thoroughly mix thawed samples and centrifuge before using.

Minimum Sample Volume

3 µL

Preparing the Reagents

All reagents are liquid and ready to use.

Storage and Stability

Store reagents away from light and heat. Do not use products beyond the expiration date printed on the product labeling.

Discard products at the end of the on-board stability interval.

Do not use products beyond the expiration date printed on the product labeling.

Calibrator Material

Dimension LIP CAL

Quality Control Material

Refer to Siemens Dimension LIPASE Instruction for Use (see attachment)

Liquicheck Unassayed Chemistry Control (Human) Levels 1 and 2

Reference # 691 (Level 1)

Reference # 692 (Level 2)

Reference # 690X (2 X 10 mL)

Interferences

Substance	Substance Concentration Conventional Units (SI Units)	Analyte Concentration Conventional Units (SI Units)	Bias %
Hemoglobin	1000 mg/dL (0.6 µmol/L) 600 mg/dL (0.4 µmol/L) 500 mg/dL (0.3 µmol/L)	75 U/L 147 U/L 77 U/L	31 8 5
Bilirubin, conjugated	40 mg/dL (474.5 µmol/L)	75 U/L 149 U/L	1 1
Bilirubin, unconjugated	40 mg/dL (683.8 µmol/L)	76 U/L 152 U/L	4 3
Lipemia (Intralipid)	3000 mg/dL (33.9 µmol/L)	69 U/L 135 U/L	1 1

- Do not use hemolyzed samples, as they may cause significant interference with this assay.
- In very rare cases, gammopathy, in particular type IgM (Waldenstrom's macroglobulinemia), may cause unreliable results.

Calculation of Results

The system reports results in U/L.

Results of this assay should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

Analytical Measuring Range

6 U/L–250 U/L

Dilutions

Dilute and retest serum and lithium heparin plasma specimens with lipase levels > 250 U/L to obtain accurate results.

For automated dilutions, the instrument uses system water. Ensure that sufficient sample volume is available to perform the dilution.

Specimen	Dilution Factor	Autodilution Sample Volume µL
Serum and plasma	1.5	2

If patient results exceed the measuring interval of the assay when using automated dilution, or if laboratory protocol requires manual dilution, manually dilute the patient sample.

For manual dilutions, perform the following actions:

- Use Dimension/Dimension Vista Enzyme Diluent to prepare a manual dilution.
- Ensure that results are mathematically corrected for dilution. If a dilution factor is entered when scheduling the test, the system automatically calculates the result.

Sensitivity

N/A

Expected Values

A reference interval for healthy adults was established in accordance with CLSI Document EP28-A3c and verified on the Dimension clinical chemistry system.

The reference interval for lipase for healthy adults is 16–77 U/L for serum and lithium heparin plasma. This interval was obtained from a study of 128 healthy adults. Specimens were collected prospectively. The reference interval was determined by calculating the 2.5 and 97.5 percentiles of the distribution of values. These data were established on the Dimension clinical chemistry system.

Hemolyzed and icteric samples were excluded from the study.

As with all *in vitro* diagnostic assays, each laboratory should determine its own reference interval for the diagnostic evaluation of patient results. Consider these values as guidance only.

Critical Values

N/A

Reporting

The instrument calculates and prints the concentration of lipase in U/L using the calculation scheme described in the Dimension® Operator's Guide.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

- Samples with results in excess of 250 U/L should be repeated on dilution.
- Samples with results less than 6 U/L should be reported as "Less than 6 U/L."

Limitations

The instrument reporting system contains flags and comments to provide the user with information regarding instrument processing errors, instrument status information and potential errors in results. Refer to the Dimension® Operator's Guide for th meaning of report flags and comments.

Note Appendices L1 and L3 of CLSI QMS02-A6, published 2/28/2013, guided the creation of this document

Siemens document number: 11417324 EN Rev. 01

All Revision Dates

12/12/2023

Attachments

11641330_Rev._A_CB_Intro_DM_LIP-DM-DV_LIP_CAL_DXDCM_09017fe9806da546-1653430307239.pdf

Lipase_-_Dimension_-_Rev_01_DXDCM_09017fe980632f7f-1653343497466.pdf

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	12/12/2023
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	12/12/2023
Laboratory Services Department	Erlinda Roxas: Director Laboratory Services	10/3/2023

Status **Active** PolicyStat ID **12799419**

Origination	10/1/2012
Last Approved	12/12/2023
Effective	12/12/2023
Last Revised	12/12/2023
Next Review	12/11/2025
Owner	Erlinda Roxas: Director, Laboratory Services
Policy Area	Laboratory Services

L.SPH.39 Total Bilirubin

POLICY:

The TBI method for the EXL ® clinical chemistry system is an in vitro diagnostic test intended to quantitatively measure total bilirubin in **human serum** and **plasma** . Measurements of total bilirubin are used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gallbladder disease.

CLINICAL SIGNIFICANCE

Bilirubin is a brownish yellow substance found in bile. It is produced when the liver breaks down old red blood cells. Bilirubin is then removed from the body through the stool (feces) and gives stool its normal brown color.

Bilirubin circulates in the bloodstream in two forms:

Indirect (or un-conjugated) bilirubin. This form of bilirubin does not dissolve in water (it is insoluble). Indirect bilirubin travels through the bloodstream to the liver, where it is changed into a soluble form (direct or conjugated).
Direct (or conjugated) bilirubin. Direct bilirubin is soluble (it dissolves in water) and is made by the liver from indirect bilirubin.
Total bilirubin and direct bilirubin levels are measured directly in the blood, whereas indirect bilirubin levels are derived from the total and direct bilirubin measurements.
The most obvious symptom of high bilirubin levels is jaundice, a condition in which the skin and whites of the eyes appear yellow. Jaundice is caused by the buildup of bilirubin in the blood and skin from liver disease (hepatitis), blood disorders (hemolytic anemia), or blockage of the tubes (bile ducts) that allow bile to pass from the liver to the small intestines.
Excessive buildup of bilirubin (hyperbilirubinemia) in a newborn baby sometimes causes brain damage,

blindness, physical abnormalities, and even death. Therefore, some babies who develop jaundice may be treated with special lights (phototherapy) or a blood transfusion to reduce their bilirubin levels.

PROCEDURE:

There are at least four distinct bilirubin fractions that make up total bilirubin in serum. The direct reacting fractions are mono-and diconjugated bilirubin (ß and γ-bilirubin) and the delta fraction (δ-bilirubin), which is tightly bound to albumin. Unconjugated bilirubin (-bilirubin) is water-insoluble and reacts only after addition of an accelerator such as caffeine [1] . The TBI method is a modification of the Doumas reference method [2] , which is a modification of the diazo method described by Jendrassik and Grof in 1938 [3] . Diazotized sulfanilic acid is formed by combining sodium nitrite and sulfanilic acid at low pH. Bilirubin (unconjugated) in the sample is solubilized by dilution in a mixture of caffeine/benzoate/acetate/EDTA. Upon addition of the diazotized sulfanilic acid, the solubilized bilirubin including conjugated bilirubins (mono and diglucoronides) and the delta form [4] (biliprotein-bilirubin covalently bound to albumin) is converted to diazo-bilirubin, a red chromophore representing the total bilirubin which absorbs at 540 nm and is measured using a bichromatic (540, 700 nm) endpoint technique. A sample blank correction is used.

$$\text{Solubilize d bilirubin} + \text{Diazotized sulfanilic acid} \longrightarrow \frac{\text{Red Chromophore}}{(\text{absorbs @540 nm})}$$

REAGENTS

See The EXL ® insert sheet for details of reagents used in this method. Reagents are stored at 2-8°C. Refer to carton for expiration date of individual unopened reagent cartridges. Sealed or un-hydrated cartridge wells on the instrument are stable for 30 days. Once well have been entered by the instrument, they are stable for 5 days.

SPECIMEN COLLECTION AND HANDLING

Serum, lithium heparin plasma, and EDTA plasma can be collected by normal procedures [5] . Serum and plasma specimens should be separated from cells within 2 hours after venipuncture [5] . Bilirubin is extremely photosensitive. Care should be taken to protect sample from both daylight and fluorescent light to avoid photodegradation.

Specimens may be kept at 4°C for up to 5 days and may be frozen at -20°C for up to 6 months [6] . Specimens should be free of particulate matter. To prevent the appearance of fibrin in serum samples, complete clot formation should take place before centrifugation. Clotting time may be increased due to thrombolytic or anticoagulant therapy.

PROCEDURE

Materials Provided

Flex® reagent cartridge, Cat. No. DF167

Materials Required But Not Provided

TBI/DBI Calibrator Cat. No. DC167
Quality Control materials
Purified Water Diluent (Cat. no. 710615901) or reagent grade water

Test Steps

Sampling [c] , reagent delivery, mixing, processing and printing of results are automatically performed by the EXL ® system. For details of this processing, refer to your EXL ® system manual.

[c] The sample container must contain sufficient quantity to accommodate the sample volume plus dead volume. Precise container filling is not required.

Test Conditions

	Cuvette 1
Sample Volume	10 µL
Reagent 1 Volume	250 uL
Reagent 2 Volume	47 uL
Temperature	37 °C
Reaction period	522.4 sec
Wavelength	540, 700 nm
Type of measurement	Bichromatic endpoint
Units	mg/dL

CALIBRATION

The general calibration procedure is described in your EXL® system manual. The following information should be considered when calibrating the TBI method:

Assay range	0.1 -25.0 mg/dL
Reference Material	Primary standards or secondary calibrators such as TBI/DBI Calibrator, Cat. No. DC167
Suggested Calibration Levels	0, 10, 25 mg/dL

Calibration Scheme, Replicates	3 levels in triplicate
Calibration Frequency:	Each new reagent cartridge lot. Every 90 days for any one lot
Assigned Coefficients:	C_0 :[0.00] C_1 :[0.078]

Note: Level 1 calibrator for TBI is not included in the TBI/DBI calibrator carton. Purified Water Diluent (Cat. no. 710615901) or reagent grade water should be used as the Level 1 calibrator for the TBI method.

QUALITY CONTROL

Two levels of controls are run once every 24 hours. Currently used controls with means and standard deviations are posted n the computer and on the analyzer. See the Chemistry Policy Manual: Chemistry QC Program for details.

KNOWN INTERFERING SUBSTANCES

Hemolysis and Lipemia Interference Information

The TBI method was evaluated for interference according to CLSI/NCCLS EP7-A. Bias is the difference in the results between the control sample (without the interferent) and the test sample (contains the interferent) expressed in percent. Bias exceeding 10% is considered interference.

Substance Tested	Test Concentration [j, k]	TBI Concentration	Bias [l] %
Hemoglobin	1000 mg/dL	1.1 mg/dL	<10
	1000 mg/dL	24.8 mg/dL	<10
Lipemia (Intralipid ®)	200 mg/dL	1.1 mg/dL	<10
	600 mg/dL	1.1 mg/dL	+18
	600 mg/dL	25.6 mg/dL	<10

Other Limitations

Results: > 25.0 mg/dL

Manual dilution: Dilute with purified water 1:4 (1 part of sample with 3 parts of purified water) to obtain results within the assay range. Enter dilution factor (4). Reassay. Resulting readout is corrected for dilution.

Auto-dilution (AD): The recommended auto-dilute sample volume is 5 uL for serum and plasma. Refer to your EXL ® system manual.

Results: < 0.1 mg/dL should be reported as "less than 0.1 mg/dL"

The instrument reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing such error messages should be held for follow-up. Refer to the EXL ® system

manual.

Neonatal Bilirubin Test

The accuracy of neonatal bilirubin results in the range of 5 to 25 mg/dL is verified by participating in the College of American Pathologist 2-Challenge Proficiency Testing Program Neonatal Bilirubin (NB2) Survey. Assessment of adequacy for th agreement with target values in the range of the clinical guidelines for clinical purposes is achieved upon evaluation of these surveys. Appropriate corrective action is performed when results are outside of acceptable ranges.

REFERENCE INTERVAL

0.2 – 1.0 mg/dL

The reference interval was validated in a confirmatory study using 30 serum samples.

SPECIFICITY

Hemolysis and Lipemia Interference Information

The TBI method was evaluated for interference according to CLSI/NCCLS EP7-A. Bias is the difference in the results between the control sample (without the interferent) and the test sample (contains the interferent) expressed in percent. Bias exceeding 10% is considered interference.

Substance Tested	Test Concentration [j, k]	TBI Concentration	Bias [l] %
Hemoglobin	1000 mg/dL	1.1 mg/dL	<10
	1000 mg/dL	24.8 mg/dL	<10
Lipemia (Intralipid ®)	200 mg/dL	1.1 mg/dL	<10
	600 mg/dL	1.1 mg/dL	+18
	600 mg/dL	25.6 mg/dL	<10

Intralipid ® is a registered Trademark of Fresenius Kabi AG, Bad Homburg, Germany

[j] Samples with hemolysis greater than 1000 mg/dL of hemoglobin will be flagged with a "Hemoglobin" error message. Refer to your EXL® system manual.

[k] Samples with Intralipid ® concentrations greater than 600 mg/dL may be flagged with an "Abnormal Reaction" error message. Refer to your EXL® system manual.

[l] Do not attempt to correct analyte results based on these results.

BIBLIOGRAPHY

1. Burtis CA, Ashwood ER. Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia: W.B. Saunders Company, 1999: p. 1136.

2. Doumas BT, Perry BW, Sasse EA, et al. Standardization in bilirubin assays: Evaluations of selected methods and stability of bilirubin solutions, Clin Chem 1973; 19:984–993.
3. Jendrassik L, Grof P. Vereinfachte photometrische Methode zur Bestimmung des Blutbilirubin, Biochem Z 938; 297:81.
4. Doumas BT, et al. Delta bilirubin: absortption spectra, molar absorptivity, and reactivity in the diazo reaction. Clin Chem 1987; 33: 769-774.
5. Burtis CA, Ashwood ER. Tietz Fundamentals of Clinical Chemistry, 5th ed. Philadelphia: W.B. Saunders Company, 2001: pp. 31-41.
6. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests, 2nd ed. Washington, DC: AACC Press, 1997: p. 3-85, 4-492.
7. Clinical and Laboratory Standards Institute/NCCLS. Interference Testing in Clinical Chemistry; Approved Guideline. CLSI/NCCLS document EP7-A [ISBN 1-56238-480-5]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19807-1898, USA, 2002.
8. Kaplan LA, Pesce AJ. Clinical Chemistry: Theory, Analysis, and Correlation, 3rd ed. St. Louis, MO: Mosby, Inc, 1996: p. 712.
9. Clinical and Laboratory Standards Institute/NCCLS. Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition. CLSI/NCCLS document EP5-A2 [ISBN 1-56238-542-9]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19807-1898, USA, 2004.
10. https://doclib.siemens-healthineers.com/rest/v1/view?document-id=710391
11. College of American Pathologist Accreditation Checklist, LSV.40675 "Neonatal Bilirubin Testing." Retrieved October 21, 2023.

All Revision Dates

12/12/2023, 11/1/2016

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	12/12/2023
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	12/12/2023

Laboratory Services Department	Erlinda Roxas: Director Laboratory Services	10/21/2023

Status Active PolicyStat ID 14834492

Origination	2/1/2014	Owner	Sul Jung: Associate Director of Pharmacy Services
Last Approved	12/5/2023		
Effective	12/5/2023	Policy Area	Pharmacy Services
Last Revised	12/5/2023		
Next Review	12/4/2026		

PH.16 Pharmaceutical Borrowing and Loaning

POLICY:

The loaning or borrowing of drugs shall take place only after alternate methods of procurement, such as a secondary vendor or a wholesaler, have been pursued. These products must have proof of pedigree (see policy PH.13 Drug Supply Chain Security Act [DSCSA]). The transaction must occur only amongst entities licensed with the California Board of Pharmacy.

PROCEDURE:

A. During normal business hours (8:00 a.m. – 4:30 p.m., Monday through Friday), the Pharmacy Buyer or a pharmacist shall be responsible for the loaning or borrowing of drugs. After normal business hours, the loaning or borrowing of drugs shall be performed under the direction of the supervising pharmacist.
    1. Preparation of medication to be loaned may be prepared by a pharmacy buyer or technician including completion of Attachment A, processing of transaction with DSCSA tracking system (completing T3 form), and packaging.
    2. Final check of medication against T3 form must be completed by a pharmacist and the action approved on DSCSA tracking system.

