SIERRA VIEW
MEDICAL CENTER

SIERRA VIEW LOCAL HEALTH CARE DISTRICT
BOARD OF DIRECTORS MEETING
465 West Putnam Avenue, Porterville, CA – Board Room

AGENDA
March 28, 2023

OPEN SESSION (5:00 PM – 5:05 PM)

The Board of Directors will call the meeting to order at 5:00 P.M. at which time the Board of Directors will undertake procedural items on the agenda. At 5:05 P.M. the Board will move to Closed Session regarding the items listed under Closed Session. The public meeting will reconvene in person at 5:30 P.M. In person attendance by the public during the open session(s) of this meeting is allowed in accordance with the Ralph M. Brown Act, Government Code Sections 54950 et seq.

Call to Order

I. Approval of Agendas
Recommended Action: Approve/Disapprove the Agenda as Presented/Amended

The Board Chairman may limit each presentation so that the matter may be concluded in the time allotted. Upon request of any Board member to extend the time for a matter, either a Board vote will be taken as to whether to extend the time allotted or the chair may extend the time on his own motion without a vote.

II. Adjourn Open Session and go into Closed Session

CLOSED SESSION

As provided in the Ralph M. Brown Act, Government Code Sections 54950 et seq., the Board of Directors may meet in closed session with members of the staff, district employees and its attorneys. These sessions are not open to the public and may not be attended by members of the public. The matters the Board will meet on in closed session are identified on the agenda or are those matters appropriately identified in open session as requiring immediate attention and arising after the posting of the agenda. Any public reports of action taken in the closed session will be made in accordance with Gov. Code Section 54957.1

III. Closed Session Business

A. Pursuant to Evidence Code Sections 1156 and 1157.7; Health and Safety Code Section 32106(b): Chief of Staff Report (Time Limit – 5 minutes)

Bindusagar Reddy Zone 1 | Gaurang Pandya Zone 2 | Hans Kashyap Zone 3 | Liberty Lomeli Zone 4 | Areli Martinez Zone 5

B. Pursuant to Evidence Code Sections 1156 and 1157.7; Health and Safety Code Section 32106(b):

1. Evaluation – Quality of Care/Peer Review/Credentials

2. Quality Division Update –Quality Report

C. Pursuant to Gov. Code Section 54956.9, Exposure to Litigation to subdivision (d)(2): Conference with Legal Counsel. BETA Claim No. 23-000400 (Time Limit – 5 minutes)

D. Pursuant to Gov. Code Section 54962; Health and Safety Code Section 32106(b): Discussion Regarding Trade Secrets, Pertaining to Service (1 Item) Estimated Date of Disclosure – July 2024

E. Pursuant to Gov. Code Section 54956.9, Exposure to Potential Litigation (d)(2): Conference with Legal Counsel; Government Code Sections 54957(b)(1) and 54957(b)(2) and Pursuant to Gov. Code Section 54962; Health and Safety Code Section 32106(b): Discussion Regarding Trade Secrets, Pertaining to Service (1 Item) Estimated Date of Disclosure – December 2023

F. Pursuant to Gov. Code Section 54962; Health and Safety Code Section 32106(b): Discussion Regarding Trade Secrets, Pertaining to Service (1 Item) Estimated Date of Disclosure – July 2024

G. Pursuant to Gov. Code Section 54956.9(d)(2), Conference with Legal Counsel about recent work product (b)(1) and (b)(3)(F): significant exposure to litigation; privileged communication (1 Item)

To the extent items on the Closed Session Agenda are not completed prior to the scheduled time for the Open Session to begin, the items will be deferred to the conclusion of the Open Session Agenda.

IV. Adjourn Closed Session and go into Open Session

Bindusagar Reddy, Zone 1 | Gaurang Pandya, Zone 2 | Hans Kashyap, Zone 3 | Liberty Lomeli, Zone 4 | Areli Martinez, Zone 5

SIERRA VIEW MEDICAL CENTER

SIERRA VIEW LOCAL HEALTH CARE DISTRICT
BOARD OF DIRECTORS AGENDA
March 28, 2023

OPEN SESSION

V. Closed Session Action Taken

Pursuant to Gov. Code Section 54957.1; Action(s) to be taken Pursuant to Closed Session Discussion

A. Chief of Staff Report
Recommended Action: Information only; no action taken

B. Quality Review

1. Evaluation – Quality of Care/Peer Review/Credentials
Recommended Action: Approve/Disapprove Report as Given

2. Quality Division Update –Quality Report
Recommended Action: Approve/Disapprove Report as Given

C. Conference with Legal Counsel Re: BETA Claim No. 23-000400
Recommended Action: Approve/Deny BETA Claim No. 23-000400

D. Discussion Regarding Trade Secret – Pertaining to Service
Recommended Action: Information only; no action taken

E. Conference with Legal Counsel and Discussion Regarding Trade Secret
Recommended Action: Information only; no action taken

F. Discussion Regarding Trade Secret – Strategic Planning
Recommended Action: Information only; no action taken

G. Conference with Legal Counsel about recent work product
Recommended Action: Information only; no action taken

VI. Public Comments

Pursuant to Gov. Code Section 54954.3 - NOTICE TO THE PUBLIC - At this time, members of the public may comment on any item not appearing on the agenda. Under state law, matters presented under this item cannot be discussed or acted upon by the Board at this time. For items appearing on the agenda, the public may make comments at this time or present such comments when the item is called. This is the

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time for the public to make a request to move any item on the consent agenda to the regular agenda. Any person addressing the Board will be limited to a maximum of three (3) minutes so that all interested parties have an opportunity to speak with a total of thirty (30) minutes allotted for the Public Comment period. Please state your name and address for the record prior to making your comment.

VII. Consent Agenda
Recommended Action: Approve Consent Agenda as presented

Background information has been provided to the Board on all matters listed under the Consent Agenda, covering Medical Staff and Hospital policies, and these items are considered to be routine by the Board. All items under the Consent Agenda covering Medical Staff and Hospital policies are normally approved by one motion. If discussion is requested by any Board member(s) or any member of the public on any item addressed during public comment, then that item may be removed from the Consent Agenda and moved to the Business Agenda for separate action by the Board.

VIII. Approval of Minutes

A. **February 28, 2023 Minutes of the Annual Meeting of the Board of Directors**
Recommended Action: Approve/Disapprove February 28, 2023 Minutes of the Annual Meeting of the Board of Directors

IX. Business Items

A. **Single Audit Review**
Recommended Action: Information only; no action taken

B. **February 2023 Financials**
Recommended Action: Approve/Disapprove Report as Given

C. **Board Education**
Recommended Action: Information only; no action taken

X. CEO Report

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SIERRA VIEW MEDICAL CENTER

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XI. Announcements:

A. Regular Board of Directors Meeting – April 25, 2023 at 5:30 p.m.

XII. Adjournment

PUBLIC NOTICE

Any person with a disability may request the agenda be made available in an appropriate alternative format. A request for a disability-related modification or accommodation may be made by a person with a disability who requires a modification or accommodation in order to participate in the public meeting to Melissa Mitchell, VP of Quality and Regulatory Affairs, Sierra View Medical Center, at (559) 788-6047, Monday – Friday between 8:00 a.m. – 5:00 p.m. Such request must be made at least 48 hours prior to the meeting.

PUBLIC NOTICE ABOUT COPIES

Materials related to an item on this agenda submitted to the Board after distribution of the agenda packet, as well as the agenda packet itself, are available for public inspection/copying during normal business hours at the Administration Office of Sierra View Medical Center, 465 W. Putnam Ave., Porterville, CA 93257. Privileged and confidential closed session materials are/will be excluded until the Board votes to disclose said materials.

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MEDICAL EXECUTIVE COMMITTEE	03/01/2023
BOARD OF DIRECTORS APPROVAL	
	03/28/2023
BINDUSAGAR REDDY, MD, CHAIRMAN	DATE

SIERRA VIEW MEDICAL CENTER
CONSENT AGENDA REPORT FOR
March 28, 2023 BOARD APPROVAL

The following Policies/Procedures/Protocols/Plans/Forms have been reviewed by the Medical Executive Committee and are being submitted to the Board of Directors for approval:

		Pages	Action
I.	**Policies**:		**APPROVE**
	• Admissions and Bed Capacity	1-6	↓
	• Bedholds, Discharges and Transfers	7-11	
	• Blood Specimen – Collection of	12-16	
	• Care of Dying Patient	17-18	
	• Closing/Opening of Patient Care Units	19-21	
	• Continued Stay Review	22-23	
	• Dental Services	24-26	
	• Medical Record Forms	27-28	
	• Patient Death	29-36	
	• Pediatric Rooming-In and Parent Participation	37-38	
	• Therapeutic Phlebotomy	39-42	
	• Tube Feeding	43-45	
	• Waived & Point of Care Testing – Clinitek Status Connect Plus	46-51	
	• Waived & Point of Care Testing – Competency and Quality	52-57	
	• Waived & Point of Care Testing Gastric Occult Blood	58-60	
	• Waived and Point of Care Testing – Glucose Meter (FSBG)	61-70	
	• Waived and Point of Care Testing – Hemoglobin A1C	71-75	
	• Waived and Pont of Care Testing – Influenza A+B	76-88	
	• Waived and Point of Care Test – Rapid Detection of Respiratory Syncytial Virus (RSV)	89-100	
	• Waived & Point of Care Testing – Rapid Group A Strep	101-110	
	• Waived & Point of Care Testing – Testing for Fecal Occult Blood	111-114	

SUBJECT: **ADMISSIONS AND BED CAPACITY**	SECTION: ***Patient Management*** **Page 1 of 6**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

POLICY:

In the event of a disaster which requires assessment and admission of victims, the hospital will assess availability of treatment beds in the Emergency Department and admission beds on the in-patient units and facilitate the increased availability of beds to accommodate disaster victims by the transfer or early discharge of patients.

AFFECTED PERSONNEL/AREAS: *GOVERNING BOARD, MEDICAL STAFF, ALL HOSPITAL EMPLOYEES, VOLUNTEERS, VENDORS*

PROCEDURE:

1. The Emergency Department Physician and Charge Nurse will assess the patient's in the Emergency Department at the time of the disaster and consider:

   a. Facilitating discharge of patients who have completed Medical Screening Examination and treatment.

   b. Facilitating transfer of patients in need of admission to the in-patient units.

   c. Re-prioritizing existing patients to open up treatment rooms for higher priority disaster victims.

   d. Notify Operations Chief/Medical Care Director of need to open alternate sites for care of victims triaged as delayed and minimal.

2. The Utilization Review/Discharge Planning Department will coordinate with the in-patient units in determining those patients that may be transferred or discharged with the concurrence of the patient's attending physician.

   a. Patients may be held in Flex Care awaiting transportation arrangements.

   b. Patient's families will be notified of the transfer or discharge as soon as possible.

   c. Transfer or discharge shall not be carried out if, in the opinion of the patient's physician, such transfer or discharge would create a medical hazard for the patient.

3. Operating Room and Imaging Services will evaluate, in consultation with physicians, which cases or procedures may be cancelled or delayed during the disaster response. This information is to be communicated to the Operations Section.

4. All elective (non-casualty) admissions shall be suspended until the disaster response is terminated.

5. Tracking of bed availability will be documented on the forms:

a. "*Hospital Cumulative Inventory Status*" – This form lists treatment capacity and in-patient bed availability of surrounding hospitals. It is completed by the ED after contact with surrounding facilities on the Priority Plus Disaster Radio channel and routed to Planning section. (see "Disaster Communications")

b. "*In-Patient Bed Availability Worksheet*" –This form identifies available and potentially available beds in-house. It is completed by UR/DP and routed to Planning section. It is compiled from the *Unit Report of Available Beds* submitted by each in-patient unit. The *Unit Report of Available Beds* may be requested periodically during the disaster implementation to update status.

6. Requests for beds for disaster patients identified for admission will be made to the Planning Section. See *Admission Request List*.

7. Requests for Operating Room use will be made by the treatment unit directly to the Operating Room.

8. Requests for acceptance of patients in transfer will be made through regular channels. If the disaster incident is wide spread and affects other facilities (as in earthquake or other natural disaster, etc. requests must be made by the Liaison Officer through County OES Operations Center.

REFERENCES:

- Title 22: Section 70741, 70743, 70745, 70746
- The Joint Commission (2023~~18~~). Hospital accreditation standards. EM.09.01.01 Joint Commission Resources. Oak Brook, IL.

CROSS REFERENCES:

- Disaster Communications – SVMC Policies and Procedures

Attachment A

IN-PATIENT BED AVAILABILITY WORK SHEET

TIME	UNIT	AVAILABLE BEDS (list by rm no.)	empty	potential	TIME	Bed Assigned to patient: (list by name and tag no.)

11-99

Attachment B

EMPTY BEDS: **(list all empty bed room numbers):**

PATIENTS FOR POTENTIAL DISCHARGE/TRANSFER:

RM NO.	NAME	DIAGNOSIS	AMBULANCE	W/C	COMMENTS:

PREPARED BY:_____

11-99

Attachment C

DISASTER ADMISSION REQUEST LIST

DATE:_____

TIME	REQUESTING TREATMENT UNIT	TAG NO. / PATIENT NAME	DIAGNOSIS	ADMITTING PHYSICIAN	CARE NEEDS/ SPECIALTY UNIT/EQUIP	BED ASSIGNMENT	TIME

11-99

Attachment D

HOSPITAL CUMULATIVE INVENTORY STATUS

TIME	FACILITY	AVAILABLE BEDS	EMPTY	POTENTIAL

SUBJECT: **BEDHOLDS, DISCHARGES, AND TRANSFERS**	SECTION: **Page 1 of 5**

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PURPOSE:

To facilitate the request to hold open the resident's bed during temporary stays away from the facility. To maintain the resident's record in compliance for billing and separation of facility admissions, stays, therapeutic leaves and discharges.

POLICY:

Residents will be informed upon admission of their right to have a bed hold in the event the resident must be transferred to an acute facility or during therapeutic leave. The resident or representative will be given notice of the rights to a bed hold at the time of transfer or leave. Residents will be informed that Medi-Cal will pay for up to seven (7) bed hold days for an acute care hospitalization.

AFFECTED PERSONNEL/AREAS: *BILLING, PATIENT ACCOUNTING, CHARGE NURSE, SOCIAL SERVICES AND ADMITTING*

Transfer and Discharge Requirements

All Skilled Nursing Facilities (SNFs) must adhere to specified notice, transfer, discharge, and right to return requirements.

Each facility must permit residents to remain in the facility, and not transfer or discharge the resident from the facility unless:

1. The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;

2. The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility;

3. The safety of individuals in the facility is endangered;

4. The health of individuals in the facility would otherwise be endangered;

5. The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid;

6. The facility ceases to operate; or

7. The resident has made a material or fraudulent representation of his or her finances.

8. A facility may involuntarily discharge a resident for failure to pay his or her share of the cost. However, a resident cannot be transferred for non-payment if he or she has submitted all the paperwork necessary for the bill to be paid by a third-party payor. Non-payment occurs if a third-

party payor, including Medicare or Medi-Cal, denies the claim and the resident refuses to pay for his or her stay. Additionally, a dual-eligible resident residing in a Medi-Cal certified facility has a right to transition to Medi-Cal from Medicare if the resident needs continuing care in the facility. If a facility participates in Medi-Cal or Medicare, the facility may not transfer or discharge a resident, nor transfer a resident within the facility solely because of a change from private pay or Medicare to Medi-Cal payment. However, a facility may transfer a resident from a private room to a semiprivate room if the resident changes to Medi-Cal payment status.

Notice Provided to Resident Prior to Transfer or Discharge

Before any transfer or discharge occurs, the facility must notify, in writing, the resident and, if known, the family member or legal representative of the transfer or discharge and the reasons for the move. The reasons for the move must be recorded in the resident's clinical record. This notice must be made by the facility at least 30 days before the resident is transferred or discharged unless the transfer is made for medical, health and safety reasons, or in cases of facility closure.
Except in an emergency, a facility may not transfer a resident to another room within the facility against his or her wishes, unless given prior reasonable written notice.

Notice to the LTC Ombudsman

The Local LTC Ombudsman will be provided notice, the same time as the resident or the resident's representatives, when a facility-initiated transfer or discharge occurs. The facility will send a notice to the local LTC Ombudsman for any transfer or discharge that is initiated by the facility, whether or not the resident agrees with the facility's decision. The facility does not need to notify the LTC Ombudsman of transfers initiated by the resident. The facility will provide a copy of the notice to the LTC Ombudsman, as soon as practicable, if a resident is subject to a facility-initiated transfer to a general acute care hospital on an emergency basis.

BEDHOLDS

1. The facility shall not be required to offer a bedhold if the resident requires a level of care greater than that provided by the facility upon the resident's return. If the facility fails to follow this procedure, then the resident will be offered the next available bed.

2. The resident may terminate the bedhold option during the seven (7) day period by notifying the facility in writing. The facility will bill only for bedhold days prior to the written request to end the bedhold.

3. If the resident's attending physician notifies the facility in writing that the resident's treatment at the acute care facility will exceed seven (7) days from the date of admission, the facility will not be required to maintain a bedhold for the resident.

4. If the MediCal eligible resident is transferred from the facility and does not request a bedhold, the facility shall extend the resident readmission rights to the next available bed. If a resident's hospitalization or therapeutic leave exceeds the bedhold period, then the resident shall be

admitted to the next available bed if he/she requires the services of the facility and is eligible for MediCal nursing facility services.

5. The Medicare program does not make payments for ~~b~~bedholds, thus any Medicare resident exercising his/her right to maintain a bedhold shall pay the facility's private daily rate during the period of the bedhold.

6. Any privately funded resident exercising his/her right to maintain a bedhold shall pay the facility's daily rate for the period of the bedhold. The resident's insurance may or may not cover cost for a bedhold. MediCal will reimburse for up to seven (7) bedhold days. If MediCal coverage for a bedhold does not exist, the bedhold will be considered to be a non-covered service and the resident shall be obligated to pay the facility's daily private rate for each day of the bedhold.

7. A bedhold option shall be extended to MediCal eligible residents even if he/she has outstanding MediCal balances and if hospitalized beyond the State's bedhold policy, he/she must be readmitted to the first available bed. Once readmitted, however, the resident may be transferred if the facility can demonstrate that non-payment of charges exists and documentation and notice requirements are followed. The facility is not required to hold the same bed or room previously occupied by the resident.

8. If the resident or responsible party desires in advance that a bedhold is to be provided to the resident, the resident shall acknowledge it in writing with parties upon completion of admission agreement, and it will become a part of the resident record. However, the resident will still receive notification at the time of transfer. In cases of emergency transfer, notice "at the time of transfer" means that the responsible party shall be provided with written notification within 24 hours of the transfer. The notice of bedhold is also considered to be served if the resident's copy of the notice accompanies the resident and transfer records to the acute care facility.

9. If the resident does not return to the facility by midnight (11:59 p.m.) of the eighth day, the facility may discharge the resident. (Bedhold starts on the day of transfer; however, the discharge day will not be counted.)

It is not necessary to initiate a bedhold if the resident goes to an acute facility for an outpatient procedure or on a therapeutic leave, and returns the same day.

RESIDENTS RIGHTS TO RETURN TO THE FACILITY, SPECIFIC TO ALL SNF AND ICF REQUIREMENTS:

1. All SNFs shall afford any resident transferred to a general acute care hospital a bed hold of at least seven days and inform each current resident or resident's representative in writing of the resident's right to exercise this bed hold provision.

2. Whenever a resident is transferred to a hospital, the facility must provide written notice to a resident of the bed hold policy. The resident or the resident's representative shall inform the facility within 24 hours if the resident desires the facility to hold a bed for him or her. Residents must be permitted to return to the facility if they exercised their right to a bed hold. Moreover, a nursing facility must establish and follow a written policy under which a resident, whose hospitalization or therapeutic leave exceeds the bed-hold period, is readmitted to the facility immediately upon the first availability of a bed in a semi-private room if the resident requires the services provided by the facility.