B. Schedule II Controlled Substances shall be transferred utilizing DEA Form 222. The Director of Pharmacy Services shall be notified prior to initiating the transfer process of schedule II controlled substances.

C. Only drugs which are packaged in fully labeled containers, including the generic name, trade name, name of the manufacturer, manufacturer's lot number and expiration date, shall be loaned to or borrowed from another pharmacy.
    1. Do not loan or borrow medications that are unit dosed by the pharmacy.

D. The amount loaned or borrowed should be determined by estimating the supply needed to adequately provide coverage through the next business day or until the expected date of the next shipment.

E. If an outside pharmacy is requesting to borrow medications, the Loan/Borrow Form (Attachment A) shall be emailed or transmitted to the requesting pharmacy to be completed. The completed form shall be emailed or transmitted back to the the Department of Pharmacy Services prior to distribution of the medication. A copy of the completed Loan/Borrow form shall be submitted to the Pharmacy Operations Supervisor.

    1. Complete the loaning transaction through DSCSA tracking system. Print out two copies of the T3 document. Send one T3 to the loaning pharmacy and keep one copy to be submitted to the Pharmacy Operations Supervisor with Attachment A.

F. If the Department of Pharmacy Services is requesting to borrow from an outside pharmacy, the Loan/Borrow Form shall be completed in duplicate and signed by both the lender and the borrower. The original copy is submitted to the Pharmacy Operations Supervisor.

    1. The outside pharmacy must provide complete T3 document prior to the Department of Pharmacy Services accepting medication for use.

G. The expiration date, lot number, manufacturer, and National Drug Code (NDC) number of each medication shall be noted on the Loan/Borrow Form.

H. The Pharmacy Buyer shall maintain a binder containing all outstanding forms. These transactions should be reconciled within thirty days of the transaction date.

I. Upon returning a borrowed medication or receiving a medication loaned, the date, amount and individual's initials will be noted on the Loan/Borrow form and retained for six (6) years. Each of these transactions must be accompanied by a new T3 document.

J. Borrowing and loaning of 340B drugs is prohibited without review and approval from the Director of Pharmacy Services or designee.

All Revision Dates

12/5/2023, 9/20/2021, 7/19/2018, 2/1/2016

Attachments

A: Loan-Borrow Form

Approval Signatures

Step Description	Approver	Date

Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	12/5/2023
Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	12/5/2023

Status **Active** PolicyStat ID **14549048**

Origination	12/4/2023
Last Approved	12/4/2023
Effective	12/4/2023
Last Revised	12/4/2023
Next Review	12/3/2024
Owner	Beatriz Cachu: 340B Program Administrator
Policy Area	Pharmacy Services

PH.18.02 340B Drug Pricing Program: Federally Qualified Health Center

Purpose

This policy serves as the basis for the Federally Qualified Health Center (FQHC) covered entity (CE) County of Ventura's (CH098480) policy and procedures for the 340B Drug Pricing Program (340B Program), which requires drug manufacturers to provide outpatient drugs to eligible health care organizations, including the covered entity (CE) County of Ventura [CH098480], at significantly reduced prices. The CE uses savings from the 340B Program following its intent to reach "more eligible patients and provide more comprehensive services."

Background

A. Section 340B of the Public Health Service Act (1992), *(See Reference I)*, requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign a pharmaceutical pricing agreement (PPA) with the Secretary of the Department of Health and Human Services (DHHS).
    1. This agreement limits the price that manufacturers may charge certain covered entities for covered outpatient drugs.

B. The 340B Program is administered by the federal Health Resources and Services Administration (HRSA) in the Department of Health and Human Services (DHHS).

C. Upon registration on 340B Office of Pharmacy Affairs Information System (OPAIS), the CE:
    1. Agrees to abide by specific statutory requirements and prohibitions.
    2. May access 340B drugs.

340B Policy Statements

A. The CE shall comply with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than an eligible patient of the entity.

B. The CEs have systems and internal controls in place to ensure ongoing compliance with all 340B requirements:

    1. Audit Process *(See Section "340B Program Compliance, Monitoring and Reporting")*
    2. Purchasing process *(See Section "Inventory Management")*
    3. Shipping and receiving process *(See Section "Inventory Management")*

C. Registration & Recertification *(See Section "340B Program Enrollment Recertification")*

D. The CEs maintain auditable records demonstrating compliance with the 340B Program.

    1. These records are reviewed by the CE monthly as part of its 340B oversight and program compliance. *(See Section "340B Program Compliance, Monitoring and Reporting")*

E. Policy review, updates, and approval shall be updated and approved by the CEs' Compliance Committee whenever there is a rules clarification, regulations change, or change in guidelines to the 340B Program requirements. Otherwise, the policy shall be reviewed and approved annually by key stakeholders.

Definitions

A. Child Site: An offsite location that is eligible to participate in the 340B Program because it is part of the Covered Entity but is separately registered with the Office of Pharmacy Affairs (OPA) because it has a different street address than the Covered Entity's main facility. A Covered Entity does not need to register outpatient clinics and departments located within the four walls of the entity's main facility. OPA guidance establishes a Medicare cost report test to determine whether an offsite clinic is part of the Covered Entity and, therefore, eligible to use 340B drugs. Under this test, an offsite clinic's costs must be reimbursable on the hospital's Medicare cost report. In implementing this guidance, OPA has taken the position that, to be 340B eligible, an offsite clinic's costs must appear on a reimbursable line of a hospital's most recently filed cost report. A Covered Entity pharmacy is not a Child Site.

B. Covered Entity: The statutory name for facilities and programs eligible to purchase discounted drugs through the 340B Program. Covered entities include federally qualified health center look-alike programs; certain disproportionate share hospitals owned by, or under contract with, State or local governments; and several categories of facilities or programs funded by Federal grant dollars, including federally qualified health centers, AIDS drug assistance programs, hemophilia treatment centers, STD and TB grant recipients, and family planning clinics.

C. Covered Outpatient Drug: The category of drugs for which manufacturers must give 340B discounts to covered entities under the 340B Program. For a product to qualify as a Covered Outpatient Drug, it must be FDA-approved, prepared, and dispensed pursuant to a prescription, and used on an outpatient basis. For a Covered Outpatient Drug to be paid for by Medicaid or Medicare Part B, a manufacturer must enter into both a Medicaid Drug Rebate Agreement and a Pharmaceutical Pricing Agreement (PPA) that covers the Covered Outpatient Drug. The Medicaid statute includes a limiting provision that excludes from the definition of "Covered Outpatient Drug" any drug, biological product, or insulin that is "provided as part of, or incident to and in the same setting as" certain specified services and paid for by Medicaid as part of payment for those services and not as direct reimbursement for the drug.

D. Duplicate Discount: When a manufacturer gives both an up-front 340B discount to a Covered Entity at the time of purchase and a post-purchase discount to a state Medicaid agency after Medicaid pays the Covered Entity for the drug and submits a rebate request to the manufacturer under the Medicaid rebate program. Both the 340B and Medicaid rebate laws protect manufacturers from duplicate discounts. A Covered Entity must comply with the prohibition against duplicate discounts by: (1) billing Medicaid at no more than actual acquisition cost plus a dispensing fee; OR (2) "carving out" Medicaid drugs from its 340B program.

E. Eligible Patient Definition: An individual is a "patient" of a covered entity only if:

   1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
   2. The individual receives health care services from a health care professional who is either employed by the covered entity or under contractual or other arrangement such that responsibility for the care provided remains with the covered entity.

F. Parent Site: The main facility of the Covered Entity that becomes eligible to use 340B drugs by virtue of the entity's enrollment in the 340B Program. In contrast, outpatient clinics that have a

different street address than the entity's main facility, which are commonly called "child sites," must be separately registered with OPA before they can begin using 340B drugs.

Covered Entity Eligibility

Policy

A. The CE must meet the requirements of the Health Resources and Services Administration (HRSA), *(See Reference II)*, to be eligible for enrollment in, and the purchase of drugs through the 340B Program.

Purpose

A. To ensure the CE's eligibility to participate in the 340B Program.

Procedure

A. The CE's basis for 340B eligibility is determined by meeting the definition of "Federally Qualified Health Center" in section 1905(l)(2)(B) of the Social Security Act. The CE is receiving a grant under 330 of the Public Health Service Act.

B. CE has identified locations where it dispenses or prescribes 340B drugs including:

The main health center site and associated sites included in the scope of grant or FHCA-LA designation. These sites are operational in the HRSA Electronic Handbook (EHB) and registered on 340B OPAIS.

1. Covered entities should maintain auditable records, policies, and procedures related to the definition of covered outpatient drug that is consistent with the 340B statute and Social Security Act.
2. Define covered outpatient drugs based on section 1927(k) of the Social Security Act.

C. Entity ensures that 340B OPAIS is complete, accurate, and correct for all 340B eligible locations (main and associated sites, and contract pharmacies.)

1. All off-site locations that use 340B drugs are registered on the CE's 340B OPAIS.
2. All main/assoicated site addresses, billing and shipping addresses, the authorizing official, and the primary contact information are correct and up to date.
3. The CE regularly reviews its 340B OPAIS records.
4. The CE informs HRSA immediately of any changes to its Medicaid information by updating the 340B OPAIS Medicaid Exclusion File. The data included in the Medicaid Exclusion File is provided by covered entities for drugs billed under Medicaid fee-for-service and does not apply to Medicaid managed care organizations.

D. The CE annually certifies the CE's information on 340B OPAIS.

340B Program Enrollment Recertification

Policy

A. The CE shall maintain the accuracy of 340B OPAIS and be actively registered to participate in

the 340B Program.

Purpose

A. To ensure the CE is appropriately registered and maintains accurate records on 340B OPAIS.
    1. Registration dates:
        a. January 1–January 15 for an effective start date of April 1
        b. April 1–April 15 for an effective start date of July 1
        c. July 1–July 15 for an effective start date of October 1
        d. October 1–October 15 for an effective start date of January 1
    2. 340B Contract Pharmacy Guidelines *(see reference VII)*

Enrollment

A. The CE is eligible to participate in the 340B Program.
B. The CE identifies upcoming registration dates and deadlines.
C. The CE identifies authorizing official and primary contact.
D. The CE has available the required documents:
    1. Medicare cost report:
        a. Worksheet S
        b. For outpatient facilities: Worksheet C, Worksheet A, and Working trial balance.
    2. Notice of Award Authorization
E. The CE completes registration on 340B OPAIS (https://340bopais.hrsa.gov/).

Recertification Procedure

A. The CE shall recertify information listed on 340B OPAIS annually.
B. 340B Crosswalk is compared to the OPAIS database to ensure all contact and address information is listed accurately.
C. Any changes or corrections to clinic / contract pharmacy information can be completed during recertification period. However, new clinics cannot be registered at this time.
D. Ensure there are no clinic termination(s) to be completed.
E. NPI numbers, Primary Contact and Authorizing Official's (AO) contact information is verified and confirmed.
F. Review and verify contract pharmacy name, store #, address listed on the OPAIS database match the covered entity's contract pharmacy agreement.
G. Ensure all contract pharmacy agreements are current and match the copy of the Third-Party Administrators.
    1. The Authorizing official completes the annual recertification by following the directions in the recertification email sent from HRSA to the CE prior to the stated

deadline.

H. The CE submits specific recertification questions to 340b.recertification@hrsa.gov.

New Outpatient Facilities

A.

1. The CE will determine that a new outpatient service or facility is eligible to participate in the 340B Program.
    a. The criteria used include that the outpatient service must be fully integrated into hospital, appear as a reimbursable service or clinic on the most recently filed cost report, have outpatient drug use, and have patients who meet the 340B patient definition.
2. The CE updates the HRSA Electronic Handbook (EHB) to correctly reflect the new service site/facility.
3. The CE's authorizing official completes the online registration process during the registration window.
    a. Submit any updated Medicare cost report information, as required by HRSA: http://www.hrsa.gov/opa/eligibilityandregistration/hospitals/disproportionatesharehospitals/index.html

New Contract Pharmacies

A. The CE has a signed contract pharmacy services agreement.
    1. The CE's Contracts Division reviews the contract and verifies that all federal, state, and local requirements have been met.

B. The CE has contract pharmacy oversight and monitoring policy and procedure developed, approved, and implemented.

C. The CE's authorizing official, or designee completes the online registration during one of four registration windows.
    1. Within 15 days from the date of the online registration, the authorizing official certifies online that the contract pharmacy registration request was completed.

D. The CE begins using the contract pharmacy services arrangement only on or after the effective date shown on 340B OPAIS.

Changes to Information in 340B OPAIS

A. Ventura County Medical Center's registered and eligible clinics that move to new locations can continue with 340B eligibility if only a 'Change Request Form' is submitted with new address. Once approved by the Office of Pharmacy Affairs, clinic can continue to be 340B eligible.
    1. Clinic expansions and cost centers that are eligible and listed on the current Medicare cost report are registered during the next registration period by the Authorizing Official. 340B drugs shall not be used at the expansion location until clinic is registered and approved by OPAIS.

340B Program Roles, Responsibilities and Education

Policy

A. The CE participating in the 340B Program must ensure program integrity and compliance with 340B Program requirements. 340B key stakeholders will participate in education and training as needed to ensure that these key stakeholders have the knowledge to guarantee compliant 340B operations.

Purpose

A. To identify The CE's key stakeholders and determine their roles, responsibilities, and education in maintaining 340B Program integrity and compliance.

Committee Oversight

A. The CE will maintain a roster of all key stakeholder's roles, responsibilities, and education within the CE's 340B Program.

B. The CE's Compliance Committee is responsible for the oversight of the 340B Program.

C. The CE's Compliance Committee:

1. Meets on a quarterly basis with all key stakeholders.
2. The CE maintains readily retrievable meeting agendas and minutes.
3. Reviews 340B rules, regulations, and guidelines to ensure consistent policies procedures and oversight throughout the entity.
4. Identifies activities necessary to conduct comprehensive reviews of 340B compliance
    a. Ensure that the organization meets compliance requirements of program eligibility, patient definition, 340B drug diversion and duplicate discounts via ongoing multidisciplinary teamwork.
    b. Integrate departments such as information technology, legal, pharmacy, compliance, and patient financial services to develop standard processes for contract/data review to ensure program compliance.
5. Oversees the review process of compliance activities and audits, as well as taking corrective actions based on findings.
6. The Compliance Committee assesses if the results of audits are indicative of a material breach. (*See Section "340B Material Breach and Noncompliance Disclosure"*)
7. Reviews and approves work group recommendations (process changes, self-monitoring outcomes and resolutions).

D. HRSA Audits:

1. Upon notification of a HRSA audit, all key stakeholders (Pharmacy, Compliance, Finance, Purchasing, Contract Pharmacies, etc.) will be informed of the audit.

2. The CE will comply with all requests for information from HRSA during the pre-audit period.
3. During an on-site HRSA audit, all key stakeholders will be involved, and the CE will fully cooperate with the auditor throughout the audit process.

E. Manufacturer Audits

1. The CE will respond to all manufacturer requests for information related to 340B purchases in a timely manner.
2. Upon notification of a manufacturer audit, all key stakeholders will be informed of the audit.
3. The CE will respond to all requests for information from a manufacturer in a timely manner.
4. During the on-site manufacturer audit, all key stakeholders will be involved as necessary, and the CE will fully cooperate with the auditor throughout the audit process.

Education and Stakeholder Certification

A. Education

1. The CE determines any educational requirements for each 340B Program role.
2. Education and training may consist of any of the following:
    a. Initial basic training upon hire
    b. On-demand modules on the Apexus website
    c. 340B University
    d. 340B conferences
    e. Complete Advance 340B Operations Certification Exam
    f. Participate in HRSA and 340B Health webinars
    g. Participate in statewide 340B workgroup calls
    h. Other 340B related activities

B. The CE provides educational updates and training, as needed.

Patient Eligibility/Definition

Policy

A. Per the Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 340B drugs are to be provided only to individuals eligible to receive 340B drugs from covered entities. (*Reference VIII*)

Purpose

A. The CE ensures that 340B drugs are dispensed, administered, and prescribed only to eligible

patients.