Nursing Unit Procedures:

1. Obtain a physician's order for transfer to the acute facility for treatment or for a therapeutic leave and for bedhold.

2. Complete an Interfacility Transfer Form for acute transfers. Send the original with the requested copies of the resident's record and place a copy of the transfer form on the DP/SNF record.

3. Copy all reports, physician's progress notes, and other parts of the record as requested by the receiving facility. Clearly mark these as copies, and send with the resident. (Do not send the DP/SNF chart.)

4. Document on the resident's record that he/she was transferred to acute facility, and was placed on bedhold status. (Do not discharge the resident from the DP/SNF Facility.)

5. Notify the resident and/or the resident's responsible party of the transfer and the right to initiate a bedhold. Document their decision in the resident record. (Nursing and/or Social Service). Notify the Admitting Office of the resident's transfer to acute or therapeutic leave, and his/her placement on bedhold status (Nursing or Program Secretary). The Bedhold Notification Form shall be used to document notice to the resident/family of the bedhold.

6. Maintain the resident's record open on the unit.

7. If the resident returns to the facility within the seven (7) day bedhold period, document this in the nursing notes section of the resident's record.

8. Verify that the physician has written an order to resume care and treatment, and note if there are additional orders based on the resident's change of condition.

9. Initiate and complete a new MDS only if the resident has experienced a permanent change in his/her condition that affects functional level.

10. If the resident does not return to the facility by midnight (11:59 p.m.) of the eighth (8^{th}) day, then discharge the resident, and break down and organize the resident's record according to the facility's policy and send to Medical Records. (Bedhold starts on the day of transfer, however, the discharge day will not be counted.)

11. Open a new resident record if the resident returns to the facility after bedhold has expired. (Readmit the resident and follow MDS instructions for admission.)

12. Remember that the acute facility should open an acute or outpatient chart with a new account number when the resident is received.

13. Medicare and private insurance do not routinely pay for bedholds, and these residents should be discharged when transferred to acute, if the resident or insurer declines to pay privately for the bedhold option. It is not necessary to discharge these residents for outpatient procedures.

14. The bedhold is recorded on the "CENSUS REPORT," in the Unit Resident Transfer Log, and in the individual resident record.

REFERENCES:

- Thomson Reuters (Revised edition April 1, 1990) Barclay's California Code of Regulations, §72520, §72527, §73504, §73523-, San Francisco, California, Title 22.

- Med Pass, Inc.,(Updated February 6, 2015) Facility Guide to OBRA Regulations, 483.12 (B) CCR , 483.13 (a) United States of America, Med Pass Inc.

- California Department of Public Health, AFL 17-27 Assembly Bill (AB) 940, Health and Safety Code section 1439.6. Retrieved from cdph.ca.gov.

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SUBJECT: **BLOOD SPECIMEN – COLLECTION OF**	SECTION: ***Provision of Care, Treatment and Services (PC)*** **Page 1 of 5**

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PURPOSE:

The purpose of this policy is for performing a venipuncture to obtain a blood specimen for the purpose of diagnostic testing.

POLICY:

Arm veins are the best source from which to obtain blood. Usually one or more veins in this area are visible. The veins appear blue and are slightly raised above the skin surface, except in obese people. The best veins are those which are full but well supported by subcutaneous tissue to prevent rolling during introduction of the needle. Hand veins may be used when the arms are bandaged, severely traumatized, edematous, burned, have casts on or if the patient is receiving IV fluids through the forearm. Note: NEVER draw above an IV; the intravenous fluid will dilute and contaminate the specimen. Use the other arm if possible, or use the hands.

SPECIAL CONSIDERATIONS FOR BLOOD BANK SPECIMENS

All blood specimens drawn from a **peripheral vein** for the purpose of blood bank testing will be obtained and labeled by a certified/licensed lab person or licensed nursing person or physician in the presence of a second certified/licensed lab person or licensed person. Both personnel involved in obtaining the specimen will each initial the specimen labels and/or additional forms as required, and confirm that the BBK# has been accurately transcribed from the patient's wrist band to the specimen label.

EXCEPTION: Outpatient laboratory services will utilize a two-person check when drawing blood bank specimens and the second person may be a non-licensed person.

AFFECTED AREAS/PERSONNEL: *REGISTERED NURSES (RN), LICENSED VOCATIONAL NURSES (LVN), CERTIFIED LAB PERSONNEL, MEDICAL ASSISTANTS (MA)*

EQUIPMENT NEEDED:

1. Alcohol prep
2. Vacutainer holder
3. Multisample needles
4. Syringes
5. Needles
6. Tourniquet
7. Vacutainer tubes

8. Bandage

9. Cotton balls

10. Gloves

PROCEDURE:

1. Check physician orders.

2. Identify patient using the two patient identifier system.

3. Explain procedure to patient.

4. Position patient.

   a. Reclining position is preferred. There is no way to predict how a patient is going to react to a needle puncture and some people may faint.

   b. Sitting in a comfortable chair with arm supports is acceptable. **Never** draw blood from a patient who is standing up or sitting on a high stool.

   c. Position the arm so the vein is accessible, and so you are able to work in a comfortable position. A small pillow or rolled towel may be used to help support the extended arm if needed.

5. Proper lighting is necessary.

6. Select vein.

7. Apply the tourniquet about midway between the elbow and the shoulder. Apply enough tension to compress the vein but not the artery.

8. Have the patient make a fist, or if needed, they may clench and unclench their hand a few times. Don't leave the tourniquet in place longer than two minutes before venipuncture or let the patient "pump" their fist to distend the veins. Either practice may cause "hemoconcentration" and alter some laboratory values.

9. Always palpate or feel for the vein, even when you can see it. This gives practice in finding deeper, unseen veins, the vein will feel like an elastic tube that "gives" under finger pressure. Be sure the structure you feel is not pulsating (artery).

10. Attach an unused sterile needle to a syringe or a Vacutainer blood collection holder, keeping the needle sterile at all times.

a. Use available assembled equipment.

b. Usually 21 or 22 gauge needles are used with occasionally a 23-gauge chosen for especially tiny veins. Care should be taken when using a 23-gauge to prevent hemolysis of the specimen. (Use 20cc syringe if more than one (1) tube of blood is necessary).

11. Apply gloves. Scrub the area for venipuncture with alcohol prep pad/betadine in a circular motion. Use betadine cleansing when drawing blood cultures.

a. Allow the area to dry to prevent pain and hemolysis.

b. Necessary to reduce the body's natural flora.

12. The vein should be "fixed" or held taut during the procedure by placing your left thumb about an inch below the site and press down on the arm and at the same time pull the skin toward the hand. The fingers of the left hand should be around and underneath, grasping the arm as the thumb holds the vein in place. Alternatively, the vein may be held in place by placing your index finger above the site and your thumb below the site, slightly pulling on the skin.

13. Hold the needle bevel up in line with the vein at about a 15-degree angle with the skin. Insert the needle through the skin and into the vein with a clean, smooth motion. Do not jab, stab, hesitate or insert the needle very slowly. As the needle enters the vein, a little "give" will be felt.

14. While holding the needle steady, push collection tube into Vacutainer holder and let blood flow into the tube. The following order of draw is required:

- Sterile tubes for culture (blood culture bottles)
- Sodium Citrate tube (blue stopper)
- Serum tubes (with or without clot activator)
- Heparin tube (green stopper)
- EDTA tube (lavender stopper and/or pink stopper)
- Oxalate-fluoride tube (gray stopper)

When more than one type of additive tube is used, draw using the following order:

- Blue stoppered (Draw a "waste" tube prior to blue tube if this is the only tube being drawn)
- Green stoppered
- Purple stoppered
- Pink stoppered
- Gray stoppered

15. Prior to syringe draw, move the plunger in the barrel before inserting needle. For a syringe draw, pull back on the plunger until the syringe is full.

    a. Prevents plunger from sticking.

    b. Immediately (DO NOT LET THE BLOOD SET) fill the collection tubes in the order indicated above.

16. The tourniquet should remain in place until the collection is complete. Release the tourniquet just before the needle is removed to avoid a hematoma (swelling filled with blood).

17. Withdraw the needle gently and immediately place a clean, dry cotton over the puncture site and apply pressure. Bending the arm to hold pressure may keep the needle puncture wound open and allow blood to escape freely through the wound into the tissues, causing a hematoma. Keeping the arm extended while applying pressure helps to minimize that risk.

18. Mark tubes with patient name, date, time, test and initial in the presence of the patient.

19. Dispose of sharps in sharp container. Do not recap used needles or attempt to remove the needle from the holder with your fingers.

20. Remove the needle from the Vacutainer holder by inserting it into the needle collection container and twisting.

21. Inspect the puncture wound. If all or most of the bleeding has stopped, apply an adhesive bandage. If the patient is on anticoagulants or their disease state slows their clotting process, you may need to hold pressure for five minutes or more. Do not leave the patient until bleeding is under control.

22. Transport specimen to blood processing area.

23. SPECIAL STATEMENT regarding Standards of Care Guidelines 31.1, Universal Precautions (Referenced OSHA 1910. 1930.

    These infection control precautions are mandated by the Occupational Safety and Health Administration (OSHA) and recommend that all blood and certain body fluids are treated as potentially infectious for human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), and other bloodborne pathogens:

    - Employees are provided and required to wear appropriate personal protective equipment (PPE) and other engineering/work practice controls to eliminate or minimize employee exposure to bloodborne pathogens as mandated in OSHA regulation 1910.

- Gloves are to be worn when there is anticipation of contact with blood, other potentially infectious materials, mucous membranes, and nonintact skin.
- Gowns, aprons or other protective body clothing are to be worn when contamination of clothing with blood or other potentially infectious materials are anticipated.
- Masks or combinations with protective eyewear are to be worn when performing procedures likely to generate sprays or splashes of blood or other potentially infectious materials into the eyes, nose, or mouth.
- Hands and other skin surfaces are to be washed immediately if contaminated with blood or other potentially infectious materials.
- Utilize safety devices for needles and other sharps and do not manipulate by hand (e.g. recapping, purposely bending or breaking, or removing from syringes, etc.)
- Needles and other sharps are to be placed in puncture-resistant containers for disposal.
- All specimens and items with blood or other potentially infectious materials are to be transported in containers that prevent leakage.
- Blood and body fluids spills are to be cleaned up promptly with an appropriate germicide, such as bleach solution or phenolic.

REFERENCES:

- Nettina, S.M. (2019). *Lippincott Manual of Nursing Practice*. (11th Ed). Wolters Kluwers, Philadelphia.
- Standards of Care Guidelines 31.1. (1996). Universal Precautions. CFR §1910 & §1930 (Referenced OSHA).
- Order of Blood Draw Tubes and Additives (2019), CLSI.org

SUBJECT: **CARE OF THE DYING PATIENT**	SECTION: ***Provision of Care, Treatment and Services (PC)*** **Page 1 of 2**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

To define management of the acutely dying or palliative care patient in relation to the administration of comfort medications and guidelines for provision of emotional support.

DEFINITIONS:

1. Acutely dying: a patient with an incurable illness where all treatment to prolong life is ineffective or determined by the patient, family/significant others and physicians to no longer be of benefit. The patient is expected to expire within several hours to several days.

2. Palliative care: measures taken to improve quality of life of patients facing life-threatening illness through relief of suffering, treatment of pain and physical, psychosocial and spiritual support.

POLICY:

It is the policy of this facility to provide emotional and religious support to terminally ill patients and family as well as meeting their physical comfort needs. A Palliative Care Referral will be initiated on the patient identified as acutely dying or meeting criteria for Palliative Care and in conference with the provider, staff, patient and family as appropriate. Care will be directed toward maximizing comfort, maintaining dignity and providing support for patients, their families and significant others.

AFFECTED AREAS/ PERSONNEL: *RN, LVN, CNA, Palliative Care Team*

PROCEDURE:

A. Emotional and spiritual support.

   1. Be aware of and attempt to understand the emotional stages of shock, denial, anger and acceptance that patient and family go through when facing death.

   2. Allow patient and family to express their feelings. Be a good listener.

   3. Do not offer false hope or false information to patient or family.

   4. Show concern for patient and visitors and respect their desire for privacy.

   5. When leaving patient's room, give assurance of return in an attempt to alleviate loneliness, isolation and/or fear.

   6. If a patient's level of consciousness changes, continue to talk to the patient and conduct all conversations as though patient can hear and understand.

   7. Maintain a personal objective approach.

8. Smile and offer as calm and gentle a touch as possible.

9. Refer to social services or religious help as requested or needed.

B. Physical comfort

1. A Palliative Care Referral will be initiated if the patient meets criteria for Palliative Care and in conference with the provider, staff, patient and family as appropriate or if the patient is identified as acutely dying.

2. The Inpatient Palliative Care Team will evaluate the patient upon referral and implement Physician's Orders for Comfort Care.

3. Nursing will administer comfort care accordingly, utilizing numeric scales for pain and anxiety when possible. When numeric scales are not feasible, non-verbal indicators will be utilized.

REFERENCES:

- Center to Advance Palliative Care (CAPC) 2017, End of Life Care, www.capc.org
  No One Dies Alone, (NODA)-SVMC

CROSS REFERENCES:

- Physician's Orders for Comfort Care

SUBJECT: **CLOSING / OPENING OF PATIENT CARE UNITS**	SECTION: ***Provision of Care, Treatment and Services (PC)*** **Page 1 of 3**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

To establish the process for consistent control and security of the medications and crash carts when a patient care unit opens or closes due to lack of census.

POLICY:

When closing or opening a patient care unit due to lack of census, the involved departments will ensure that appropriate precautions have been taken to preserve the integrity of the unit with specific attention to medications, medication refrigerator temperatures, and crash carts.

AFFECTED PERSONNEL/AREAS: *ALL PATIENT CARE UNITS; PHARMACY; AND NURSING*

PROCEDURE:

CLOSING A UNIT**:**

When it has been decided by the Department Director or designee and/or the Nursing House Supervisor, after attempting to reach the Nursing Leader of that department, to close a particular patient care unit (e.g. 3North, 3 South, 3East, 3West, Pediatric area, Telemetry and/or ICU), the individual making the decision to **close** a particular unit shall notify the following:

PHARMACY

1. After Pharmacy Hours – the Nursing House Supervisor shall:

    a. Notify the Manager of Pharmacy of the closure;

    b. The next scheduled shift, the pharmacist will remove all available medications from the medication refrigerator and place back into the regular stock in pharmacy.

2. During Pharmacy Hours -- the Department Director or designee or Nursing House Supervisor shall notify the Pharmacist of the intent and time of closure of a designated unit.

    a. The Pharmacist shall follow the above outlined procedure.

DIETARY

1. After business hours – the Nursing House Supervisor shall leave a message for the Director of Food & Nutrition that a designated unit will be closed and the date and time.

    a. Dietary personnel will remove all stocked patient food items and either utilize them to restock other patient care units or return to regular stock within the dietary department.

2. During business hours – the Department Director or designee or Nursing House Supervisor will notify the Director of Food & Nutrition that a designated unit will be closed and the date and time.

   a. Dietary personnel will remove all stocked patient food items and either utilize to restock other patient care units or return to regular stock within the dietary department.

INFORMATION TECHNOLOGY DEPARTMENT (IT):

- After business hours – the Nursing House Supervisor shall leave a message for the Director of IT as to where the Workstations On Wheels (WOWs) have been relocated for use by the staff. They will be accountable to leave a clear message for the Department Director or designee as to where their WOWs have been relocated.

  NOTE: It will be the responsibility of the Nursing House Supervisor to ensure that all WOWs being "loaned" to another department are clearly marked as belonging to their originating department.

- During business hours – The Department Director or designee and/or Nursing House Supervisor shall notify the Director of IT of the closure and where the WOWs are being relocated for staff use. They will be accountable to leave a clear message for the Department Director or designee as to where their WOWs have been relocated.

  NOTE: It will be the responsibility of the Nursing House Supervisor to ensure that all WOWs being "loaned" to another department are clearly marked as belonging to their originating department.

CRASH CARTS:

- The adult crash cart on the designated unit for closure shall be removed by either the Department Director or designee and/or the Nursing House Supervisor and returned to Central Processing Department (CPD) to be placed in circulation for use in the rest of the hospital.

  NOTE: The Pediatric BRASLOW cart shall be moved to the unit where Pediatric patients are to be housed when hospitalized.

OPENING A UNIT:

When it has been decided by the Department Director or designee and/or the Nursing House Supervisor to re-open a particular patient care unit (e.g. 3North, 3 South, 3East, 3West, Pediatric area, Telemetry and/or ICU), the individual making the decision shall notify the following:

DIETARY

1. After business hours – the Nursing House Supervisor shall leave a message for the Director of Food & Nutrition that a designated unit is to be opened and the date and time.

   a. Dietary personnel will restock all patient food items.

2. During business hours – the Department Director or designee or Nursing House Supervisor will notify the Director of Food & Nutrition that a designated unit is to be opened and the date and time.

   a. Dietary personnel will restock patient food items as needed.

INFORMATION TECHNOLOGY DEPARTMENT (IT):

- After business hours – the Nursing House Supervisor shall notify the appropriate department to return the "borrowed" WOWs to their home unit.
- During business hours – The Department Director or designee and/or Nursing House Supervisor shall notify the appropriate department to return the "borrowed" WOWs to their home unit.

CRASH CARTS:

- The adult crash cart on the designated unit for opening shall be retrieved from CPD storage aged prior to the closed unit receiving any patients.

SUBJECT: **CONTINUED STAY REVIEW**	SECTION: **Page 1 of 2**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

To promote effective and efficient use of hospital resources that will assure quality patient care and provide physicians with assistance in identifying alternatives to inpatient care.

POLICY:

Patients will be reviewed during their stay to ensure appropriate level of care, and appropriate utilization of resources.

AFFECTED AREAS/ PERSONNEL: *UTILIZATION REVIEW/CASE MANAGEMENT*

PROCEDURE:

1. On the assigned review date, the chart is screened using InterQual and/or Milliman Care Guidelines (MCG) continued stay criteria to ensure the patient still requires hospitalization.

2. The ***Utilization Review/***Case Manager verifies that there are no delays in treatment and that resource utilization is appropriate. Cases in which unrelated outpatient work-ups are scheduled after the primary problem has been treated are referred to the Physician Advisor (Chair of the Utilization Review Committee) or outside Physician Reviewer.

3. If the documentation does not reflect the need for continued hospitalization, the attending physician will be contacted for further information.

4. If the patient no longer meets the criteria for continued stay, the Physician Advisor or outside Physician Review will be contacted to review the case.

5. If the patient continues to require acute hospitalization, a new review date (not to exceed three days) is assigned.

6. If it is clear that continued stay is medically unnecessary, or that services will not be covered by the payor, the Physician Advisor or outside Physician Reviewer will request that Case Management (CM) issue a denial in accordance with all Peer Review Organization (PRO) guidelines. (See policy Hospital Issued Notice of Non-Coverage Guidelines).

REFERENCES:

- ~~The Joint Commission (2019). Hospital accreditation standards. Joint Commission Resources. Oak Brook, IL.~~

- California Code of Regulations (2022). Title 22, Chapter 7, Section 70717. Retrieved from ~~https://govt.westlaw.com/calregs/Browse/Home/California/CaliforniaCodeofRegulations?guid=ID7365A90D4BB11DE8879F88E8B0DAAAE&originationContext=documenttoc&transitionType=Default&contextData=(sc.Default)&bhcp=1.~~ https://www.law.cornell.edu/regulations/california/22-CCR-70717

- The Code of Federal Regulations, Title 42, Chapter IV, Part 456; 2023. Retrieved from ~~https://gov.ecfr.io/cgi-bin/text-idx?SID=081f76e24505608d15acede2e74ace93&mc=true&tpl=/ecfrbrowse/Title42/42cfrv4_02.tpl#0.~~
- https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-456

CROSS REFERENCES:

- Hospital Issued Notice of Non-Coverage Guidelines

SUBJECT: **DENTAL SERVICES**	SECTION:

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

To ensure residents' dental service needs are assessed and provided as needed.