Patient Eligibility

A. An individual is a patient CE is 340B eligible only if:

1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity.

B. The CE recognizes clinic registered outpatients, and/or any status prior to admission from an eligible location may be eligible to receive 340B Covered Outpatient Drugs.

C. The CE often provides specialty care after a referral. The prescriptions written for conditions treated by the CE's specialty providers in the outpatient clinics are eligible for 340B prices at the CE's contracted pharmacies with the patient outcomes and follow-up remaining the responsibility of our contracted providers.

D. CE staff are eligible as patients ONLY when they meet all the same criteria required under the patient definition.

340B Program Compliance, Monitoring and Reporting

Policy

A. The CE is required to maintain auditable records demonstrating compliance with the 340B Program requirements.

Purpose

A. To provide an internal monitoring program to ensure comprehensive compliance with the 340B Program.

Diversion and Duplicate Discounts

A. The CE complies with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulation, public notices, and guidelines including, but not limited to, selling, giving, or otherwise transferring of covered outpatient drugs purchased under the program to anyone other than a "patient of the covered entity." (See Section "*Patient Eligibility/Definition*".)

B. The CE maintains compliance with 42 USC §256b(a)(5)(A)(i) which prohibits duplicate discounts; that is, manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must have mechanisms in place to prevent duplicate discounts.

1. The CE will append the appropriate modifiers on all claims. Physician Administered Drug claims require a "UD" modifier. The "UD" modifier informs California Department of Health Care Services (DHCS) that a 340B purchased drug was used for the claim. The CE maintains and reviews Medicaid provider numbers and NPI numbers quarterly and assures that they are properly reflected in the Medicaid

Exclusion File (MEF).

Medicaid Carve-In

A. The CE dispenses or administers 340B purchased drugs to Medicaid patients.

B. The CE bills Medicaid per state Medicaid reimbursement requirements. This is audited monthly using internal audits.

C. The CE reviews its 340B OPAIS Medicaid Exclusion File (MEF) records quarterly. Any changes in our MEF information shall be communicated to HRSA immediately by updating 340B OPAIS before the 15th of the month prior to the quarter when the change would take effect.

D. Medicaid reimburses the CE for 340B drugs per state policy and does not seek rebates on drug claims submitted by the CE.

E. All Medicaid prescriptions are excluded from the CE's contract pharmacies. This includes both fee-for-service (FFS) and geographic managed care (GMC) plans.

F. Covered outpatient drugs are only billed to Medicaid for the state of California.

Program Assurance

A. The designation of all outpatient clinics (340b-eligible or non-340B) are identified when clinics are first created. These clinics are reviewed and audited quarterly.

B. The CE voluntarily contracts with an independent consultant to conduct an annual external audit of our program that has been approved by the Compliance Committee.

C. To demonstrate the ongoing responsibility for health care, the CE shall provide health care to the individual at a registered site of the CE within 15 months of a written prescription.

D. The CE determines outpatient locations and status that meet the following criteria:

1. Registered clinics that provide care to outpatients.

E. The CE determines provider eligibility as either employed by the covered entity or provides health care under contractual or other arrangements such that responsibility for the care provided remains with the CE.

F. At no time are prescriptions rewritten solely for the purpose of patient eligibility for 340B prescriptions.

Program Self Audits & Maintenance

A. The CE routinely conducts internal monthly reviews of each registered contract pharmacy and clinics for compliance with 340B Program requirements.

B. The following elements will be reviewed when conducting self-audits:

1. The prescription shall be written from a site of care that is registered on 340B OPAIS and included as a reimbursed outpatient service cost center on the most recently filed Medicare cost report; and
2. The patient shall have had an eligible encounter in the last 15 months; and
3. The patient shall meet the eligibility defined by HRSA and DHHS; and
4. The provider shall be eligible at the time the prescription is written.

C. The CE reviews 340B OPAIS quarterly to ensure the accuracy of the information for the parent site, off-site locations, and contract pharmacies.

D. The CE reviews the Medicaid Exclusion File (MEF) quarterly to ensure the accuracy of the information for the parent site, off-site locations, and contract pharmacies.

    1. One randomly selected claim from each clinic with a 340B medications administered is audited every month.
    2. The CE shall confirm that the Medicaid number and/or National Provider Index numbers used to bill Medicaid on the Medicaid Exclusion File are accurate.

E. The CE reconciles purchasing records and dispensing records to ensure that covered outpatient drugs purchased through the 340B Program are administered only to patients eligible to receive 340B drugs and that any variances are not the result of diversion.

F. The CE reconciles dispensing records to patients' health care records to ensure that all medications dispensed were provided to patients eligible to receive 340B drugs.

G. The CE will randomly select records from a drug utilization file and perform the audit monthly for all contract pharmacies.

H. The CE reconciles dispensing records and Medicaid billing practices monthly, to demonstrate compliance with Medicaid billing and duplicate discount.

I. Provider listing is retrieved from reporting monthly, and reviewed for accuracy and is shared with a third-party administrator for outpatient contract pharmacy operations.

J. All audit results shall be presented to the Compliance Committee every quarter.

Record Keeping and Data Management

A. The CE maintains records of 340B-related transactions for a minimum of 7 years in a readily retrievable and auditable format.

    1. This will be stored in a network location and kept up to date on a monthly basis for internal and external audit purposes.

B. The CE reviews and maintains data being sent to all third parties as part of its audit and maintenance process.

C. The CE maintains complete and auditable records of an individual's health care.

D. The CE has an electronic medical record shared between hospital and clinics. No undocumented care is provided under the CE.

Inventory Management

Policy

A. The CE must be able to track and account for all 340B drugs to ensure the prevention of diversion.

Purpose

A. Ensure the proper procurement and inventory management of 340B drugs.

Background

A. 340B inventory is procured and managed in the following settings:
    1. Clinic site administration
    2. Contract pharmacies

B. The CE uses the following inventory method:
    1. Physical 340B-only inventory

Procedure for Purchasing and Logistics

A. The CE has registered 340B eligible hospital-based clinics.
    1. Clinics eligible for 340B pricing are listed on the Health Resources and Services Administration website. (*See Reference VI*)
    2. Clinics eligible for 340B pricing shall receive medication using 340B eligible accounts dedicated to 340B-eligible clinics.
    3. Requisitions for 340B pharmaceuticals are submitted in the electronic health record by clinic staff.
    4. When the 340B order arrives at the hospital pharmacy, they are received, quantified, and separated by clinic and delivered to the 340B eligible clinic or picked up by the 340B eligible clinic.
    5. Returns
        a. Returns shall be processed by inventory management staff and are returned for credit to their corresponding account in a timely manner.
    6. Wasted 340B Medication
        a. Purchases made in clean 340B only areas have their inventory wasted on site in appropriately labeled medication waste bins without credit.
        b. Pharmacy staff is to communicate wastages to 340B Program Administrator.

Contract Pharmacy Operations

Policy

A. Covered entities are required to provide oversight of their contract pharmacy arrangements to ensure ongoing compliance. The covered entity has full accountability for compliance with all requirements to ensure eligibility and to prevent diversion and duplicate discounts. Auditable records shall be maintained to demonstrate compliance with those requirements.

Purpose

A. To ensure that the CE remains responsible for all 340B drugs used by its contract pharmacies in accordance with HRSA requirements and guidelines. (*See Reference VII*)

Procedure

A. The CE maintains regular contact with third party administrators (TPA) to ensure compliance with applicable federal and state policy and legal requirements. This includes at minimum monthly calls with each TPA.

B. The CE contracts with TPAs to facilitate both the design and implementation of the 340B contract pharmacy program.

C. The CE has a written contract in place for each contract pharmacy location that meets HRSA requirements. These contracts follow the suggested 12 essential elements of contract pharmacy agreements. (*See Reference VIII*)

    1. Copies of the written contracts for each contract pharmacy location shall be maintained in the Pharmacy Department and shall be made available to HRSA or impacted drug manufacturer upon request.

D. The CE registers each contract pharmacy location on the CE's 340B OPAIS prior to the use of 340B drugs at that site.

E. The CE must notify OPAIS of any changes to its contract pharmacy program, including when a contract pharmacy relationship has ended.

F. The contract pharmacy may provide other services to the CE or its patients.

G. The CE may not restrict patients from using a contract pharmacy; all patients may use the pharmacy of their choice.

H. Both parties will adhere to all applicable federal, state, and local laws.

I. The CE uses a virtual replenishment model using an 11-digit-to-11-digit NDC match for its contract pharmacies.

J. 340B-eligible prescriptions are presented to contract pharmacies via e-prescribing, hard copy, fax and/or phone.

    1. Each prescription is verified by the Third Party Administrator (TPA) for patient, prescriber, and outpatient clinic eligibility via encounter data file provided daily and provider file provided monthly.
    2. Updates may be made to these mechanisms by the CE at minimum monthly intervals or sooner if need be.

K. Contract pharmacies may dispense prescriptions to 340B eligible patients using non-340B drugs.

L. The CE implements a bill-to, ship-to arrangement with the contract pharmacies.

    1. Each individual contract pharmacy orders 340B drugs based on 340B eligible use as determined by the TPA, from CE's contracted wholesalers.
    2. Orders are created by the TPAs or pharmacy and placed using their preferred ordering method.
    3. Invoices are billed and reviewed on a bi-weekly basis to the CE.

M. Contract pharmacy receives shipments directly.

N. Contract pharmacy will verify quantity received with quantity ordered.

1. Identifies inaccuracies.
2. Resolves inaccuracies.
3. Documents resolution of inaccuracies.

O. The CE receives and reviews the invoice for drugs shipped to its contract pharmacies for accuracy on a bi-weekly basis.

P. Contract pharmacies are included in the CE's internal-audit process.

Q. Prescriptions that are found to be ineligible in the event of monthly audit shall be submitted to the TPA to process a reversal. These reversal requests are to be tracked to ensure approval of the pharmacy and completion. If a prescription cannot be reversed, it will need to be tracked accordingly and directly with the manufacturer during the next accumulator review.

Material Breach and Non-Compliance Disclosure

Policy

A. Covered entities are responsible for contacting HRSA as soon as reasonably possible if there is any material breach by the covered entity or any instance of noncompliance with any of the 340B Program requirements. (*See Reference IX*)

Purpose

A. To define the CE's material breach of 340B compliance and self-disclosure process.

Non-Compliance

A. The CE's established threshold of what constitutes a material breach of 340B Program compliance is any error that includes 10% of our total 340B purchases. Any errors less than that shall be reviewed by the Compliance Committee to determine materiality. Any instance of non-compliance that the Compliance Committee decides to consider material shall be reported to HRSA.

1. The CE ensures that identification of any threshold variations occurs among all its 340B settings, including contract pharmacies during monthly audits.
2. Such violations require self-disclosure. Violations identified through internal self-audits, independent external audits, or otherwise that exceed this threshold, and that remain non-correctable within a 6-month period from the time of review, shall be immediately reported to HRSA.

B.
1. The CE assesses materiality.
    a. The CE maintains records of materiality assessments.

Disclosure

A. The CE reports identified material breach immediately to HRSA and applicable manufacturers along with a corrective action plan to address the violation.

1. The CE will maintain records of material breach violations, including manufacturer resolution correspondence.

References

I. Section 340B of the Public Health Service Act (1992) http://www.hrsa.gov/opa/programrequirements/phsactsection340b.pdf

II. Health Resources and Services Administration (HRSA) https://www.hrsa.gov/about/index.html

III. Section 330 of the Public Health Service Act (PHS) https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter6A/subchapter2/partD&edition=prelim

IV. 340B Policy Releases https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/prohibitionongpoparti cipation020713.pdf

V. GPO prohibition entity purchase via GPO https://www.340bpvp.com/content/contentSearch.html?category=content&Ntt=1242&main-submit.

VI. HRSA OPAIS Database https://340bopais.hrsa.gov/

VII. 340B Contract Pharmacy Guidelines https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf

VIII. Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf

IX. HRSA Entity Self-Disclosures https://www.hrsa.gov/opa/self-disclosures/self-disclosure.html

All Revision Dates

12/4/2023

Approval Signatures

Step Description	Approver	Date
Authorizing Official	Theresa Cho: Chief Executive Officer, Ambulatory Care	12/4/2023
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	12/4/2023
Pharmacy Services	Beatriz Cachu: 340B Program Administrator	11/30/2023
Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	11/30/2023

Status **Active** PolicyStat ID **14895046**

Origination	1/16/1992
Last Approved	12/15/2023
Effective	12/15/2023
Last Revised	12/15/2023
Next Review	12/14/2025
Owner	Jessica Rodriguez: Manager, Cardiopulmonary Services
Policy Area	Respiratory Care

R.09 Arterial Blood Gas Sampling and Testing Proficiency Program

POLICY:

To establish the procedure for an ongoing program of Proficiency Testing (PT) in accordance with all College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA '88) standards to assure accuracy in blood gas sampling and analysis at both Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH).

PROCEDURE:

A. All Respiratory Care Department staff members will participate in a program of proficiency testing per CAP and CLIA standards. The Proficiency Testing Surveys as administered by CAP will be used.

B. All samples will be run in accordance with standards established by CAP directions.

C. Proficiency samples will be run using the same methods as for patient sample analysis and shall be integrated into normal workloads.

D. Staff performing proficiency tests or otherwise involved in the proficiency process are prohibited from a variety of activities, including communicating with the staff of other facilities about the proficiency event, data or any other information. Formal comparison of results - even between analyzers - is prohibited as is any special preparation of the analyzer prior to the test (other than normal maintenance cycles allow for). Having a "special" analyzer for proficiency testing is prohibited.

    1. There is to be no communication between the Blood Gas Laboratory staff at VCMC and SPH or with any other Laboratory regarding proficiency testing samples prior to the ending date for submission of data to the proficiency testing vendor utilized.

E. Participation in the CLIA-sanctioned program will not preclude participation in other proficiency study programs that the Respiratory Care Department may utilize. Such other programs may not ensure compliance with applicable CLIA standards and are for internal use only.

F. It is prohibited to send or receive proficiency samples or any QC or calibration verification samples to any laboratory.

G. The Respiratory Care Laboratory at VCMC and SPH will rotate the "primary" analyzer when multiple analyzers are present performing the same testing and are enrolled together in the same proficiency program. This will be the analyzer which is reported to CAP and CMS for accreditation purposes.

    1. Staff will perform the Survey and then submit results to CAP. The analyzer can continue to be used after the Survey testing as per normal procedures.

EVALUATION OF PROFICIENCY TESTING:

A. Documentation of review of all successfully tested results or investigatory follow-up to exceptions shall be recorded along with the Survey Test documentation. Documentation of evaluation may also be kept in a separate binder dedicated to problem evaluations.

B. **Exception Evaluation:** Documentation of the investigation into exceptions will be reviewed by the Respiratory Care Department Manager or designee and the Laboratory Medical Director on a timely basis with signatures to document that report of review.

    1. **Report Form:** The forms established by the Respiratory Care Department for Exception Review will be utilized with supporting documentation as may be necessary.
    2. **Clerical Review:** All documents should be reviewed for clerical errors.
        a. Review testing information recorded electronically with transcribed data.
        b. Clerical review will include documentation of results not submitted for grading and why submission of that data did not occur.
    3. **Technical Errors:** If the exception is not found to be of a clerical nature, the following information should be evaluated and documentation included with the report:
        a. Reagent (cartridge) expiration and installation dates prior to the exception.
        b. Calibration records prior to and subsequent to the exception including trending data that may indicate bias.
        c. Quality Control records prior to and subsequent to the exception, including trending data that may include bias.
        d. Relevant Maintenance Logs prior to and subsequent to the exception.
        e. Documentation of any necessary contact with Laboratory vendors that occur during investigation.
        f. Assessment of potential impact on patient results during the time period prior to and subsequent to the exception. Review should include assessment of the magnitude of any observed bias revealed during QC and calibration data review as well as the distribution of patient results

observed during the testing period as compared to other time periods.

4. As appropriate, Exception Review information should be shared with general Department staff as part of the ongoing Quality Improvement program of the Respiratory Care Department.

C. **Bias Review:** There are two ways to determine if bias is present. If it is determined that bias may be present, further review of relevant analyzer data may be indicated to determine if corrective actions are needed. Results of bias review should be included with Survey Exception reports as they occur.