POLICY:

It is the policy that each resident admitted to this facility shall be encouraged and assisted by all those responsible for his care to obtain and maintain an adequate level of oral health through periodic examination and other required dental treatments by the contracted dentist. The attending physician may elect to do the oral exam and will document in the History and Physical or in the Dental form provided. An oral/dental assessment will be completed after the resident's admission at the next scheduled dentist visit and annually thereafter.

The facility shall maintain an agreement with an Advisory Dentist to advise and assist the facility in providing proper dental care to all residents residing in the facility. All nursing personnel shall be properly trained in the correct procedures for resident oral hygiene, denture care, and for supervision and carrying out orders of the attending physician and/or dentist concerning medication, treatment and oral hygiene as written on the resident's chart. In addition, all nursing personnel shall be given in-service training so that they might recognize symptoms or oral pathology and report the same to attending physician and/or dentist annually.

All residents' dentures shall be properly cleaned and maintained as prescribed by correct hygiene procedures. All dentures shall be readily identifiable.

Contracted dentist will be available for dental emergencies. Dental emergencies are defined as broken teeth, abscessed tooth, and severe dental caries, which cause intense pain.

All dental complaints and/or appointments will be kept in a dental log maintained by the Social Services designee.

AFFECTED PERSONNEL/AREAS: *REGISTERED NURSE; DENTIST; SOCIAL SERVICE DESIGNEE, ATTENDING PHYSICIAN*

PROCEDURE:

The Administrator is responsible for the following procedures:

1. Initiates and maintains a written agreement with an Advisory Dentist for the facility.

2. Consults with the Advisory Dentist in matters affecting the dental health and dental care of the residents in the facility.

3. Evaluates, at least annually, the performance and effectiveness of the Advisory Dentist to determine if the facility's agreement should be renewed.

4. Ascertains that the Director of Nursing is maintaining proper dental care and oral hygiene procedures in the practices of all nursing services personnel.

The Advisory Dentist is responsible for the following procedures:

1. Provides dental consultation to the Administrator, licensed nursing personnel, and when necessary, the attending physicians.

2. Conduct, at least annually, in-service training in dental care, oral hygiene and dental pathology for the nursing staff at the facility.

3. Reviews the facility's Dental Service policy upon update, minimum annually, and recommends revisions when required.

4. When necessary, serves as a liaison between the resident's physician and resident's dentist.

5. When circumstances warrant, provides emergency dental services.

6. Advisory Dentist is allowed to bring his own equipment and supplies for use on the unit.

7. When necessary, the Advisory Dentist will do more extensive dental procedures in the Operating Room.

The Director of Nursing or designee is responsible for the following procedures:

1. Ascertains that all licensed personnel are checking their assigned residents to make sure they are receiving correct oral hygiene care and, that in weekly summaries, they are including information on the condition of the residents' mouth, teeth, dentures and gums as well as their general ability to chew and eat.

2. Ascertains that dental problems are addressed, when present, in the resident's Plan of Care.

3. Ascertains that all residents' dentures are identifiable.

4. If residents' dentures are lost or damaged, assures the dentist is contacted immediately and an appointment made to repair or replace the dentures. A theft and loss report will be made, an investigation of the loss will be conducted if necessary, and a dental consult will be made to replace the dentures.

5. Maintains a dental log of all complaints and/or appointments for residents.

Licensed Nurses are responsible for the following procedures:

1. Registered Nurse assesses the resident's dental/oral condition.

2. The Director of Staff Development/Speech Therapist gives instruction to nurse assistants at least annually in correct procedures for the resident's oral hygiene and dental care.

3. Checking the performance of residents and the conditions of residents to ascertain that they are receiving correct oral hygiene.

4. Making recommendations to the resident regarding "self-care" dental hygiene practices.

5. Checks residents' rooms to make sure that dentures and denture cups are being properly cared for by the nurse assistants.

6. Licensed Nurses will chart, in the weekly summaries and nurses' progress notes in the Electronic Medical Record, the condition of the resident's mouth, teeth, gums, tongue and dentures, as well as chewing ability and overall oral condition.

7. Contacting the physician (or Director of Nursing) when a dental problem/mouth problem is present.

8. Carrying out prescribed orders by the attending physician and/or dentist for treatment and medication for oral health problems.

9. Assisting the dentist when he/she visits a resident.

Nurse Assistants are responsible for the following procedures:

1. Giving oral hygiene and denture care – The mouth is one of the least clean areas of the body in terms of bacteria present. Therefore, extra care should be taken to maintain oral hygiene.

2. If at all possible, resident should brush after every meal. The mouth should also be rinsed at that time. In some cases, the resident can brush his/her own teeth.

REFERENCES:

- California Code of Regulations (2021). Title 22. §72031
  Retrieved from
  https://govt.westlaw.com/calregs/Browse/Home/California/CaliforniaCodeofRegulations?guid=ID7365A90D4BB11DE8879F88E8B0DAAAE&originationContext=documenttoc&transitionType=Default&contextData=(sc.Default)&bhcp=1.

- Med Pass, Inc. (Updated February 6, 2015) Facility Guide to OBRA Regulations, 483.55. United States of America, Med Pass Inc.

CROSS REFERENCE:

- SVMC Policy and Procedure: THEFT AND LOSS

PURPOSE:

To define a single, comprehensive system for the development, communication, and control of new and revised medical record forms.

To assist in interdisciplinary communication and involvement of new or revised medical record forms and forms containing patient health information (PHI).

To assure the appropriate review of medical record forms and forms containing PHI are within acceptable parameters for effective documentation for quality care.

AFFECTED AREAS/PERSONNEL: *ALL HOSPITAL PERSONNEL AND DEPARTMENTS*

DEFINITIONS:

Medical record paper form: Any Sierra View Medical Center (SVMC) approved paper filled permanently in the medical record and identified by an official form number assigned by Materials Management.

Medical record electronic template: Any SVMC electronically-created template for the medical record.

Document owner: The department initiating a new or revised medical record form.

Clinical worksheet: Any clinical worksheet or data collection sheet for internal clinical purposes containing PHI.

POLICY:

1. All new and revised medical record forms that are part of the medical record by either electronic creation, scanning or imaging upload and include, but are not limited to, clinical, administrative, and research information must be submitted to the Health Information Management (HIM) Director.

2. All new and revised medical record forms will be processed through an approval process, which may include approvals by various medical staff and/or committees and final approval by MEC (Med Exec) and the Board.

3. All clinical worksheets or data collection worksheets containing PHI must be submitted to the HIM Director for review and verification of formatting. Must contain: THIS IS NOT PART OF THE PERMAMENT MEDICALR ECORD, RETURN TO:

PROCEDURE:

1. Requests to create or change a medical record form (electronic or paper) are submitted to the HIM Director.

2. All medical record forms must be reviewed and approved by the Director of Health Information Management and all appropriate committees to assure the content, format and completion mechanisms are in place and documentation meets appropriate regulatory requirements

3. The document owner is responsible to verify that the abbreviations on the form comply with the Approved Abbreviation list. Whenever space permits, abbreviations should not be used.

4. The document owner is responsible for any associated policy and procedure update or creation, the education, and implementation of the new or revised form (electronic or paper).

5. Once all appropriate approvals are completed, final approval is provided to the forms vendor for production. Production of a medical record form is 10-15 business days from the approval date.

6. Forms which have been approved may not be altered in any way without re-submission.

7. Delivery of medical records forms include, but may not be limited to:

   a. Clinical Forms are delivered by the vendor in the appropriate unit-specific cart(s).

   b. Non-Clinical forms are delivered and distributed by Materials Management to the appropriate department.

CROSS REFERENCES:

- ABBREVIATIONS IN THE MEDICAL RECORD
- POLICY AND PROCEDURE SYSTEM

SUBJECT: **PATIENT DEATH**	SECTION: ***Provision of Care, Treatment and Services (PC)*** **Page 1 of 8**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

To outline the process to be followed when a patient expires in the hospital.

POLICY:

All patients who expire in the hospital setting will be treated with respect and dignity. Nursing personnel will offer consolation/assistance to the family in their time of grief and will offer assistance in obtaining religious support as requested. Additionally, nursing personnel will report deaths to the appropriate authorities as indicated by the law and will facilitate the timely removal of the body to the appropriate mortuary.

AFFECTED AREAS/PERSONNEL: *ALL PATIENT CARE AREAS*

PROCEDURE:

PRONOUNCEMENT

1. When a patient expires in the hospital, pronouncement of death will be made by a physician in attendance of the patient (i.e., Emergency Department (ED) physician, primary physician, Code Blue Team Leader).

2. Patients who have a "No Code" or "No Code with Comfort Measures" may be pronounced dead by a registered nurse (RN) who has successfully completed the Standardized Nursing Procedure for Pronouncement of Death.

ORGANIZATIONAL REPORTING

1. Notification of appropriate personnel, including:

   a. Nursing Shift Manager – contacts administrative representative if necessary

   b. Primary Care Physician and/or consulting staff– if not in attendance at death

   c. Patient Unit– if patient is off the unit (i.e., Surgical Services Department, Radiology Department)

   d. Admitting/Patient Registration Department

   e. Clergy– if appropriate.

2. At or near the time of notification of death of any patient, the Donor Network will be contacted for assistance in determining organ donor potential. (*Complete information worksheet for reporting deaths.)*

CORONER'S CASES

It is the decision of the Coroner to determine the extent of the investigation necessary. He/she may instruct how to release the body without investigation. *(See: Deaths Reportable to the Coroner policy)*

NOTIFIICATION OF DEATH TO FAMILY/NEXT OF KIN

1. Before notifying the family, the nurse who will notify the family shall verify the identity of the decedent and the correct family member who is to be called.

2. Timing notification: Families desire to be contacted about a death immediately, regardless of how late at night it is.

3. Physical Surroundings: It is never a good idea to notify someone of a death in a public area. When families hear the news of death in a formal setting, they are more likely to be psychologically prepared to accept the reality of the death. Escort IMMEDIATE FAMILY to a private room. The room should be a place where the family can remain for some time, uninterrupted by other staff or visitors. For their own safety, have those present sit down before breaking the news. Interacting with family at the hospital may facilitate other matters (i.e., mortuary preference, tissue/organ donation, etc.).

4. Telephone Notification: Even though most initial family contacts are made by phone, the telephone is a poor instrument for ACTUAL notification of death. Statements such as "I'm told he isn't doing well" or "I'm told he has been badly injured – could you come in right now?" may be appropriate to facilitate prompt family responses. Plan to direct the conversation to avoid telling more than is appropriate for the circumstances. Do not force notification.

a. Make sure family members know exact address of the hospital and easy-to-follow directions, including both the route to the facility and where to go upon arrival.

b. Give the full name and location of the person to contact on arrival at the hospital and inform security to let them in.

c. If family members are adamant about receiving notification over the telephone, respect their right to know. If family member appears hesitant or unable to cope, offer to speak to someone else present. After the notification, find out if the person is home alone. If asked before, the person might suspect "crank" call or it could produce extreme anxiety. Never ignore reported thoughts of suicide or homicide. If someone threatens suicide at such a time, stay on the phone and talk it through. Try and locate a trained professional to go to the home while you continue on the phone. If the person hangs up, call local police immediately. If there is no adult in the home, ask the oldest child how to get in touch with an adult relative. If there is no address, depend on public personnel to obtain one via phone number. d. If the family lives more than one hour from the hospital, telephone notification should be considered.

5. Sequential Notification Technique

a. The person reaching out to the family should ask the family members what they already know about the situation.

b. Give a BRIEF description of additional events that led up to the patient's arrival at the hospital.

c. Give information regarding the resuscitative efforts made on behalf of the patient at the hospital.

d. Conclude with the victim's response to the treatment, the statement of death, and a brief explanation of the cause of death.

e. NEVER START the death notification with the statement of death. NEVER begin with the statement, "I have bad news for you" or "I'm sorry, but…".

f. Sit close, be willing to listen and give empathetic responses. It is also important to touch, hug and even cry with those in grief.

g. Do not reinforce denial. Speak of deceased person in appropriate terms such as "How was he?"

h. Restrain and seek out a physician if any consideration is made to potentially sedate, and then as absolutely as necessary. Sedation produces numbness and blocks the pain. Feeling pain and crying is part of the emotional response to grief.

6. When information is of a sensitive nature, use terminology such as "alleged," reportedly," or "appears to be" – In case of homicide, DO NOT contact family members or notify anyone of the death without SPECIFIC permission from investigating law enforcement staff.

NOTIFICATION OF THE CORONER

1. Call the Tulare County Sheriff's Department Dispatch Center as soon as possible to decrease waiting time. The appropriate person will be dispatched to take the report.

2. Do not release the body to the mortuary until instructed to do so by the Coroner's investigators or Deputy Sheriff.

3. All known facts relating to significant health history, circumstances surrounding the death, or any other information should be documented on the patient's chart.

4. Cases of special interest and all trauma deaths should be communicated to the staff pathologist by the attending physician and/or the ED Physician to provide first-hand information in the determination of cause of death and need and extent of autopsy.

5. In trauma deaths and/or for known autopsy requests, on the Release of Remains form, write "**DO NOT embalm until discussed with Pathologist**". This alerts the mortuary to possible special circumstances.

CARE OF THE BODY

1. If the patient is **NOT** a Coroner's Case, the lines can be removed and the patient prepared for family viewing and disposition to the mortuary.

2. A registered nurse (RN), licensed vocational nurse (LVN), certified nursing assistant (CNA), or operating room (OR) technician may perform post mortem care as outlined:

   a. Body alignment, general cleanliness, and closure of the eyes

   b. Removal of tubes and catheters

   c. Replacement of dentures or give to mortuary

   d. Jewelry – note type and location on body. DO NOT remove if Coroner's case **(see below).**

   e. Labeling of body – ensure patient ID band is in place on patient's body.

3. Post mortem care must not be given when the interventions conflict with the religious affiliation of the patient.

FOR CORONER'S CASES – CARE OF THE BODY

1. Once the patient has been pronounced dead, the body will **NOT** be searched. Determining the identification will be the responsibility of the Coroner's Investigators. No valuables (money, jewelry, watches, wallets, etc.) should be removed or given to the family members if requested. Once the investigation is complete, the Coroner will handle release of effects.

2. All tubes, IV lines (fluids can be turned off), etc., should remain in place and undisturbed in all trauma related deaths and possible suicides or homicides. The investigating officer may request their removal on completion of their preliminary investigation.

FETAL DEATHS

1. Fetal deaths **beyond the 20th week** of gestation, which occur in the Emergency Department, will be reported to the Coroner. The gestational age is the interval from date of last normal menses to the estimated death date of the fetus.

2. For **inpatient settings** – the fetal death is reported for the following:

   a. If the mother is involved with criminal activity or tests positive for illegal drugs.

   b. Death involving trauma.

c. Death over **20 weeks** where the mother has **NOT** received prenatal care **AND** the cause of death is not apparent (i.e., nuchal cord around the neck).

NOTE: The MD can choose to sign the death certificate and needs to state "Intrauterine Death, etiology undetermined". If the MD is comfortable signing the death certificate based on autopsy findings, the Coroner does not need to be notified. If there is any doubt regarding the criteria, contact the Coroner.

3. Fetal Burial will be necessary based on the following criteria:

a. Any live birth must be buried by a mortician. A live birth has occurred when a heartbeat, breathing, crying or movement of voluntary muscle occurs.

b. A stillbirth must be buried by a mortician if any two (2) of the following occur:

- Over 20 weeks gestation.
- Over 500 grams in weight (17 oz.)
- Over 28 cms in length (11 in.)

CARE OF THE FAMILY

1. Persons accompanying the patient will be made comfortable in a quiet room.

2. If family is not present at the hospital and does not know of the patient's accident, illness, or death, they should be contacted by phone and asked to come to the hospital. Notification of death by phone should be avoided. If identification of the patient or family's location is unknown, it will become the responsibility of the Coroner's Office to make the notification.

3. Always be sure that the next of kin have been notified before giving out names of the deceased to news media.

4. Informing the family of the death should be the duty of the physician. Support of nursing personnel is important. If prolonged resuscitation efforts are being done, a nurse should see that the family is kept informed of what is being done and the patient's response and prognosis. Such preparation for the final announcement may be helpful to the family and staff.

5. Family members who wish to view the body will be assisted to do so, if possible. Nursing and physician judgment is important.

6. A staff member should be assigned to assist the family in calling religious assistance, other family members, obtaining transportation, etc.

7. Prior to leaving the hospital, a responsible family member should be asked to make known their preference for mortuary.

8. The family member should be asked to sign the "Authority for Release of Remains" form. This form remains on the patient's chart. The mortuary also signs the form when the body is picked up.

NO MORTUARY PREFERENCE / NO FAMILY AVAILABLE / MORGUE SERVICES:

If there is no mortuary preference given or family is not available to make a preference known, the on-call mortuary should be contacted (see schedule below) to remove the deceased and placed in their Morgue. ***At no time should the body remain in the hospital setting longer than 4 hours***.

Porterville

Myers – EVEN months
248 North E. Street
784-5454

Porterville Funeral & Cremation – ODD months
765 W. Henderson
784-6485

Lindsay

Webb-Sanders – EVEN months
163 S. Mirage Avenue
562-3084

Myers – ODD months
199 Honolulu Street
562-7015

At the time of signing the "Release of Remains", an inquiry will be made to the family regarding the patient's possible desire to be a tissue donor (bone, skin, corneas). The responses will be documented on the form. Donor Network will reach out to the family of the patient.

DOCUMENTATION

1. The physician is responsible for the following:

   a. Completing the Death Certificate or Medical Examiner's form, whichever is appropriate.

   b. Completing a note in the patient chart.

   c. Obtaining an autopsy permit if applicable.

2. It is the responsibility of the nurse to complete the patient record (i.e., Code Blue Form, Operating Room Nurses Notes, Emergency Department Flow Sheet). The documentation will include:

   a. the sequence of events,

   b. time of death,

   c. name of physician who officially pronounced the patient dead, and

d. disposition of the body.

REFERENCE:

- Title XXII, §70829 (2019). Retrieved from https://govt.westlaw.com/calregs/Browse/Home/California/CaliforniaCodeofRegulations?guid=ID7365A90D4BB11DE8879F88E8B0DAAAE&originationContext=documenttoc&transitionType=Default&contextData=(sc.Default)&bhcp=1.

CROSS REFERENCES:

- Patient Care Services Manual -- (1) Standardized Nursing Procedure for Pronouncement of Death, Code Status Order Form, Potential Organ & Tissue Donor.
- Deaths Reportable to the Coroner

SUBJECT:	SECTION:
PEDIATRIC ROOMING-IN AND PARENT PARTICIPATION	**Page 1 of 2**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

The Pediatric Area in the Clinical Decision Unit encourages the participation of parents during the hospitalization of their child. Nursing will work with the parents as they participate and help them to understand their child's illness. Parent/child education will be initiated so that appropriate care will be continued after discharge.

POLICY:

The nursing personnel must observe all children and carry out procedures on a 24-hour basis regardless of the parent's absence or presence. The staff assumes responsibility for the child's welfare, even though some procedures are delegated to the parent.

AFFECTED PERSONNEL/AREAS: *CLINICAL DECISION UNIT STAFF*

PROCEDURE:

1. Accommodation:
   a. The nurse in charge is notified and a cot is provided in a private room.
   b. The cafeteria is available for families to dine while they are staying with the patient.
2. Isolation:
   a. Rooming-in parents will be expected to follow isolation procedures as outlined by the nursing staff.
   b. All visitors will be asked to follow isolation protocols as appropriate
3. Safety:
   a. Although a cot is provided for the rooming-in parent, **all patients must sleep in their crib/bed.**
   b. Crib rails will be fully raised at all times.
   c. Bed rails are to be up X3 with lower rail closest to bathroom down, as per fall risk policy.
   d. Fall risk precautions are to be followed at all times on all pediatric patients. (See fall preventions policy)
4. Valuables:

Rooming-in parents are encouraged to leave all valuables at home.