1. Examine SDI (standard deviation indexes) results. If the average of the SDI results is greater than +/- 2.0, bias may be present and further investigation is required.
2. Review all five (5) results for that proficiency event. Determine if all five (5) test results are either "+" or "-," that is, if all test results are above or all below the median expected value.

D. **Proficiency Testing Ungraded:** If a CAP Proficiency Test has been performed with intention to submit for grading by CAP, but was not submitted, that test event must be investigated and documented.

1. Possible causes for failure to grade could include, but are not limited to:
    a. Late submission of data
    b. Failure to submit
    c. Failure to complete required forms
    d. Damage to samples in transport, where replacement samples are not available from CAP.
2. The investigation should include reasons for failure to grade and, as able, correlation of ungraded values with CAP Evaluation Summary data for that proficiency testing event.

REFERENCE:

CLIA Reference on Proficiency testing: 42CFR Part 493.801.

All Revision Dates

12/15/2023, 9/3/2021, 1/16/1992

Approval Signatures

Step Description	Approver	Date

Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	12/15/2023
Laboratory Services	Brad Adler, MD: Medical Director, Laboratory Services	12/15/2023
Respiratory Care	Jessica Rodriguez: Manager, Cardiopulmonary Services	12/15/2023

Status **Active** PolicyStat ID **15050018**

Origination	11/28/1989
Last Approved	1/18/2024
Effective	1/18/2024
Last Revised	1/18/2024
Next Review	1/17/2026
Owner	Jessica Rodriguez: Manager, Cardiopulmonary Services
Policy Area	Respiratory Care

R.20 Blood Gas Laboratory RapidPoint 500 Analyzer Quality Control Program

POLICY:

To establish the procedures for the Blood Gas Laboratory RapidPoint 500 Analyzer Quality Control program at Ventura County Medical Center and Santa Paula Hospital.

PROCEDURE:

A. It will be the policy to run a Quality Control program for the RapidPoint 500 analyzers. Much of this program will be in fully computerized and computer managed mode.

1. The RapidPoint 500 analyzers will utilize the Siemens Diagnostics' Automatic Quality Control (AQC) system. This system consists of three (3) replaceable cartridges, one of which is the AQC. The AQC will need to be replaced every 28 days.
2. The AQC system will be set to run all three (3) levels of quality control every eight (8) hours.
3. All staff will have the ability to manually program the analyzer for the QC cycle.
4. External quality control testing after Measurement/Automatic Quality Control Cartridge changes: The Rapidpoint 500 has a measurement cartridge which has a 28 day or set number of sample life span, whichever comes first. Once the measurement cartridge has been replaced and the internal quality control completed, 3 level external Quality Control testing (using Siemens Rapid QC Complete level 1, 2, and 3) must be performed prior to specimen processing. All printed Quality Control results will be placed into the external Quality Control log book and reviewed and signed off by the Blood Gas Lab Director or designee. External Quality Control results will be uploaded into the RapidComm data management system. The testing material is Siemens Rapid QC Complete level 1, 2,

and 3. All internal and external Quality Control test results must be within ranges. Any analyte that fails to fall within Siemens Rapid QC Complete established range is considered out of control and the instrument cannot be utilized for specimen processing. Corrective action must be initiated based upon manufacturer's guidelines found in the Rapidpoint 500 operator's manual. The above outline task for the Rapidpoint 500 measurement cartridge will apply for the Auto Quality Control cartridge as well. All test parameters of the external testing program must pass in order to process blood gas specimens. In the event of a failure immediate on site remedial action must be taken or Siemens Tech-support must be contacted (800-229-3711) to correct the deficiency. All corrective actions taken must be documented in the Quality Control Corrective Action Log book.

B. **AQC Values and Assessments:** Acceptable ranges and means for each analyte on each level will be established and statistical analysis performed, including standard deviations, etc.

1. **Establishing Initial Values:** AQC values were set during installation of the instruments. The Rapidcomm information system has its evaluation system to set "Target Value and Absolute Limits." Siemens Diagnostic has designed the system so that periodic lot changes will not occur. Therefore, the initial values should not require changes over the life of the instruments.
2. **Monitoring and Reassesment of QC Values:** Any AQC failure will be flagged on the display panel of the instrument, and will not allow reporting of results for any analyte (or calculated value based on that analyte) that has sustained AQC failure. In the event of an AQC failure, staff has the ability to manually cycle calibrations. If after repeated calibrations there are still AQC failures, staff should notify a key operator or Siemens Diagnostics technical support.
    a. **Weekly Evaluations:** Key operator staff will review QC data on a weekly basis. This should generally be done on Monday.
    b. **Overriding AQC failures:** It will not be the policy of this Laboratory to allow any AQC failure to be overridden by any operator. The ability to override is inherent in the analyzer software, but is only granted to Level One operators (top level). Level One operations will be assigned to "Key" operators, with the majority of staff assigned as Level Three operators.
3. **DOCUMENTATION**
    A. **Quality Control Logs:**
        1. **Computer records:** Shall be maintained in the Rapidcomm stand-alone computer. All individual data points will be retained by the Rapidcomm information manager.
        2. **Communication Log:** There is a daily report sheet for each shift in the department report room for staff to log procedures that are not covered by the normal Rapidcomm maintenance logs or to communicate other issues to staff.

All Revision Dates

1/18/2024, 8/26/2016, 4/25/2016, 2/10/2016

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	1/18/2024
Laboratory Services	Brad Adler, MD: Medical Director, Laboratory Services	1/18/2024
Respiratory Care	Jessica Rodriguez: Manager, Cardiopulmonary Services	1/16/2024

Status **Active** PolicyStat ID **14957755**

Origination	7/10/2006
Last Approved	1/9/2024
Effective	1/9/2024
Last Revised	1/9/2024
Next Review	1/8/2026
Owner	Jessica Rodriguez: Manager, Cardiopulmonary Services
Policy Area	Respiratory Care

R.54 Designees in the Blood Gas Laboratory

POLICY:

To establish the duties and responsibilities of the Blood Gas Laboratory designees.

PROCEDURE:

I. **DESIGNEES:**

A. **Includes:** The Department Manager and Laboratory Medical Director may assign a qualified Respiratory Therapist to act as Blood Gas Designee. (See attachment of Respiratory Care Blood Gas Designees.)

1. Qualified Respiratory Therapist, as outlined by College of American Pathologists, may act as Blood Gas Technical Consultants

B. **Examples of Designee Responsibilities:** Designees may, at the Manager's discretion, assume any of the following duties:

1. Management and oversight of Blood Gas Laboratory operations.
2. Development of policies and procedures relevant to Laboratory operations.
3. Oversight of staff activity in the Laboratory, including safe practices.
4. Development and implementation of staff competency standards and assessments.
5. Supervision of Quality Control activities, including Proficiency Studies and Calibration Verification activities.
6. Lead role in the Quality Assessment process.
7. Review of documents produced in the course of Laboratory operations, such as canceled specimen lists, proficiency and Calibration Verification Material (CVM) documents.

8. Review all Blood Gas analysis daily, weekly and monthly reports as required and take any correction actions as may be deemed necessary.
9. Conduct inservice education for staff as may be required.
10. Review maintenance/correction logs maintained for the Blood Gas Laboratory and take corrective action as needed.
11. If the Medical Director is unavailable, the designee is authorized to sign documents for the purpose of timely.

C. The Medical Director will personally document via memo his/her personal, on-site assessment of the adequacy of physical and environmental conditions as well as the adequacy of staffing for Laboratory operations.return of CAP surveys, etc.

D. The Medical Director will evaluate the performance of the technical consultants and designees on a yearly basis.

E. Please see attachment A

All Revision Dates

1/9/2024, 12/12/2023, 7/27/2022, 2/13/2019, 10/24/2013

Attachments

R.54 Org Chart 2024.xlsx

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	1/9/2024
Laboratory Services	Brad Adler, MD: Medical Director, Laboratory Services	1/8/2024
Respiratory Care	Jessica Rodriguez: Manager, Cardiopulmonary Services	1/4/2024

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Medical Executive Committee Document Approvals

January 2024

a. Policies & Procedures / Clinical Practice Guidelines / Forms / Orders

1.	100.241 The Use of Blood Clotting Factors	page	2-5
2.	AC.36 Vaccine Administration in the Outpatient Ambulatory Care Clinics	page	6-8
3.	CA.06 Cancer Registry Abstracting	page	9-14
4.	CA.25 Cancer Program Psychosocial Distress Screening	page	15-16
5.	CA.26 Cancer Program Survivorship Program	page	17-18
6.	ICU.24 Adult Intensive Care Unit Admission and Scope of Service	page	19-20
7.	OB.13 Admission and Assessment of the Post-Partum Patient	page	21-24
8.	T.13 Multiple Casualty Incident (MCI)	page	25-32
9.	Standardized Procedure for Ordering COVID-19 Testing	page	33-34
10.	S.95 Standardized Procedure for Certified Registered Nurse First Assistant (CRNFA)	page	35-39

b. Medical Staff Forms

1.	AHP Ongoing Professional Practice Evaluation (OPPE) Form	page	40
2.	CRNFA Privilege List	page	41-42

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Medical Executive Committee Document Approvals

January 2024

a. Policies & Procedures / Forms / Orders

The following were reviewed and recommended for approval by the appropriate Departments, Committees, and the Medical Executive Committee

#	Title	Summary	Frequency	Page
1.	100.241 The Use of Blood Clotting Factors	No changes	Triennial	2-5
2.	AC.36 Vaccine Administration in the Outpatient Ambulatory Care Clinics	New	Triennial	6-8
3.	CA.06 Cancer Registry Abstracting	Updated abstract data requirements and coding/staging references according to the most current standards for oncology registry entry.	Triennial	9-14
4.	CA.25 Cancer Program Psychosocial Distress Screening	Revised to meet the most current NCCN distress screening tools	Triennial	15-16
5.	CA.26 Cancer Program Survivorship Program	Minor revision to reflect the 2024 Survivorship committee plans	Triennial	17-18
6.	ICU.24 Adult Intensive Care Unit Admission and Scope of Service	Revised to reflect new admission criteria and new reference attachment	Triennial	19-20
7.	OB.13 Admission and Assessment of the Post-Partum Patient	Policy revised to reflect the most current perinatal nursing guidelines/published literature	Triennial	21-24
8.	T.13 Multiple Casualty Incident (MCI)	Policy revised to reflect the new trauma book guidelines	Triennial	25-32
9.	Standardized Procedure for Ordering COVID-19 Testing	No changes	Triennial	33-34
10.	S.95 Standardized Procedure for Certified Registered Nurse First Assistant (CRNFA)	New	Triennial	35-39

b. Medical Staff Forms

1.	AHP Ongoing Professional Practice Evaluation (OPPE) Form	Process revised from chart audits to an overall practice assessment	40
2.	CRNFA Privilege List (Approved by Dept of Surgery)	New practitioner type: Certified Registered Nurse First Assistant for surgical cases	41-42

Current Status: *Pending* **PolicyStat ID:** *14407931*

VENTURA COUNTY HEALTH CARE AGENCY

Origination:	*11/10/2020*
Effective:	*Upon Approval*
Last Approved:	*N/A*
Last Revised:	*11/10/2020*
Next Review:	*3 years after approval*
Owner:	*Sul Jung: Associate Director of Pharmacy Services*
Policy Area:	*Administrative - Patient Care*
References:	

100.241 The Use of Blood Clotting Factors

Purpose:

To provide guidance for the safe administration of therapeutic interventions related to bleeding disorders.

Policy:

Bleeding disorders represent a group of congenital and acquired disorders that can have debilitating and life-threatening complications. Consistent therapeutic intervention can reduce the impact of these complications. The National Hemophilia Foundation maintains a list of recommendations. Ventura County Medical Center (VCMC) will base its policy on these recommendations.

Blood protein components have many therapeutic uses. Albumin and intravenous and intramuscular immunoglobulins have numerous known and novel uses. Blood clotting factors are used extensively in people with known deficiencies. Both advanced fractionation techniques and recombinant technology have led to many factors. The medical utility has expanded to amelioration of bleeding during trauma and surgery, and reversal of anticoagulant medications.

Different than blood cellular components (and fresh frozen plasma (FFP)), neither blood typing nor cross matching is needed. The agents are typically lyophilized and require reconstitution, making them similar to a pharmaceutical.

Procedure:

Oversight and Evaluation:

A. Oversight

1. The Blood Usage Committee has oversight on all blood clotting factors. Clinical Practice Guidelines and policies regarding the use of blood clotting factors require approval from Blood Usage Committee. The Blood Usage Committee is responsible for promoting adherence to policy and guidelines.
2. Pharmacy and Therapeutics Committee shall review any new agents and, as needed, new uses for established agents. The Pharmacy Department shall ensure there is sufficient supply of factors for hematology, trauma, obstetrics, and emergency medicine.
3. Patient-supplied factor products: Hemophilia patients have routine and on demand factor for home infusion. Many are trained in safe intravenous administration. The products have the benefit of

patient specific dose, immediate availability and reliable response in the patient. They however have not followed standard chain of custody. Their use will be determined by the attending physician.

4. Factor utilization shall be reported to the Blood Usage Committee.

Treatment Recommendations:

A. **Hemophilia**

1. Recombinant factor is the standard as the history of Human Immunodeficiency Virus (HIV) still looms large. However, using same brand in previously treated patients avoids therapeutic confusion.
2. Urgent evaluation
    a. Bleeding, trauma and delays can be devastating for patients with hemophilia. Treatment of suspected bleeding should be prompt and not await diagnostic testing. When in doubt, administer clotting factor replacement therapy. Consultation with the patient's hematologist or VCMC hematologist is required but should not delay initial care.
3. Factor replacement therapy must be administered prior to surgery or an invasive procedure (lumbar puncture, arterial blood gas, arthrocentesis, etc.). Intramuscular injections should be avoided if at all possible. If they must be given, factor replacement therapy should precede the injection.
4. Dose factor up to the "closest vial" and infuse the full content of each reconstituted vial. A moderate excess of factor concentrate will not create a hypercoagulable state but will prolong the therapeutic level of the product administered; thus it is prudent to "round up."
5. An inhibitor is an antibody that neutralizes the activity of replacement factor. The treatment of bleeding in these patients is tailored.

B. **Hemophilia A without Inhibitor**

1. The treatment of choice for individuals with hemophilia A (factor VIII deficiency) is recombinant factor VIII or else the patient's product of choice.
2. When treating an individual with mild hemophilia A who is responsive to desmopressin, the dose and prior responsiveness are usually known. The dose of desmopressin is 0.3 mcg/kg subcutaneously or intravenously.

C. **Hemophilia B without Inhibitor**

1. The treatment of choice for individuals with hemophilia B (factor IX deficiency) is recombinant factor IX or else the patient's product of choice.

D. **von Willebrand's Disease (vWD)**

1. Excessive mucotaneous bleeding is hallmark of vWD. Most patients have less von Willebrand Factor (vWF) (type 1) and have variable bleeding.
2. Pressure, other local measures, desmopressin, tranexamic acid and estrogens are first line treatment for bleeding episodes.
3. Von Willebrand plasma concentrates are available for morbid or non-responsive bleeding. These plasma concentrates contain Factor VIII. Activities for vWF is listed as Ristocetin Cofactor (RCO) units alongside Factor VIII activity. Recombinant von Willebrand factor does not contain factor VIII, so recombinant factor VIII at 1.3:1 will need to be co-administered.
4. Type 3 patients are nearly completely deficient. Type 2 patients have defective vWF. Bleeding is typically worse in Type 2 and 3 patients. Desmopressin is inactive in these patients.

E. Rare bleeding disorders: In 2016, factor concentrates are available for protein C deficiency, factor X and factor XIII deficiency. Hospital availability of these factors are under the supervision of Blood Usage Committee and Pharmacy and Therapeutics Committee.

Trauma:

A. In addition to FFP, blood derivatives have been effectively used in patients with traumatic and surgical bleeding. Trauma service, through Blood Usage Committee, manages and updates recommendations for the use of blood factors in trauma and surgery.