5. Parent Participation:

   a. Every effort is made to involve and include the parent in the care of their child. This includes, but is not limited to:

   - Assisting at bath time.
   - Feeding or assisting at meals.
   - Participation in recreational activities.
   - Assisting with procedures which may eventually be required at home.
   - Parent/child education regarding plan of care and discharge.
   - A parent may be requested to leave the room by medical or nursing staff for certain tests, procedures or treatments.

REFERENCE:

- Nettina, S. (2019). Lippincott Manual of Nursing Practice (11th ed.). Lippincott-Raven, Ambler, PA.

CROSS REFERENCE:

- Fall Prevention (Adult and Pediatric) Policy

SUBJECT: THERAPEUTIC PHLEBOTOMY	SECTION: Page 1 of 4

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

To provide guidelines for removal of excess peripheral blood volume for the treatment of Hemochromatosis, Polycythemia Vera, Porphyria Cutanea Tarda and other hematologic disorders.

DEFINITIONS:

- ***Phlebotomy:*** Procedure to remove blood from a person, usually 250cc to 500cc.
- ***Hemochromatosis:*** Iron overload disorder or iron loading disorder.
- ***Polycythemia Vera:*** Chronic life-shortening Myeloproliferation disorder, characterized by an increased red cell mass (from a single cell clone).
- ***Porphyria Cutanea Tarda:*** Most common type or porphyria. Associated with chronic liver failure, characteristic skin lesions and blistering and erosions of sun-exposed areas.

POLICY:

Therapeutic phlebotomy will be performed at the Cancer Treatment Center by nursing staff under the direct supervision of a provider, qualified to assist in an emergency.

AFFECTED PERSONNEL/AREAS: CTC NURSING STAFF

EQUIPMENT:

- Blood collection kit with needle (16 or 17 gauge)
- Blood pressure assembly
- Tape
- Gauze dressing and tape
- Tourniquet
- Stress ball

SPECIAL PRECAUTIONS:

- Patients should be well hydrated prior to the procedure. Offer oral fluids.
- Withdrawal should not exceed a maximum of 500cc of blood (450cc = 1 pound or 1 unit) to be removed at any one time unless otherwise ordered by provider, with relevant supporting data. If more than one unit is to be removed during the procedure, consider obtaining an order for and starting an IV for fluid replacement.

- If systolic blood pressure is less than 90 mmHg and or pulse greater than 130 beats per minute, contact provider before proceeding with phlebotomy
- Relevant target levels as pertains to the diagnosis (i.e. Hemoglobin, hematocrit, ferritin) should be specified, obtain clarification from ordering provider if necessary, hold once target(s) achieved.
- Appropriate protective apparel should be donned while performing phlebotomy (gloves).

Adverse reactions include fainting, dizziness, nausea/vomiting, hyperventilation, hematoma, bleeding, convulsing, cardiac and respiratory difficulties. Observe the patient closely. DO NOT LEAVE the patient alone during or after the procedure for 15 minutes. In the event of an adverse reaction stop the procedure immediately, institute Basic Life Support (BLS) measures to sustain life if necessary. Summon backup help at the outset of any resuscitation effort and call 9-1-1 for patients with unstable vital signs.

PROCEDURE:

1. Obtain chart and supplies
2. Offer the patients fluids of choice.
3. Obtain physician's order specifying amount to be withdrawn, frequency, and desired target levels.
4. Explain procedure to the patient.
5. Obtain written consent of the patient.
6. Collect vital signs prior to beginning procedure.
7. Place the patient on a stretcher chair (converts to supine position) or bed
8. Identify antecubital fossa or accessible vein and put on gloves.
9. Wipe phlebotomy site thoroughly with alcohol or chlorhexidine swabs using a circular motion from the center of the site out.
10. Insert needle into the vein and secure with tape. After the tubing is attached release the tubing. Blood should be flowing freely into the bag.

11. Monitor vital signs and observe patient throughout the procedure and 30 minutes after the procedure is over.

12. When the desired amount of blood has been withdrawn, clamp the tubing remove the needle and place gauze over the entry site, keeping constant pressure on the site for the next five minutes.

13. Hold unclamped tubing up to allow blood to drain by gravity into the bag, clamp tubing dispose of blood, bag tubing and needle in a small red hazardous waste container.

14. If there has been no bleeding at the venipuncture site for 5 minutes, apply a dressing Take care to maintain circulation and patient comfort. Patient should remain lying down for at least 10 minutes after phlebotomy.

15. Repeat vital signs.

16. Document phlebotomy site, vital signs before and after, amount of blood taken, patient tolerance of the procedure and any adverse reactions, the duration of the procedure, patient teaching.

17. Review After Phlebotomy discharge instruction with the patient.

INSTRUCTIONS TO PATIENT AFTER PHLEBOTOMY

1. If you experience bleeding from the needle site in your arm, apply firm pressure and raise your arm straight up for 5 to 10 minutes with your fingers over the bandage at the puncture site. If this does not stop the bleeding, you should proceed to the Emergency Department or consult a provider as soon as possible.

2. If you should feel faint, light "headed", or dizzy after leaving the Hospital, sit down immediately, and put your head lower than the rest of your body until the feeling disappears. If such feeling continues, call your provider or go to the Emergency Department.

3. You may resume your normal (non-strenuous) physical activities upon discharge from the Cancer Treatment Center. We advise you not to participate in any strenuous physical activity or return to hazardous occupation for at least 24 hours following phlebotomy.

REFERENCES:

Infusion Nurses Society (2016). Infusion Therapy Standards of Practice. pp 138-139. Retrieved from https://source.yiboshi.com/20170417/1492425631944540325.pdf

UptoDate (2022). Prognosis and Treatment of Polycythemia Vera and Secondary Polycythemia. Retrieved from https://www.uptodate.com

AABB Reference Standard 5.4.1A

AABB Technical Manual, 20th Ed., pp 144

American Red Cross (2022). What to do Before, During and After Your Donation. Retrieved from https://www.redcrossblood.org/donate-blood/blood-donation-process/before-during-after.html

CROSS REFERENCES:

Physician Notification Criteria Policy
Emergency Response and Transfer Policy

SUBJECT: **TUBE FEEDING**	SECTION: **Page 1 of 3**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

To standardize enteral feeding administration and promote patient safety while receiving enteral feeding.

POLICY:

Enteral feeding products will be ordered, received, and stored by the Food and Nutrition Services Department. Any damaged products will be disposed and customer service will be notified.

1. Enteral feeding containers will be rotated using first in, first out (FIFO).

2. Tube Feedings (enteral feedings) are handled and administered using methods that minimize the risk of contamination of the feeding. Formulas are purchased from approved vendors and closed system feedings are used as part of Hazard Analysis Critical Control Point (HACCP) procedures per Enteral Formulary endorsed by Pharmacy and Therapeutics Committee. Modular nutrient components, food grade coloring, medications or water (formula dilution) are not added to enteral formula containers. Full strength formulas are used.

3. Modality:

    a. Continuous Feeding: Pump-assisted continuous drip infusion.

    b. Cyclic Feeding: Pump or gravity drip over a time period that is less than 24 hours. Nocturnal feeding is a form of cyclic feeding.

    c. Intermittent Feeding: Feeding by pump or gravity drip, administered in a timeframe ranging from 20-60 minutes, provided anywhere from 4-6 times per day.

    d. Bolus Feeding: Providing a set volume of formula at specified times over a very short period of time. A typical feeding regimen might provide 240 mL of formula over a 4 to 10 minute timeframe, with infusions 3-6 times per day. Bolus feedings typically mimic normal meal patterns.

4. Open vs Closed Systems:

    a. Closed System: Ready to hang sterile closed system formulas can hang up to 48 hours per manufacturer's guidelines. If more than one feeding set is used or if more than one RTH container is used with a single feeding set, the maximum safe hang time is 24 hours.

    b. Open System (sterile decanted formula) are limited to a hang time of (8) eight hours. Reconstituted powder formula is limited to a hang time of (4) four hours. Administration sets, and feeding bag, for open system enteral feedings should be changed at least every 24 hours.

5. Formulas reconstituted in advance should be immediately refrigerated and discarded within 24 hours of preparation if not used. Formulas should be exposed to room temperature for no longer than 4

hours after which they should be discarded. Use purified water or sterile water for irrigation supply and formula reconstitution.

6. Orders for non-formulary products are substituted per protocol as approved by Pharmacy and Therapeutics Committee. If there is no equivalent formulary product, or "no substitution" is indicated by the ordering physician, the product will be special ordered, if able. Expired formulas are not used.

7. ICU Standard of Care order set: Please see electronic orders for TF regimen

8. Non-Critical Care Area Guidelines for Gastric Residuals:
   Gastric residual volume (GRV) will be checked once per shift
   If <250ml, then return residual, continue infusion
   If >250ml **and** symptoms of intolerance are present (abd distention, nausea, vomiting, diarrhea) hold feeding and notify MD. Return up to 250ml GRV
   If >250ml **without symptoms** of intolerance, return up to 250ml GRV, continue feeding and recheck in 2 hrs. If still greater than 250ml, hold feeding and notify MD

AFFECTED PERSONNEL/AREAS: *FOOD AND NUTRTITION SERVICE, PATIENT CARE AREAS*

PROCEDURE:

1. Food and Nutrition Services is notified of any patient/resident on enteral feeding via the electronic medical record as a Diet order, in the Dietary Special Needs category.

2. Nursing will order an enteral pump and tubing set from Distribution.

3. The enteral tube feeding order should specify the modality, feeding rate or amount per feeding, total number of feedings per (24) hours and water flushes. Food and Nutrition Services supplies the enteral products. The dietitian must be consulted for all enteral feeding orders.