B. Warfarin prevents synthesis of factors II, VII, IX, and X. Kcentra contains useful amounts of these factors to rapidly correct the acquired bleeding diatheses of warfarin. Vitamin K is preferred for reversal in non-acute patients. See *CPG.56 Management of Bleeding Associated with Anticoagulants and Antiplatelet Therapies* for more information.

C. It is noted that thrombin and fibrinogen are blood derivatives used topically for bleeding.

Pharmacy:

A. Supply

1. The Pharmacy Department shall maintain inventories of recommended recombinant blood factors and blood factor concentrates.
2. As congenital hemophilia will present in a range of ages, multiple vial sizes shall be maintained.

B. Preparation

1. The pharmacist shall double check the product with the order, taking care to ensure recombinant products when ordered.
2. The Pharmacy Department shall prepare factor according to USP <797> standards and the package insert. Doses may be adjusted to the full contents of the vials in inventory according to policy PH.80 Handling and Dispensing of Blood Derivative Products.
    a. A moderate excess of factor concentrate will not create a hypercoagulable state but will prolong the therapeutic level of the product administered. The total doses ordered and doses delivered will be equal or higher than original dose ordered.
3. Emergency department must have readily accessible factor replacement products so that they are available within 1 hour of the patient's arrival.
4. If factor is not available, the Pharmacy Department can use the patient's own supply after approval from the attending physician.

Factor Administration:

A. Nursing staff shall confirm that the order and product reflect correct factor type (a recombinant or pooled plasma), units/kg dosing and total dose ordered and dose delivered in addition to following policy *100.025 Medications: Ordring, Administration and Documentation*.

B. Route

1. Intravenous route is always used.
2. In situations in which patients are hemodynamically stable and are not requiring volume replacement, the smaller gauge needles will be utilized for obtaining IV access (25 gauge butterfly

needles in young infants, 23 gauge butterfly needles in older children and adults).

3. Tourniquets will not be applied tightly to extremities because they may cause bleeding. Butterfly needles are more common than intravenous catheters for administration of factor.
4. Factors are pushed over 1-3 minutes.

All revision dates: 11/10/2020

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Tracy Chapman: VCMC - Med Staff	pending
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	12/5/2023
Blood Usage Committee	Francisco Bracho: MD	11/3/2023
Blood Usage Committee	Sul Jung: Associate Director of Pharmacy Services	9/27/2023

Current Status: *Pending* **PolicyStat ID:** *13910463*

VENTURA COUNTY HEALTH CARE AGENCY

Origination:	*N/A*
Effective:	*Upon Approval*
Last Approved:	*N/A*
Last Revised:	*N/A*
Next Review:	*3 years after approval*
Owner:	*Cynthia Fenton: AC Director of Nursing*
Policy Area:	*Ambulatory Care - Patient Care Services*
References:	

AC.36 Vaccine Administration in the Outpatient Ambulatory Care Clinics

PURPOSE:

To vaccinate our population safely and fully with CDC approved vaccines at age-appropriate intervals to promote the health and wellness of Ventura County families.

POLICY:

The Healthcare Agency firmly believes in the safety and effectiveness of vaccines to reduce and prevent serious diseases and save lives and reduce illnesses of our patients. We base our treatment decisions on respected literature and current studies that support the use of vaccines as the single most important intervention we perform as health care providers. The vaccine schedule is the results of years of scientific study on millions of patients and is recommended by several respected professional organizations; The Centers for Disease Control and Prevention (CDC), Academy of Pediatrics, Advisory Committee on Immunization Practices (ACIP) and others which can be found in the resources section of this document.

1. DEFINITION(S):

ACIP: Advisory Committee on Immunization Practices
CAIR: California Immunization Record
CDC: Centers for Disease Control
EHR: Electronic Health Record
EUA: Emergency Use Authorization
MA: Medical Assistant
VAERS: Vaccine Adverse Effect Reporting System
VIS: Vaccine Information Sheet

PROCEDURE(S):

1. Prior to the patients scheduled appointment for vaccine administration, clinic staff shall print the patient's CAIR report and perform a chart check to compare vaccine status.

2. Import into the patients EHR any documented historical vaccines administered outside of the clinic (Retail Pharmacies and/or mass vaccination sites).

3. Identify any care gaps between vaccine administered and age-appropriate recommended

schedule of vaccines for the patient. Ensure proper dosing interval between vaccine series have been observed.

4. Clinic staff shall determine if the vaccines are available in the clinics inventory and within date.

5. Supply CAIR report to the Provider to identify vaccine care gaps prior to provider visit and vaccine conversation with patient.

6. Once patient is in the clinic, obtain vaccination card or vaccination records from the patient and confirm the documentation matches EHR.

7. Provider or assignee gives the patient the current Vaccine Information Sheet (VIS) or Emergency Use Authorization (EUA) sheet to review.

8. Clinic staff completes the screening questionnaire for vaccines verbally with the patient or caregiver.

9. Provider reviews the screening questionnaire for contraindications or severe reactions of previous vaccines prior to vaccine administration.

10. Provider to review and address concerns or answer any questions patient or caregiver may have.

11. Provider to place order in the EHR and verify which vaccines are to be administered.

12. Verbal consent shall be obtained from the patient, agreeing to the vaccine administration.

13. Delegated MA may administer ordered vaccine(s) once a double check has been performed with another licensed clinic personnel. See policy AC.35 Ambulatory Care Medication Management.

14. Vaccine administration shall be documented in the patients EHR and in CAIR.

15. For discrepancies or documentation errors discovered in CAIR, contact your local CAIR Representative for Ventura County for corrective action.

16. All Adverse Events shall be reported to VAERS and RLDatix.

REFERENCE(S):

The Centers for Disease Control and Prevention, U.S. Department of Health, and Human Services
Advisory Committee on Immunization Practices
American Academy of Pediatrics
American Academy of Family Physicians
American College of Obstetricians and Gynecologists
American Academy of Physician Associates
American College of Nurse-Midwives
National Association of Pediatric Nurse Practitioners
The Joint Commission, 2022 Standards for Ambulatory Care

All revision dates:

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
MEC/Oversight	Tracy Chapman: VCMC - Med Staff	pending
P&T Committee	Sul Jung: Associate Director of Pharmacy Services	12/5/2023
Chief Executive Officer, AC	Theresa Cho: Chief Executive Officer, Ambulatory Care	11/30/2023
Chief Medical Quality Officer, AC	Rachel Stern: Chief Medical Quality Officer	11/29/2023
	Cynthia Fenton: AC Director of Nursing	8/29/2023

VENTURA COUNTY
HEALTH CARE AGENCY

Origination:	*1/1/2012*
Effective:	*Upon Approval*
Last Approved:	*N/A*
Last Revised:	*12/15/2023*
Next Review:	*3 years after approval*
Owner:	*Judy Borenstein: VCMC - Nursing*
Policy Area:	*Cancer Program*
References:	

CA.06 Cancer Registry Abstracting

POLICY:

Reportable cases must be abstracted within six months from their date of diagnosis if they are analytic cases, or six months from the date they were first admitted to Ventura County Medical Center/Santa Paula Hospital as either an inpatient or outpatient if they are non-analytic cases. Abstract information is entered and maintained using the CNExT software application. Both the software and database are stored in the Cancer Registry computer network located in the Cancer Registry office. If a patient has multiple primaries, a separate abstract must be prepared for each primary. The Cancer Committee must review and approve any changes in abstract form and/or content.

PROCEDURE:

A. Data items that must be included in each CNExT abstract and are required by the Commission on Cancer, the State of California Cancer Registry and/or SEER:

1. Accession Number
2. Sequence Number
3. Medical Record Number
4. Social Security Number
5. Military Medical Record Number Suffix
6. Last Name
7. First name
8. Middle Name (Middle Initial)
9. Patient Address (Number and Street) at Diagnosis
10. Patient Address (Number and Street) at Diagnosis-Supplemental
11. City/Town at Diagnosis (City or Town)
12. State at Diagnosis (State)
13. Postal Code at Diagnosis(Zip Code)
14. County Code at Diagnosis
15. Patient Address (Number and Street) - Current

16. Patient Address (Number and Street) - Current Supplemental
17. City/Town Current
18. State- Current
19. Patient Identification (continued)
20. Postal Code-Current (Zip Code)
21. Telephone
22. Place of Birth
23. Date of Birth
24. Age at Diagnosis
25. Race
26. Spanish Origin
27. Sex
28. Primary Payer at Diagnosis
29. Comorbidities and Complications
30. Following Physician (Follow-up Physician)
31. Primary Surgeon
32. Physician #3 (Other Physician)
33. Physician #4 (Other Physician)
34. Cancer Identification
35. Class of Case
36. Facility referred From
37. Facility Referred to
38. Date of First Contact
39. Date of Initial Diagnosis
40. Primary Site
41. Laterality
42. Histology
43. Behavior Code
44. Grade/Differentiation
45. Diagnostic Conformation
46. Tumor Size
47. Regional Lymph Nodes Examined
48. Regional Lymph Nodes Positive
49. Stage of Disease at Diagnosis
50. Date of Surgical Diagnostic and Staging Procedure

51. Surgical Diagnostic and Staging Procedure
52. Surgical Diagnostic and Staging Procedure at This Facility
53. Clinical T 2018
54. Clinical N 2018
55. Clinical M 2018
56. Clinical Stage Group 2018
57. Clinical Stage (Prefix/Suffix) Descriptor
58. Staged By (Clinical Stage)
59. Pathologic T 2018
60. Pathologic N 2018
61. Pathologic M 2018
62. Pathologic Stage Group 2018
63. Pathologic Stage (Prefix/Suffix) Descriptor
64. Staged By (Pathologic Stage)
65. SEER Summary Stage 2000
66. Mets at Diagnosis- Distant Lymph Nodes
67. Mets at Diagnosis - Bone
68. Mets at Diagnosis - Brain
69. Mets at Diagnosis - Liver
70. Mets at Diagnosis - Lung
71. Mets at Diagnosis - Other
72. ~~CS~~ Site~~-~~ Specific ~~Factor 1~~Data Items

    ~~Derived AJCC T~~

    ~~Derived AJCC T Descriptor~~

    ~~Derived AJCC N~~

    ~~Derived AJCC N Descriptor~~

    ~~Derived AJCC M~~

    ~~Derived AJCC M Descriptor~~

    ~~Derived AJCC Stage Group~~
73. TNM, Mixed Stage AJCC T Code
74. TNM Mixed Stage T Descriptor
75. TNM Mixed Stage AJCC N Code
76. TNM Mixed Stage N Descriptor
77. TNM Mixed Stage AJCC M code
78. TNM Mixed Stage AJCC M Descriptor

79. TNM, Mixed Stage AJCC Stage Group
80. Derived SS1997
81. Derived SS2000
82. First Course of Treatment
83. Date of First Course of Treatment
84. Date of First Surgical Procedure
85. Date of Most Definitive Surgical Resection of Primary Site
86. Surgical Procedure of Primary Site
87. Surgical Procedure of Primary Site at This Facility
88. Surgical Margins of the Primary Site
89. Scope of Regional Lymph Node Surgery
90. Scope of Regional Lymph Node Surgery at This Facility
91. Surgical Procedure/Other Site
92. Surgical Procedure/Other Site at This Facility
93. Date of Surgical Discharge
94. Readmission to the Same Hospital within 30 days of Surgical Discharge
95. reason for No Surgery of Primary Site
96. Date Radiation Started
97. Location of Radiation Treatment
98. Radiation Treatment Volume
99. Regional Treatment Modality
100. Regional Dose: cGy
101. Boost Treatment Modality
102. Boost Dose: cGy
103. Number of Treatments to This Volume
104. Radiation/Surgery Sequence
105. Date Radiation Ended
106. Reason for No Radiation
107. Date systemic Therapy Started
108. Chemotherapy
109. Chemotherapy at This Facility
110. Hormone Therapy (Hormone/Steroid Therapy)
111. Hormone Therapy at This Facility (Hormone/Steroid Therapy)
112. Immunotherapy
113. Immunotherapy at This Facility

114. Hematologic Transplant and Endocrine Procedures
115. Date Other Treatment Started
116. Other Treatment
117. Other Treatment at This Facility
118. Palliative Care
119. Palliative Care at This Facility
120. Outcomes
121. Date of First Recurrence
122. Type of First Recurrence
123. Date of last Contact of Death
124. Vital Status
125. Cancer Status
126. Following Registry
127. Follow-Up Source
128. Next Follow-Up Source (Next Follow-up Method)
129. Case Administration
130. Abstracted By
131. Facility Identification Number (FIN)
132. Archive FIN
133. Commission on Cancer (CoC) Coding System- Current

B. Additional data items that must be included per Cancer Committee request and approval are:
   1. Current oncology indicators defined and approved by Cancer Committee.
   2. Additional site-specific information currently requested and approved by the Cancer Committee.

C. Coding and Staging Manuals:
   Coding and staging manuals used to abstract include:
   1. Surveillance Epidemiology and End results (SEER) Summary Staging Guide
   2. American Joint Committee on Cancer (AJCC) TNM Staging Guide, 8th Edition
   3. International Classification of Diseases for Oncology, 3rd Edition, ~~2000~~ICD-O 3.2
   4. Standards for Oncology Registry Entry (STORE)
   5. SEER extent of Disease ~~2000~~2018 Coding and Coding Instructions, 3rd Edition

D. Detailed definitions for the data items can be found in (STORE)

E. The specific procedures and codes for entering data items into CNExT can be found in Standards for Oncology Registry Entry(STORE)

F. The following staging systems are used for all primaries:
   1. SEER Summary Stage, version 3.1
   2. SEER Extent of Disease, 3rd Edition

3. AJCC Manual for Cancer Staging, 8th Edition

G. In addition to the above, the following site specific staging systems are also used:
   1. Female genital cancer : International Federation of Gynecology and Obstetrics (FIGO) staging system
   2. Colorectal cancer: Duke's Staging system
   3. Prostate Cancer: Urologists prostate staging system.

H. If the entire first course of treatment is not documented in the patient chart, a "first course of treatment summary" letter must be sent to the appropriate physician(s) and/or facility to obtain this information. Complete first course treatment information must be entered into the abstract.

Reference:

Standards for Oncology Registry Entry

All revision dates: 12/15/2023, 2/9/2021, 4/24/2018, 4/28/2016

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Cancer Committee	Tracy Chapman: VCMC - Med Staff	pending
Cancer Program Manager	Judy Borenstein: VCMC - Nursing	12/15/2023

VENTURA COUNTY HEALTH CARE AGENCY

Origination:	*1/1/2012*
Effective:	*Upon Approval*
Last Approved:	*N/A*
Last Revised:	*12/15/2023*
Next Review:	*3 years after approval*
Owner:	*Judy Borenstein: VCMC - Nursing*
Policy Area:	*Cancer Program*
References:	

CA.25 Cancer Program Psychosocial Distress Screening

POLICY:

Ventura County Medical Center/Santa Paula Hospital serves the psychosocial needs of cancer patients by utilizing a multidisciplinary approach to care, and integrating psychosocial care and distress screening into the assessment, planning, implementation and evaluation of cancer care on the patients' care continuum.

PROCEDURE:

The National Comprehensive Cancer Network (NCCN) Distress Screening Tool Version 2.2023 is utilized for cancer patient distress screening in the Ventura County Hematology-Oncology Outpatient Clinic during, or proximal to, the initial patient visit. The purpose of the Distress Screening Tool is to best determine the severity of the patient's distress as well as the nature of the individual patient's needs for distress reduction through the provision of services.

~~The NCCN Distress Screening Tool measures patients' distress with regard to relevant social work issues. Most notably measured social work issues include Practical Problems: (1) Child Care; (2) Housing; (3) Insurance/Financial; (4) Transportation; (5) Work/School; and (6) Treatment decisions; and Family Problems: (1) Dealing with children; (2) Dealing with partner; (3) Ability to have children; (4) Family health issues. Most notably measured psychological issues include Emotional Problems: (1) Depression, (2) Fears, (3) Nervousness, (4) Sadness, (5) Worry, and (6) Loss of interest in usual activities. Most notably measured medical issues include Physical Problems: (1) Appearance, (2) Bathing/Dressing, (3) Breathing, (4) Changes in Urination, (5) Constipation, (6) Diarrhea, (7) Eating, (8) Fatigue, (9) Feeling Swollen, (10) Fevers, (11) Getting around, (12) Indigestion, (13) Memory/concentration, (14) Mouth sores, (15) Nausea, (16) Nose dry/congested, (17) Pain, (18) Sexual, (19) Skin dry/itchy, (20) Sleep, and (21) Tingling in hands/feet.~~

The NCCN Distress Screening Tool measures patients' distress with regard to relevant social work issues. Most notably measured include Physical Concerns: (1) Pain; (2) Sleep; (3) Fatigue; (4) Tobacco use; (5) Substance use (6) Memory or Concentration; Sexual Health (7) Changes in eating (8) Loss or change of physical abilities: Emotional Concerns (1) Worry or anxiety; (2) Sadness or depression; (3) Loss of interest or enjoyment; (4) Grief or loss (5) Fear (6) Loneliness (7) Anger (8) Changes in appearance (9) Feelings of worthlessness or being a burden . Social Concerns: (1) Relationship with spouse or partner (2) Relationship with children (3) Relationship with family members (4) Relationship with friends or coworkers (5) Communication with health care team (6) Ability to have children. Most notably measured Practical Concerns: (1) Taking care of myself (2) Taking care of others (3) Work(4) School (5) Housing (6) Finances (7) Insurance

(8) Transportation (9) Child Care (10) Having enough food (11) Access to medicine (12) Treatment decisions. Spiritual or Religious concerns: (1) Sense of meaning or purpose (2) Changes in faith or beliefs (3) Death, dying, or afterlife (4) Conflict between beliefs and cancer treatments (5) Relationship with the sacred (6) Ritual or dietary needs.

Nurse Navigators assist the patient to complete the NCCN Guideline Distress Screening Tool. The physician also completes a distress assessment with the patient. Patients who score five (5) or greater on the NCCN Distress Screening Tool are flagged and further assessed for psychological (emotional) problems, social work (practical problems and family problems) issues and medical (physical) problems. Patients with more indicators of practical and family problems indicate the need for social work intervention; more indicators of emotional problems indicate the need for psychological or psychiatric referrals; and more indicators of physical problems indicate the need for medical referral to oncologist or nursing staff.

Each year, the Psychosocial Services Coordinator presents a report to the Cancer Committee which includes:

- Number of patients screened
- Number of patients referred for distress resources or further follow-up
- Where patients were referred (on-site or by referral)
- The screening process
- Timing of screening
- Identified tool
- Distress level triggering referral service
- Distress Screening(s) results
- Referral for provision of care
- Follow-ups documented in patients' medical records to facilitate integrated, high-quality care

All revision dates: 12/15/2023, 1/1/2012

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Cancer Committee	Tracy Chapman: VCMC - Med Staff	pending
Cancer Program Manager	Judy Borenstein: VCMC - Nursing	12/15/2023

Current Status: *Pending* **PolicyStat ID:** *14896422*

VENTURA COUNTY HEALTH CARE AGENCY

Origination:	*1/1/2015*
Effective:	*Upon Approval*
Last Approved:	*N/A*
Last Revised:	*12/15/2023*
Next Review:	*3 years after approval*
Owner:	*Judy Borenstein: VCMC - Nursing*
Policy Area:	*Cancer Program*
References:	

CA.26 Cancer Program Survivorship Program

POLICY:

The Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH) Cancer Program is in accordance of American College of Surgeons Commission on Cancer by the development of a Survivorship Program. The program will be developed and implemented by a Survivorship Program Committee. The Committee includes, but is not limited to, a team of Physicians, nurses, social worker, and other allied health care workers. The Committee is responsible for the referral of Cancer Survivors to one or more of three selected programs as advised by the American College of Surgeons (ACS) Commission on Cancer (CoC)

PROCEDURE:

The Survivorship Committee will meet Monthly to continue program development, review progress, and discuss data to identify achievements and areas for improvement.

Services utilized by the survivorship programs may include, but are not limited to the following:

- Financial support services
- Formalized referrals to experts in cardiology, pulmonology, sexual dysfunction, or fertility counseling.
- Treatment Summaries
- Survivorship Care plans
- Screening Programs for cancer recurrence
- Screening for new cancers
- Seminars for survivors
- Rehabilitation services
- Nutritional services
- Psychological support & psychiatric services
- Support Groups
- Physical Activity programs

Adult cancer patients will be referred to the Survivorship Program Coordinator by infusion nurses, physicians, or other personnel. The program coordinator will arrange for referrals to one or more of the three services chosen by the Survivorship Program Committee.

Data will be collected by nurses, physicians, and social workers to monitor participation in the program.The Survivorship Committee will evaluate the program annually to monitor progress, and identify any modifications needed to improve fulfilling the needs and barriers for our patient population.

Findings from the annual program evaluations will be reported to the Cancer Committee by the Survivorship Program Coordinator. The report will include the estimated number of cancer patients who participated in the referred services, identification of barriers that prevented the participants from utilizing the referred services, and evaluation of additional resources needed to improve the program.

During ~~2021~~2024 The Survivorship committee plans to refer Survivors to the Following 3 services:

- ~~Physical activity programs~~Nutrition Services
- Financial Support Services
- Psychological support/Psychiatric services.

Referral Goal to initiate Program is to refer 100% of all Breast cancer Survivors to one or more of these services.

REFERENCE: *American College of Surgeons Commission on Cancer: Optimal Resources for Cancer Care 2020 Standards*

All revision dates: 12/15/2023, 3/9/2021, 4/24/2018, 4/28/2016

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Cancer Committee	Tracy Chapman: VCMC - Med Staff	pending
Cancer Program Manager	Judy Borenstein: VCMC - Nursing	12/15/2023

VENTURA COUNTY
HEALTH CARE AGENCY

Origination:	*5/15/1996*
Effective:	*1/12/2024*
Last Approved:	*1/12/2024*
Last Revised:	*1/12/2024*
Next Review:	*1/11/2027*
Owner:	*Kelly Johnson: Director, ICU/ DOU/Telemetry*
Policy Area:	*Intensive Care Unit*
References:	

ICU.24 Adult Intensive Care Unit Admission and Scope of Service

POLICY:

The purpose of the Intensive Care Unit (ICU) is to provide the critically ill patient with a consistently high level of quality care which is aimed at the treatment of life-threatening illnesses and the maintenance of all physical and mental functions of the individual during the illness phase. It is the intent of the unit to return each patient to an optimum state of well-being where, given the limitations of his/her disease process, he/she can lead an independent, satisfying and productive life.

PROCEDURE:

Equipment:

A. All ICU patient rooms are equipped with preliminary emergency equipment (e.g., oxygen outlets, compressed air and suction, electrocardiography (ECG) monitor, and code blue alarm notification system).

B. The emergency cart within the unit is equipped with appropriate Advanced Cardiac Life Support (ACLS) drugs and equipment.

C. Each patient room is equipped with a patient call light.

ORGANIZATION:

A. The ICU is guided by the Critical Care Committee, a multidisciplinary committee including the Medical Staff and the ICU Medical Director. The ICU is directed and staffed according to the nature of the critical patient care needs anticipated and the scope of services offered.

B. The ICU Committee is responsible for the efficient development, operation, and improvement of the unit.

C. The ICU Committee chairperson is appointed by and responsible to the Chief of Staff. The Committee chairperson has received special training, acquired experience and demonstrated competence in critical care medicine.

D. The ICU Committee Chair works collaboratively with the ICU nursing leadership (e.g., the ICU Nursing Director and the Clinical Nurse Specialist) to assist in writing, reviewing and approving policies and procedures.

STAFFING

A. As much as possible, staffing needs for each shift are predicted and planned for by consideration of census and individual patient acuity. Age appropriate care shall be provided and documented according to age specific competency care standards.

B. As patient acuity dictates, consideration will be given for 1:1 Registered Nurse (RN) assignments.

C. Upon hire, the ICU RN must take and pass a written ECG test. (Passing score = 80%)

D. Annually, the ICU RN must attend and complete a skills competency assessment conducted by the unit CNS.

E. All ICU nurses must be certified in ACLS within 6 months of hire.

ADMISSION POLICY AND CRITERIA

A. Admission to the ICU shall be on the acceptance of the attending physician or his/her designee. It is the responsibility of the physician to advise the patient and his/her relatives of the need for critical care.

B. Critically and seriously ill patients who require specialized medical and nursing care shall be admitted. (see attached spreadsheet for admission criteria.

DISCHARGE CRITERIA

Stability for transfer out of the unit will be based on the ICU clinician's judgment, including but not limited to hemodynamic, ventilatory, and neurologic criteria.

All revision dates:	1/12/2024, 6/14/2023, 1/1/2017, 12/1/2013, 6/1/2013, 12/1/2009, 5/1/2006, 5/1/2004, 5/1/2001, 5/1/1998

Attachments

Updated ICU and DOU admission criteria 10.11.23 (002).xlsx

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Tracy Chapman: VCMC - Med Staff	1/12/2024
Medicine Committee	Tracy Chapman: VCMC - Med Staff	12/19/2023
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	12/18/2023
Policy Owner	Kelly Johnson: Director, ICU/DOU/Telemetry	12/18/2023

VENTURA COUNTY HEALTH CARE AGENCY

Origination:	*11/1/2001*
Effective:	*Upon Approval*
Last Approved:	*N/A*
Last Revised:	*7/25/2023*
Next Review:	*3 years after approval*
Owner:	*Kristina Swaim: Clinical Nurse Manager, OB*
Policy Area:	*OB Nursing*
References:	

OB.13 Admission and Assessment of the Post-Partum Patient

~~POLICY:~~

~~To admit a delivered mother to the Mother-Infant Unit and make an initial assessment of her condition for planning and implementing of nursing care. Each patient has individual needs depending on her physical condition.~~

~~PROCEDURE:~~

Purpose:

To establish criteria for the admission and care of patients admitted for postpartum maternal and well newborn care.

~~After the~~Following the immediate recovery period ~~immediately~~ after delivery, the Labor and Delivery (L&D) nurse will assess the patient to ensure she is stable for transfer to Post Partum which will consist of, but is not limited to, a normal amount of vaginal bleeding, alert and oriented and stable vital signs. Report will be given by the Labor and Delivery nurse to the nurse receiving the patient in the ~~Mother-Infant Unit regarding patient's history and events of her labor and delivery as well as recovery~~postpartum unit.

~~EQUIPMENT~~

~~A. OB Pack with Peri-pads, peri-bottle, chux, elastic brief panties, and toiletries.~~

~~B. BP apparatus, Stethoscope, thermometer.~~

~~C. Bed position~~

~~1. For vaginal delivery at low position since the patient is transferred via wheelchair.~~

~~2. At high position for mothers that delivered via C-Section, since those patients are transferred via gurney. With these patients, have an IV pole ready at the bedside.~~

~~GUIDELINES~~

~~A. Welcome the patient and introduce yourself to the patient.~~

~~B. Assist patient with peri-care and emptying her bladder.~~

C. ~~Explain operation of call lights, telephone, TV control and visiting policies.~~

D. ~~Transfer the patient's personal effects to the closet and bedside table.~~

E. ~~Check vital signs.~~

F. ~~Palpate Fundus – assess for size, firmness and height.~~

G. ~~Check peri-pads for amount of lochia.~~

H. ~~Check perineum e.g. condition of episiotomy, changes in perineum, etc.~~

I. ~~Check IV (if present) for patency and solution of oxytoxic drug present.~~

J. ~~Proceed with physician's orders.~~

K. ~~Assess breasts for presence of colostrum.~~

L. ~~Assist patient with feedings of the baby.~~

M. ~~For C-Section patient, check indwelling foley catheter for patency.~~

N. ~~Check abdominal dressing for any bleeding.~~

O. ~~Check patient ID band and baby ID band: two ID bands on the baby and one ID band on the mother with all having the same number.~~

Policy:

A. Patients will be admitted to the postpartum unit after delivery as a transfer or direct admission as a postpartum patient or well baby. A physician order for transfer or direct admission is required

B. Patients who may have delivered prior to admission, are in the immediate postpartum period, or infants transferred from the neonatal intensive care unit (NICU) may also be care for on the postpartum unit based on the LCP clinical judgment.

C. Patients placing their newborn for adoption or who have experienced perinatal loss can be given the option to be transferred to a different unit.

D. Using the nursing process as its framework, comprehensive care will be achieved through a collaborative interdisciplinary team approach including the medical and clinical care team, patient, family,guardian and support person(s).

E. Physical examinations should be explained appropriately and only undertaken with the patient's consent.

F. Check patient Identification (ID) band and baby ID band: two ID bands on the baby and one ID band on the mother with all having the same number.Upon admission to postpartum, a security tag will be placed on the newborns ankle which will activate the infant security system. This process should be explained to parent(s).

G. The following standards will be adhered to for all postpartum patients and newborns unless otherwise ordered by a LCP. The LCP will be notified of all major changes in the patient's condition and documentation of each notification will be made.

PROCEDURE:

I. Admission Criteria
A. Delivered maternal patient after initial recovery period, stable; delivered in-hospital or prior to arrival
B. Well newborn after initial transition period; delivered in-hospital or prior to arrival
C. Well newborn transferred from NICU

D. Maternal patient in the immediate postpartum period requiring obstetrical-focused care.

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II. Maternal-Admision Assessment

A. An admission assessment of the postpartum patient will be completed upon arrival to the postpartum department.

B. Upon admission to postpartum, care will be provided as ordered by LCP until discharge. Assessment will include, but not limited to:

1. Vital Signs (pulse, respiration, blood pressure, oxygen saturation)
2. Fundal tone, height
3. Lochia amount, color, consistency
4. Perineal laceration or incision, if applicable
5. Abdominal incision and dressing, if applicable
6 .IV Sites
7. Pain Level
8. Infant Bonding
9. Edinburgh Post Partum Depression Screening

C. Ongoing assessments are performed every shift and as indicated when the mother's condition changes

D. Skin to skin and breastfeeding on demand for stable mother and infant is encouraged.

E. Patients are encouraged to ambulate early in the recovery process per LCP orders with Registered Nurse (RN) assistance and then regularly and independently when gait is steady. Sequential compression devices (SCD's) if present, should remain in place as ordered.

F. For abnormal assessment findings, notify resident or attending physician and if needed, the Rapid Response Nurse.

III. Newborn-Admission Assessment and Routine Care *(see OB 65 Ongoing Admission and Care of the Newborn)*

DOCUMENTATION

A. All assessments and patient care notes are done in patient's ~~EHR~~Electronic Health Record (HR).

B. Vital signs in EHR.

C. Care plan for vaginal delivery or C-Section delivery.

D. Document medications in EHR.

REFERENCES:

~~AWHONN: Perinatal Nursing, 4th edition, 2013~~

AWHONN: Perinatal Nursing, 5th edition, 2021

American Academy of Pediatrics and the American College of Obstetrician and Gynecologist Guidelines for Perinatal Care (8th Ed.) Elk Grove, IL: American Academy of Pediatrics; Washington, DC: The American College of Obstetrician and Gynecologists

All revision dates: 7/25/2023, 11/20/2017, 2/1/2014, 7/1/2010, 11/1/2004

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Staff Committees: Family Medicine & OB	Tracy Chapman: VCMC - Med Staff	pending
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	7/25/2023
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	7/25/2023
Policy Owner	Kristina Swaim: Clinical Nurse Manager, OB	7/25/2023

VENTURA COUNTY
HEALTH CARE AGENCY

Origination:	*4/10/2017*
Effective:	*Upon Approval*
Last Approved:	*N/A*
Last Revised:	*10/18/2023*
Next Review:	*3 years after approval*
Owner:	*Gina Ferrer: Manager, Trauma Services*
Policy Area:	*Trauma Services*
References:	

T.13 Multiple Casualty Incident (MCI)

~~POLICY:~~

~~To provide a system-wide hospital plan for receiving and caring for multiple trauma patients.~~

~~PROCEDURE:~~

~~The Multiple Casualty Incident (MCI) plan may be implemented when the Emergency Department (ED) is to receive three (3) or more trauma patients, regardless of reported level of acuity, which cannot be safely cared for by the ED staff. See definitions for MCI and Code Triage below.~~

1. ~~Definitions:~~

- ~~Multiple Casualty Incident is defined as 3 to 14 trauma victims, regardless of acuity.~~
- ~~A Code Triage is 15 or more patients expected due to traumatic mechanism. The Emergency Department will immediately notify the Administrator on Duty (AOD) on weekdays, and nursing supervisor at all other times. The AOD, nursing supervisor, or Emergency Department Charge Nurse will then notify Paging to announce a Code Triage-External on the overhead paging system.~~
- ~~Directly involved defined as: ED, operating room (OR), post anesthesia care unit (PACU), intensive care unit (ICU), pediatrics, Medical/Surgical units, Admitting, Paging Operator, Nursing Supervisors, computer tomography (CT), Blood Bank, Environmental Services, Respiratory Services, Radiology, Trauma Services, and the Residency Program.~~
- ~~Indirectly involved includes all other patient care area and ancillary services.~~
  ~~Refer to Administrative policy 106.034, *Emergency Management Plan*, Section V-Initiation of Code Triage.~~
  ~~2. Notification:~~
  ~~Mobile intensive care nurse (MICN)/Charge Nurse to initiate MCI in REDDINET.~~
- ~~MCI Plan notification is 76666, and the number of patients (paging system)~~
- ~~Code Triage notification 76666, and number of patients (paging system)~~

~~3. Ventura County Emergency Medical Services (VCEMS):~~
~~Notification of base station hospital by VCEMS will be through direct communication through base station phone.~~

~~PROCEDURE:~~

1. ~~Trauma Team activation will be initiated to triage and stabilize arriving patients.~~
2. ~~ED to activate as early as possible for multiple victims.~~

POLICY:

To provide a system-wide hospital plan for receiving and caring for multiple trauma patients.

PROCEDURE:

The Multiple Casualty Incident (MCI) plan may be implemented when the Emergency Department (ED) is to receive three (3) or more trauma patients, regardless of reported level of acuity, which cannot be safely cared for by the ED staff. See definitions for MCI and Code Triage below.

1. Definitions:

- Multiple Casualty Incident is defined as 3 to 14 trauma victims, regardless of acuity.
- A Code Triage is 15 or more patients expected due to traumatic mechanism. The Emergency Department will immediately notify the Administrator on Duty (AOD) and the nursing supervisor. The AOD, nursing supervisor, or Emergency Department Charge Nurse will then notify Paging to announce a Code Triage-External on the overhead paging system.
- Directly involved defined as: ED, operating room (OR), post anesthesia care unit (PACU), intensive care unit (ICU), pediatrics, Medical/Surgical units, Admitting, Paging Operator, Nursing Supervisors, computer tomography (CT), Blood Bank, Environmental Services, Respiratory Services, Radiology, Trauma Services, and the Residency Program.
- Indirectly involved includes all other patient care area and ancillary services.
  Refer to Administrative policy 106.034, *Emergency Management Plan*, Section V-Initiation of Code Triage.
  2. Notification:
  Mobile intensive care nurse (MICN)/Charge Nurse to initiate MCI in REDDINET.
- MCI Plan notification is 76666, and the number of patients (paging system)
- Code Triage notification 76666, and number of patients (paging system)

3. Ventura County Emergency Medical Services (VCEMS):
Notification of base station hospital by VCEMS will be through direct communication through base station phone.

PROCEDURE:

1. Trauma Team activation will be initiated to triage and stabilize arriving patients.
2. ED to activate as early as possible for multiple victims.

1. **Nursing documentation is to be done on the** *Trauma Resuscitation Flow Sheet.*
2. Trauma surgical attending will be notified and will respond to the ED (Tier 1 response). It will be the decision of the Attending Trauma surgeon to call the back up on-call trauma surgeon, trauma medical director, and/or additional surgeons.
3. STAT registration will be initiated for all the patients.

4. In the event that the MCI will overwhelm the ED, the ED Saturation plan will be implemented. The ED Charge Nurse or Clinical Nurse Manager, ED Physician, and or Attending Trauma Surgeon will make this decision. All ED patients with assigned beds will be sent to the assigned floor regardless of readiness of bed. It will be the ED's responsibility to obtain basic holding orders including diet, activity, pain and nausea medications. It will be the responsibility of the receiving nursing units to continue the care of these patients, which could include contacting designated attending physicians for orders.
5. Any ED patients awaiting admission without assigned beds will be transported to wherever empty staffed beds are available, upon the direction of the nursing supervisor. The senior resident on the ED service will coordinate the care of patients waiting for admission with the Medical/Surgical Resident, who will assume the care and disposition of these patients.
6. Pediatric patients awaiting admission without assigned beds will be sent to Pediatrics. Any pediatric trauma patients who will need higher level of care will be transferred out to an appropriate accepting facility.
7. The nursing supervisor will report to the ED charge nurse and assist with the deployment of staff from critical care and placement of all ED admits.
8. The following nursing departments are required to send one registered nurse (RN) to the ED once the MCI has been activated.

a. ICU and PEDS RN's as determined by ED Charge Nurse and Nursing Supervisor.
b. Assignments to be determined by the ED charge nurse or trauma team.
c. Additional critical care nurse may be requested and every effort will be made to assist the ED when staffing permits.
d. ED Clinical Nurse Manager and Trauma Program Manager are to be called 24/7 and report to the ED if requested.
e. Trauma Medical Director to be called regardless of on call status.

1. Assignments will be made for the ED and overflow areas under the direction of the ED charge RN, rooms, equipment, supplies, and staff.
2. Trauma pagers and cell phones will be activated with MCI indicated and number of trauma victims.
3. Departments indirectly involved will go on stand-by until further notice
4. All members of the trauma team and ancillary services included in the trauma activations page are to report to the ED.
5. Triage and Designation of the trauma patients in the ED will be according to advanced trauma life support (ATLS) American College of Surgeons (ACS) guidelines and will be conducted by the ED physician until the attending trauma surgeon arrives or Trauma or Medical Director or Deputy Trauma Medical Director arrives. Critical factors to be taken into consideration include the number of patients, acuity, location, and available resources.
6. Charge RN or designee will be responsible for entering the patients and pertinent information into the REDDI-NET SYSTEM (this will facilitate communications between hospitals and emergency medical services (EMS).
7. Resuscitation of critical patients will be the shared responsibility of the Trauma Attending(s), ED Physicians, Senior Residents, the responding anesthesiologist(s) and the on-call Pediatrician. The final resuscitation and management decisions will be the responsibility of the trauma surgical attending or his/

her designee.

8. The Paging Department is to make every effort to triage calls requesting the ED during this time and only forward the calls when they are unable to assist the caller.
9. Operating Room (OR) preop and post anesthesia care unit (PACU) will be used if available and additional space is needed to hold or monitor ED patients during this time. This also could include trauma patients awaiting OR and intensive care unit (ICU) until ICU beds are available. The OR Charge Nurse and Nursing Supervisor will coordinate staffing of these areas.
10. All families and patients waiting in the ED will be informed of the multiple victim activation so that they can anticipate delays. The waiting room may need to be evacuated to accommodate patients.
11. Performance Review will follow as soon as possible for all multiple victim activations.
12. Critical incident stress debriefing will be considered and offered to staff following all multiple victim activations as soon as possible.
13. For 5 or more tier 1 victims potentially requiring surgical intervention, 2 OR teams will respond and 2 OR rooms will be made available until released by the attending trauma surgeon.

a. In the case of treatment of multiply injured patients, all lower extremity long bone fractures should be stabilized as soon as possible in multiply injured patients. Every attempt should be made to stabilize lower extremity long bone fractures once a patient has been determined by the trauma team and neurosurgery team to be stable enough to undergo surgery. The sequence of treatment should be femur first then tibia. Upper extremity long bone fractures should be treated once the patient has been optimized and adequately resuscitated.

14. Family Medicine and Surgery residents will respond according to their current call schedule. Additional back up residents can be activated at the request of Chief Residents and/or Residency Program Directors.

SPECIFIC DUTIES:

All ancillary services presently activated for Tier 1 trauma activations will be activated for MCI's. They are to respond to the ED as per present trauma policy.

Attending Trauma Surgeon:

- Triage/establish priorities of care/overall responsibility for MCI.
- Call in second trauma surgeon and or additional surgical staff.
- Request additional OR teams be called in.
- Release OR teams on standby.

Residents:

- Resuscitation of patients.
- Continuity of care between assigned areas.
- Assist in the OR as assigned by attending trauma surgeon.

ED Physician:

- Request activation of MCI.
- Assist in overall coordination of MCI as requested by attending trauma surgeon.
- Triage and provide destinations for victims until attending trauma surgeon arrives.
- Request additional ED physicians to respond.
- Assist with resuscitation of patients.

ED Charge Nurse:

- Take and communicate radio report.
- Remain on radio or delegate ongoing radio communication.
- Ensure trauma activation page.
- Clear the ED.
- Coordination of ED staff and responding personnel in ED and overflow areas with Nursing Supervisor.
- Assignment of nursing, tech, support personnel to rooms.
- Reddi-net update.
- Notification of ED Clinical Nurse Manager.

Trauma Program Manager:

- Assist trauma team.
- May assist trauma medical director in overall organization of MCI.
- Responsible for the performance improvement (PI) review of all MCI's.
- Responsible for any debriefing requested.
- Responsible for integration and communication with arriving families.

ED RN's:

- Accept assignment from ED charge nurse.
- Assist with immediate clearing of ED.
- Preparation of all rooms to receive trauma patients.
- Accept role of hands on nurse, scribe role to be delegated to arriving critical care nurses.
- Critical care nurse to assume care of patients going to computer tomography (CT).

ED CNA's:

- Accept assignments from ED charge nurse.
- Assist with immediate clearing of ED.

Nursing Supervisor:

- Responds immediately to the ED.
- Calls in OR teams as requested.
- Secures a place for ED admits to be sent if no beds assigned.
- Ensures all directly involved departments respond to the MCI with adequate staff.
- Ensures all involved departments are aware and prepared for response, Lab, respiratory, transport, etc., until the Hospital Incident Command (HICS) is activated. Once HICS is activated, all resource requisitions including staff will be directed to the Logistics section.
- Assists with assignments of beds.
- Notifies Administrator on Duty and Activates Hospital Incident Command System as needed, after collaborating with the on call Emergency Department Physician and/or surgeon on call
- Calls in additional Supervisors or Administrative staff as needed.
- Assists Social Worker with management of arriving families.
- Provides on-going communication with the units affected regarding actual victims, number of potential admissions, MCI status.
- Provides information to the media if directed by AOD.

Critical Care Unit:

- Receive communication initiating the MCI via the paging system and/or ED charge nurse call initiating the MCI.
- Critical Care Unit will send one person to the ED to report to the charge nurse for further instruction.
- Critical Care Unit charge nurse will prepare for potential admissions and transfers by making a list of patients who can be transferred either between units or to the Medical/Surgical areas.
- Critical Care Unit charge nurse will receive communication from the Nursing Supervisor regarding the number of potential admissions and placement of MCI victims.
- Critical Care Unit charge nurse will contact the appropriate physicians and services to transfer patients if necessary when directed to do so by the Nursing Supervisor.
- Critical Care Unit charge nurse will call in additional staff if possible to care for MCI victims in the Critical Care area.
- If additional staff is requested in the ED, the charge nurse and nursing supervisor will review patient's safety needs and send additional staff as appropriate to maintain patient care in these areas.
- Critical Care Staff will assess unit supplies and order additional supplies as needed.
- Disaster carts are available from Central Supply.

Pediatric Units:

- Receive specific communication from the shift Supervisor regarding number of potential patients and expected duration of MCI.
- Prepare to receive trauma patients from the ED.
- Prepare to discharge and/or transfer patients as able to home, facilities or to other units.
- Assess supplies and equipment needs and order, as indicated.
- Assess staffing needs and initiate calls for additional staff, as needed.

Medical Surgical Unit:

- Receive specific communication from the shift Supervisor regarding the number of potential victims and expected duration of the MCI.
- Prepare to receive patients from the Emergency Department.
- Prepare to receive existing patients from critical care areas to open beds in these areas.
- Assess supplies and equipment needs and order as indicated.
- Assess staffing needs and initiate calls for additional staff as needed.
- Prepare to send staff to ED to assist with patient care as needed.

OR/PACU

- **Report number of available OR's to nursing supervisor until HICS positions activated.**
- **Assist with triaging of surgery patients under the direction of the surgeon on call.**
- **May be asked to halt elective cases as needed.**
- **Request additional staff as needed.**

ED Radiology techs:

- Call in additional techs.
- Call in attending radiologist to assist with reads.
- Prepare to triage outpatient studies under the direction of the radiologist.

Paging Department

- Initiating emergency notifications per the MICN, nursing supervisor or AOD request.
- Notification of Administrator on Duty.
- Re-directing of incoming calls away from the ED during MCI as needed

ED Registration staff:

- Registration of incoming patients, utilizing Stat registration if needed.
- Call in additional staff if needed.

Social Services:

- Notifying family that the patient is in the ED regardless of whether another agency has done so or says they will do so.
- If unable to find family, contacting the appropriate agency for help such as law enforcement, homeless outreach, mental health outreach, etc.
- Greeting the family members in the ED waiting room and, if the physician thinks it's appropriate, escorting them to the bedside to be with the patient.
- Monitoring family coping mechanisms and provide support, if needed.
- Facilitating communication between family members and ED medical and nursing staff.
- Provide information about community resources and referrals to the family.

In the event of life-threatening injury or fatality:

- Escort the family from the ED waiting room to the Quiet Room.
- Participation in the meeting between the ED physician and family.
- Remain in the Quiet Room with the family after the meeting to answer any questions that arise after the meeting with the physician.
- Provide information about community resources and referrals, including a list of mortuaries, to the family.
- Remain in the Quiet Room with the family to provide emotional support unless they request privacy.
- Document all interventions and assessment of the family's ability to cope in the electronic health record.

Blood Bank-

- Be prepared to activate Massive Transfusion Protocol as needed.
- Communicate the need for additional blood products to local blood bank.

Environmental Services-

- Be prepared to assist in expediting room turn over.
- Request additional staff as needed.

Respiratory Services-

- Be prepared to request additional supplies, particularly ventilators.
- Request additional staff as needed.

Security

- Security Department will be responsible for securing the perimeter of the Emergency Department and assisting with crowd control.
- Will coordinate efforts with local enforcement agencies.

All revision dates: 10/18/2023, 10/11/2023, 6/9/2020, 7/26/2017

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Tracy Chapman: VCMC - Med Staff	pending
Trauma Operations, Performance & Patient Safety (TOPPS) Committee	Gina Ferrer: Manager, Trauma Services	12/28/2023
Hospital Administration	Diana Zenner: Chief Operating Officer, VCMC & SPH	12/27/2023
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	12/27/2023
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	12/27/2023
Trauma Services	Thomas Duncan: Trauma Director	12/27/2023
Trauma Services	Gina Ferrer: Manager, Trauma Services	10/18/2023

Current Status: *Pending* **PolicyStat ID:** *14829396*

VENTURA COUNTY HEALTH CARE AGENCY

Origination:	*2/3/2021*
Effective:	*Upon Approval*
Last Approved:	*N/A*
Last Revised:	*2/3/2021*
Next Review:	*3 years after approval*
Owner:	*Sherri Block: Associate Chief Nursing Executive, VCMC & SPH*
Policy Area:	*Administration - Medical Staff*
References:	

Standardized Procedure for Ordering COVID-19 Testing

Reference: Sections 2725 of the Business and Professions Code of the state of California; Section 208 (a) and 1275, Health and Safety Code, Title 16, CCR Section 1474; and California Pharmacy Law

I. SCOPE AND SETTING OF PRACTICE

A. The Registered Nurse (RN) Nursing Supervisor at Ventura County Medical Center and Santa Paula Hospital may order COVID-19 testing for an employee who is experiencing minor signs and/or symptoms of COVID-19 in order to establish whether it is safe for the employee to report to their unit in order to work their assigned shift.

B. All employees with fever, or any signs/symptoms other than mild (e.g. headache, runny nose, watery eyes, sore throat) will be sent home with instructions to follow-up with their primary care physician or employee health.

C. This standardized procedure will be in effect for the duration of the COVID-19 pandemic. It is not anticipated that the standardized procedure will be in effect for more than a year.

II. EDUCATION AND TRAINING

The RN Nursing Supervisor ordering the COVID-19 screening tests will have a didactic instruction by a physician outlining the minor signs and symptoms that the employee may have necessitating the screening test. Instruction also includes when to refer the employee to an established testing center, their primary care physician, employee health, and or the emergency room or urgent care.

III. EVALUATION OF CLINICAL CARE

Evaluation of the RN Nursing Supervisor appropriately ordering the COVID-19 test will be provided in the following ways:

A. **Initial:** For the first three cases (employees), the supervising physician will review all documentation of the test ordering by the nursing supervisor.

B. **Follow-up**: Areas requiring increased proficiency as determined by the initial or routine evaluation will be re-evaluated by the supervising physician at appropriate intervals. until acceptable skill level is achieved, e.g. direct supervision via a phone call before the nursing supervisor orders the test.

IV. POLICY

A. The Nursing Supervisor and supervising physician(s) will signify agreement to this Standardized

Procedures by signature on the attached signature form.

B. Signature on the Statement(s) of Approval and Agreement implies the following: Approval of all the policies and protocols in this document, the intent to abide by the Standardized Procedures, and the willingness to maintain a collegial and collaborative relationship with all the parties.

C. The Statement of Approval and Agreement signed by the RN Nursing Supervisor and supervising physician(s) with approving authority signatures will act as the record of RN Nursing Supervisor's authorization to implement the Standardized Procedures.

V. PATIENT RECORDS

V. Patient Records
The RN Nursing Supervisor is authorized to order tests in the patient record as outlined in this Standardized Procedure without the direct or immediate observation, supervision or approval of a physician, except as may be specified on the individual Health Care Management Standardized Procedures.

VII. NURSING PRACTICE

The RN Nursing Supervisor will order a COVID-19 screening test based on the employee sharing information related to minor signs and/or symptoms of COVID-19 but that the employee feels well enough to report to work. The nursing supervisor will screen the employee for any signs/symptoms that would necessitate referral and/or further treatment.

VIII. HEALTH CARE MANAGEMENT

Communication with a physician will be sought by the RN Nursing Supervisor if there are any questions regarding the employee that are out of the ordinary from a routine ordering of a COVID-19 test for an employee having minor symptoms that may be Covid-19 related.

All revision dates: 2/3/2021

Attachments

RN Nursing Supervisor APPROVAL AND AGREEMENT

Approval Signatures

Step Description	Approver	Date
Medical Staff Office	Minako Watabe: Chief Medical Officer, VCMC & SPH	pending
Medical Staff Office	Tracy Chapman: VCMC - Med Staff	pending
Policy Owner	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	12/5/2023

Current Status: *Pending* **PolicyStat ID:** *14920633*

VENTURA COUNTY
HEALTH CARE AGENCY

Origination: *N/A*
Effective: *Upon Approval*
Last Approved: *N/A*
Last Revised: *N/A*
Next Review: *3 years after approval*
Owner: *Gwendolyn Vontoure: Director Perioperative Services*
Policy Area: *Surgical Services*
References:

S.95 Standardized Procedure for the Certified Registered Nurse First Assistant (CRNFA)

PURPOSE

The purpose of this Certified Registered Nurse First Assist standardized procedure is to outline the standards and guidelines that must be followed to promote high-quality, safe, and effective care of the patient undergoing surgical or invasive procedures.

BACKGROUND INFORMATION

Under general direction of the Director of Perioperative Services and Surgical Leadership, the Certified Registered Nurse First Assistant (CRNFA) is responsible for the delivery of safe, effective, and quality patient-family centered care, pre-operatively, intra-operatively, and post-operatively, including tasks and procedures performed under the direction of the surgeon within scope of practice and training.

CRNFA Standardized Procedures

The CRNFA may perform the following technical functions in the following settings:

Preoperative

1. Interviews surgical patients for a comprehensive nursing documentation.
2. Performs a nursing physical assessment.

Intraoperative

1. The CRNFA may assist with the positioning, prepping, and draping of the surgical patient or perform independently if directed by the primary surgeon.
2. The CRNFA may provide retraction through:
    a. Close observation of the operative field
    b. Demonstration of stamina for sustained retraction
    c. Retaining manually controlled retractors in the position set by the surgeon with regard to surrounding tissues.
    d. The retraction of tissues or organs by use of hand or hands
    e. Packing sponges or laparotomy pads into body cavities to hold tissues or organs out of the operative field.

f. Managing instrumentation on the surgical field to prevent obstruction of the surgeon's view.
g. Anticipated retraction needs with knowledge of the surgeons' preferences and anatomical structures.

3. Perform hemostasis by:
   a. The application of electrocautery tips or clamps to vessels in a safe and knowledgeable manner as directed by the surgeon.
   b. Sponging and utilizing pressure as necessary
   c. Utilizing suctioning techniques
   d. Placing suture ligatures in the muscle, subcutaneous, and skin layers
   e. Placing hemoclips on bleeders as directed by the surgeon.
4. Perform knot tying by:
   a. Possessing knowledge of basic knot tying techniques
   b. Firmly tying knots to avoid slipping.
   c. Avoidance of undue friction to prevent the fraying of sutures.
   d. Carrying the knot down to the tissue wit the tip of the index finger and laying the strands flat
   e. Approximating the tissue rather than pulling tightly to prevent necrosis.
5. Provide closure of layers by:
   a. Correctly approximating the layers under the direction of the surgeon.
   b. Knowledge demonstration of different types of closure.
   c. Correctly approximating skin edges when utilizing skin staples.
6. Intraoperative Tissue Manipulation; under the direction of the surgeon, the CRNFA will manipulate tissue and use surgical instruments during a surgical procedure to:
   a. Expose and retract tissue.
   b. Clamp and sever tissue.
   c. Grasp and fixate with screws, staples, and other devices.
   d. Drill, ream, and modify tissues.
   e. Cauterize and approximate tissues.
7. The CRNFA will assist the surgeon at the completion of the procedure by:
   a. Affixing and stabilizing all drains.
   b. Cleaning the wound and applying dressings.
   c. Assisting with the application of casts, plaster splints, or other devices as determined by the surgeon.

Postoperative

1. The CRNFA may be dismissed from the procedure once an adequate replacement is present (physician)
2. The CRNFA will assist with patient recovery, transportation, and admission to the designated nursing unit.
3. The CRNFA will perform dressing changes, if necessary
4. The CRNFA can remove casts, drains, catheters, IV's ,or staples and sutures

Follow-up Treatment

1. The CRNFA will round on post-surgical patients and follow up directly with the Surgeon and Anesthesiologist to address immediate patient care needs.

Documentation

1. The CRNFA will document in the Electronic Health Record (Cerner), all abnormal findings, provider notifications, medications/treatments, and patient response.
    a. Preoperative Nursing Assessments
    b. Intraoperative Nursing Assessments
    c. Postoperative Nursing Assessments

Competency Assessment and Orientation Requirements

1. The CRNFA will demonstrate their knowledge base and technical skills set:
    a. Completion of a registered nurse first assistant training from an accredited graduate nursing program
    b. Completion of 120 hours of orientation in the Operating Room with a qualified surgeon.
    c. The CRNFA will observe the surgeon perform each procedure three times and perform the procedure three times under direct supervision.
    d. During orientation the surgeon will complete the CRNFA's competency assessment form.
    e. It is the responsibility of the CRNFA to complete the competency assessment, providing one copy to the Perioperative Educator.
    f. Medical indication and contraindication of the surgical procedure.
    g. The risks and benefits of the surgical procedure.
    h. Anatomy and physiology are associated with surgical procedures.
    i. The Hospital consent process
    j. The steps involved in the surgical procedure.
    k. Ability to accurately document the surgical procedure.
    l. Ability to interpret diagnostic results and implications.
    m. Complete annual skills/competency requirements

Clinical Privileges

In order to provide patient care services, the CRNFA and the supervising physician(s) must delineate clinical privileges commensurate with relevant training, experience, and competence on the Certified Registered Nurse First Assistant Privilege Checklist. Clinical privileges and the standardized procedure may be approved for up to 2 years and must be renewed. Privileges are subject to standard focused professional practice evaluations (FPPE).

1. Education Requirements:
    a. Current license issued by the California Board of Registered Nurses (BRN)
    b. Successful completion of a fully accredited RNFA program, using (AORN Core Curriculum for Registered Nurse First Assistant as the foundation)

c. At least 2 years of previous experience as an registered nurse first assistant

d. Certified Nurse Operating Room (CNOR)

Renewal of Clinical Privileges

1. Continue to meet all privileging requirements
2. Complete the ongoing professional practice evaluation (OPPE) every six months.
3. The CRNFA will submit a clinical practice outcomes log with each renewal of privileges.
    a. This log will include the number of procedures performed per year, and any adverse outcomes.
        i. If an adverse outcome occurs, a copy of the procedure note will be submitted.

POLICY

1. The CRNFA will be employed by the hospital.
2. Practice under the direct supervision of the surgeon during the procedure.
    a. Exception:The CRNFA may complete the closure of subcutaneous tissue and skin with the surgeon immediately available.
3. The CRNFA will be integrated into the block schedule, based upon:
    a. Operational needs of the Department
    b. Service Line needs
4. The CRNFA will conduct services based on the daily operating room assignments and operational needs of the department.
5. Only perform as a CRNFA and not concurrently as the Scrub Technician or Scrub Nurse.
6. The CRNFA will perform duties in the hospital surgical departments.
7. If the primary surgeon is unable to complete the surgery a qualified surgeon shall be called to complete the procedure.
8. Only in extreme emergency situations will the CRNFA be expected to assist with procedures that present an unusual hazard to life.
9. The CRNFA must adhere to the policies and procedures set forth by Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH).
10. The CRNFA must function within the scope of practice as stated by the Nurse Practice Act of the State of California.
11. The CRNFA will follow the Association of Operating Room Nurses (AORN), Registered Nurse First Assistant Standards of Practice.

DEFINITIONS

1. CRNFA: Certified Registered Nurse First Assistant (CRNFA)
    a. A Registered Nurse (RN) that has undergone specialized training to render direct patient care in the role of a surgical first assistant.
    b. In this expanded role utilizes a specialized knowledge base and skills set and judgment to competently assist the surgeon in performing a combination of nursing and medical functions.
    c. The role is governed by the Board of Registered Nursing (BRN), guided by the Association of

Operating Room Nurses Standards and Recommended Practices.

2. AORN: Association of Operating Room Nurses

Education/Training/Licensure/Certification

1. All Certified Registered Nurse First Assistants requesting privileges must complete the hospital credentialing process and provide documentation that they meet the clinical competence requirements:
   a. Current license as a Registered Nurse, issued by the California Board of Registered Nurses (BRN)
   b. At least 2 years of previous experience as an registered nurse first assistant
   c. Successful completion of a fully accredited RNFA program, using (AORN Core Curriculum for Registered Nurse First Assistant as the foundation)
   d. Certified Nurse Operating Room (CNOR)

Reference

Standardized procedures are not subject to prior BRN approval but must adhere to the following guidelines of the Board of Registered Nursing, title 16, the California Code of regulations (CCR), section 1474, and the Medical Board of California, Title 16 CCR Section 1379

All revision dates:

Attachments

S.95 Standardized Procedures for the Certified Registered Nurse First Assistant Attachment-A Approval and Agreement_1 (4) (3).docx

Approval Signatures

Step Description	Approver	Date
Surgery Committee	Tracy Chapman: VCMC - Med Staff	pending
Interdisciplinary Practices Committee	Tracy Chapman: VCMC - Med Staff	1/10/2024
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	1/5/2024
Surgical Services	Gwendolyn Vontoure: Director Perioperative Services	1/5/2024

Allied Health Professional Ongoing Professional Practice Evaluation

Confidential & Protected Peer Review Documents California Evidence Code section 1157

The following ongoing professional practice evaluation (OPPE) form must be completed by a supervising physician every **6 months** to meet The Joint Commission standards requirements to evaluate all practitioners' performance on an ongoing basis (in between credentialing/privileging cycles).

AHP's Name: _____ Specialty/Department:_____

How frequently have you worked with the above-named practitioner in the past 6 months?

☐ Frequently ☐ Periodically ☐ I have not worked with this practitioner in the past 6 months

Please assess the above-named practitioner's performance in each of the following areas.

Category	Good	Satisfactory	Needs Improvement*	Unable to Assess
PATIENT CARE				
Quality/appropriateness of patient care				
Quality of documentation/medical records				
Appropriateness use of medications/prescribing practices				
MEDICAL/CLINICAL KNOWLEDGE				
Medical/clinical knowledge				
Clinical judgment				
Technical skills				
PRACTICE-BASED LEARNING & IMPROVEMENT				
Utilizes current best practices				
INTERPERSONAL & COMMUNICATION SKILLS				
Ability to work with all members of the healthcare team				
Rapport with patients & families				
Rapport with fellow practitioners				
PROFESSIONALISM				
Commitment to continuous professional development				
Demonstration of ethical standards in treatment				
Dependability				
Reactions to stressful situations				
SYSTEM BASED PRACTICES				
Practices cost effective health care and resource allocation that does not compromise quality of care				
RECOMMENDATIONS	**Yes**	**Needs Improvement***		**No**
Does the Practitioner demonstrate the necessary qualifications/competency?				

**** Needs improvement ratings require additional information in the comment section below.***

My assessment is based on (check all that apply) ☐ Personal Observation ☐ Chart Reviews ☐ Shared Patients

Review Cycle: ☐ January-June (Due July 31st) ☐ July-December (Due January 31st)

Comments (use additional page if necessary): _____

_____

_____

Completed by *(please print)*: _____ Date: _____

Signature: _____

Delineation Of Privileges

Certified Registered Nurse First Assist (CRNFA)

Name:

Privilege	Requested	Granted	Deferred	Suspended

Basic Criteria:
a. Successful completion of RNFA training from an accredited graduate nursing program (using AORN Core Curriculum as a foundation)
b. Current Certification in Perioperative Nursing (CNOR)
c. Current BLS, ACLS, PALS, and NRP Certifications, with hands-on skills component
d. A minimum of 2 years of clinical experience as an RNFA
e. Validation of clinical experience by a qualified surgeon

Evaluation Requirements:
A minimum of the first 3 cases proctored

Renewal Criteria:
Continue to meet the basic requirements and participate in a minimum of 60 surgical cases in the previous 2 years*

** If the case volume has not been met, initial orientation requirements outlined in the standardized procedure or additional evaluation may apply*

Privileges are requested in accordance with S.95 Standardized Procedure for the Certified Registered Nurse First Assistant (CRNFA) and at the direction of the supervising surgeon.

Provide surgical exposure during procedure	___	___	___	___
Perform hemostasis	___	___	___	___
Suturing/knot tying	___	___	___	___
Interoperative tissue manipulation	___	___	___	___
Use of surgical instruments	___	___	___	___
Patient record keeping to include: preopertive nursing assessment, intraopretive nursing assessment, postoperative nursing assessment	___	___	___	___
Robotic Surgical Bedside Assistant	___	___	___	___

Initial Criteria:
a. Certificate of Training from Intuitive Surgical (Xi module)
b. Vendor bedside training to include at minimum; set up, patient positioning and equipment orientation

Evaluation Criteria:
A minimum of the first 2 cases proctored

Renewal Criteria:
a. A minimum of 8 robotic-assisted surgeries per calendar year
b. Failure to meet the minimum annual volume; repeat training and or proctoring may be required at the discretion of the Robotic Steering Committee

Delineation Of Privileges

Certified Registered Nurse First Assist (CRNFA)

Name:

Privilege	Requested	Granted	Deferred	Suspended

Acknowledgment of Practitioner:
I have requested only those privileges for which, by education, training, current experience and demonstrated performance, I am qualified to perform, and that I wish to exercise at the Ventura County Medical Center, Santa Paula Campus Hospital and/or with the VCMC Ambulatory Care System. I understand that exercising any clinical privileges granted, I am constrained by the hospital and medical staff policies and rules applicable generally and any applicable to the particular situation. I am willing to provide documentation of my current competence for the requested privileges.

Applicant’s electronic signature on file

Approve requested privileges:

Supervising Physician's Signature: _____ Date: _____

TEMPORARY PRIVILEGE APPROVAL

Department Chief’s Signature: _____ Date: _____

Evaluator Assignment: _____

[ ] INITIAL [ ] RENEWAL APPROVAL

_____
Department Chief Date