4. Any pouring or mixing of a powdered product is done by Nursing or Nutrition Services according to the product label. Any mixed product is immediately placed in the delivery container in a quantity that would limit hang time to four hours. The formula should be labeled with the patient's/resident's name, room number, date, time, formula, #ml per hour, and strength.

5. All tube feedings are administered using clean technique.

6. Tube feedings should be started as per the physician's order. The rate should be increased to goal rate over the next 24 - 48 hours as tolerated.

7. DPSNF: The dietitian is responsible for completing a nutrition assessment on the patient/resident within (72) hours of the tube feeding initiation. Recommendations regarding the appropriateness of the product, volume, calories, protein, fluid needs, and percentage of the Dietary References Intake (DRI) for all vitamins and minerals will be addressed.

8. Drug-Nutrient Interactions: All patients shall be monitored for potential drug-food interactions. Dietitians will calculate accordingly and change to bolus feeds if necessary. *Refer to policy: "Drug Nutrient Interaction and Enteral Tube Feeding Interaction."*

9. Cranberry juice and/or soda should not be used to unclog a feeding tube. To unclog a tube, use warm water, or crushed sodium bicarbonate 325 mg tablets or crushed pancrease MT 10.

CROSS REFERENCES:

- DRUG/NUTRIENT INTERACTIONS AND ENTERAL TUBE FEEDING DRUG/NUTRIENT INTERACTION

REFERENCES:

- **Krames on Demand: Gastroenterology ->Tube Feeding**
- CIHQ Acute care Accreditation, Nutrition Assessment and Care Plans (2023) California Department of Public Health, Retrieved from https://www.cdph.ca.
- Centers for Medicare and Medicaid Services, Conditions of Participation (2023). Retrieved from https://www.cms.gov/Regulations-and-Guidance.
- American Society of Enteral/Parenteral Nutrition (ASPEN) Guidelines for the Provision and Assessment of Nutrition 2016
- 2019 Abbott Nutrition Best Practice for Managing Tube Feeding, A Nurse's Pocket Manual
- American Society of Enteral and Parenteral Nutrition (ASPEN) Critical Care Guidelines 2021
- The ASPEN Adult Nutrition Support Curriculum 3rd ed. 2017
- ASPEN 2014 Gastric Residual Volume in Critically Ill Patients: A Dead Marker or Still Alive?

SUBJECT: **WAIVED & POINT OF CARE TESTING - CLINITEK STATUS CONNECT PLUS PROCEDURE -**	SECTION:

PURPOSE:

This document outlines policies and procedures that deal with automated urine dipstick testing. In an effort to be concise, some information may be excluded from the manufacturer's recommended procedure. It is recommended that operators familiarize themselves with the manufacturer's product information that accompanies each package.

SCOPE:

To assure appropriate equipment, personnel, and processes are in place for accurate and efficient urinalysis dipstick testing.

AFFECTED PERSONNEL: *CLINICAL LAB SCIENTISTS (CLS), REGISTERED NURSES (RNs), LICENSCED VOCIATIONAL NURSES (LVNs), SIERRA VIEW COMMUNITY HEALTH CENTER (SVCHC) MEDICAL ASSISTANTS (MAs), EMERGENCY ROOM TECHNICIANS*

TESTING SITES:

Sierra View Medical Center (SVMC) Urology Clinic, Sierra View Community Health Center (SVCHC), Academic Health Clinic (AHC)

PRINCIPLE:

The CLINITEK Stratus Connect Plus Analyzer is a **waived** instrument for in-vitro diagnostic screening using Siemens Multistix Reagent Urinalysis Strips. The optical system consists of six light emitting diodes, a light guide, a mirror, a lens and a detector. Light from the LEDs travels along the light guide and is reflected off the calibration bar onto the mirror. It is then directed through an aperture plate onto the lens, from where it is focused onto the detector. The light intensity detected is converted into electrical impulses, which are processed by the instrument's microprocessor and converted into clinically meaningful results.

Performed <u>ONLY</u> at the SVCHC and AHC

hCG: CLINITEST hCG Pregnancy Test is a chromatographic immunoassay (CIA) for the rapid determination of hCG in the urine. The membrane is precoated with anti-hCG capture antibody on the test line region (T) and goat anti-mouse IgG antibody on the control line (C). During testing, the urine specimen is allowed to react with colloidal gold particles coated with anti-beta hCG monoclonal antibody. The mixture then chromatographically moves along the membrane by capillary action. For a positive or borderline result, a pink-colored line with a specific antibody-hCG-antibody-colloidal gold particle complex will form on the membrane next in the test line region. A pink-colored line at the reference region (R), the area between the control line in the test line region, indicates a negative result. The appearance of a colored line in the control

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region and the reference region serves as verification that sufficient volume has been added and the proper flow occurred.

Regulatory Requirements:

The sites will have a documented quality control program, which is developed by and approved by the SVMC Lab and the CLIA Director.

- A physician's order is required prior to performing the test.
- Universal precautions must be observed when handling any patient specimen.
- The SVMC Hand Hygiene policy must be adhered to at all times.

All test results will be maintained in the Laboratory Information System (LIS) and the electronic health record.

The test report will include the following:

1. Patient's name
2. DOB
3. Date and time collected, performed and reported
4. Ordering physician
5. Reference range
6. Test units
7. Lab name

All quality control records with remedial actions will be kept in the clinic log book to be reviewed at least monthly by lab.

All product information (reagent lot #s with expiration dates) will be kept in the clinic log book.

Additional records kept by the Education Department of SVMC:

1. Monthly QC records
2. Proficiency Testing (PT) records

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Competency Assessment

All operators must read the procedure manual and complete the "Clinitek Status Connect Plus Training and Competency Record" during the initial training. Competency is assessed at orientation and annually using at least two of the following methods:

1. Performing a test on a blind specimen.
2. Lead Urinalysis CLS observes performance of routine work.
3. Each user's quality control performance is monitored.
4. Written testing specific to the method.

Only approved operators are allowed to use the machine and report results.

Competency validation is tracked electronically in the learning management system. Competency forms will be placed in employee competency files.

Calibration

The instrument uses the white calibration bar on the test table to calibrate before a test is carried out. Before positioning the test table behind the shutter for analysis, the calibration bar is positioned under the reflected "read area" for calibration to be performed by the operator.

Storage of Equipment & Supplies

Equipment and supplies will be stored at appropriate temperature per manufacturer's instructions. Electronic thermostat's are located in the supply storage locations. Staff are responsible for ensuring required temperature levels for equipment and supplies are maintained, documenting on the daily monitoring log. Link to print log is located under policy Cross References.

Quality Control

For urine chemistry, positive and negative control solutions are tested daily. The Bio-Rad Liquid Check controls level 1 (negative) and level 2 (positive) will be used. This provides a check to ensure the test strips are reacting correctly and the instrument is reading the strips and hCG Cassette properly. Testing controls also helps detect errors caused by incorrect user technique. Controls for **Urine Chemistry** must be tested at the following intervals:

- At the start of every day of patient testing.

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- When a new bottle of test strips is opened.
- Whenever test results are in doubt.
- When training instrument operators.

Controls for the **CLINITEK hCG** will be tested at the following intervals:

- Monthly
- With new shipment of cassettes
- When training instrument operators

Note: Allow controls to come to room temperature if refrigerated. New lots must have QC range verified by running with the old lot. The new lot will be verified by the lead urine CLS.

Specimen

Collect a FRESH urine specimen in a clean, dry container. Label the specimen cup using a label generated from the label printer. The label will contain the two patient identifiers (Name, DOB). Mix well before testing. Urine should be tested immediately.

Procedure for Urine Chemistry

1. Remove a reagent strip from the bottle and replace the cap tightly. Touch **START** and the display will change to the second **Prepare Test** screen. The time available for test preparation is counted down by the digital timer and countdown bar. You have approximately 8 seconds to complete these 4 steps:

    a. Dip the reagent strip into the urine sample, ensuring that all test pads are wet.

    b. Immediately remove the strip from the urine, dragging the edge of the strip against the side of sample container to remove excess urine.

    c. Blot the edge of the strip on a paper towel. Do not drag strip across towel.

    d. Place the reagent strip, with the test pads facing up, into the strip holding channel of the test table. Slide the strip along the test table until it touches the end of the channel. Be sure not to move or bump the table. At the end of the 8 second countdown, the test table with strip will automatically be pulled into the instrument, stopping first to be calibrated

then for the position of the strip in the test table to be checked. After these stops, the test table will be retracted completely and the shutter will close.

2. When the urine results are ready, the Results screen is displayed. The first page of the test results is displayed on the screen and the test table and strip is automatically pushed out of the analyzer.

3. Press DONE to transmit results to the electronic medical record.

4. Remove the used test strip and discard in the trash. Use a clean cotton swab to gently wipe the test table to prevent carryover to the next sample.

5. Results will post on computer screen of LIS for operator to verify results.

Reference Intervals

Protein	Negative
Blood	Negative
Leukocytes	Negative
Nitrite	Negative
Glucose	Negative
Ketone	Negative
pH	5 – 9
Specific Gravity	1.001-1.035
Bilirubin	Negative
Urobilinogen	≤1.0 mg/dl

Procedure for hCG

1. Collect the specimen in the same way as Urine Chemistry.

2. Turn on CLINITEK Status and turn insert so cassette holder is facing upwards.

3. Touch the **Cassette Test** screen button. Remove cassette from the pouch and place it onto test table.

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4. Touch **Start** (You have 8 seconds to complete step 4.) Holding the pipette at a slight angle, squeeze the upper bulb and draw enough sample into the pipette to fill the stem completely, with an overdrawn amount going into the reservoir (lower bulb). Then discharge the sample in the pipette stem into the sample well of the cassette by squeezing the upper bulb in one squeeze. The excess fluid will remain in the reservoir. Do not push or pull the test table. Do not reuse the provided pipette or use any other pipette with the CLINITEST hCG product.

5. The test table will automatically be pulled into the instrument. When analysis is complete, the results screen will be displayed and the result will be transmitted to the computer screen for verification.

Interpretation of Results

1. **Positive:** The instrument will automatically determine if the Test (T) region intensity is equal to or more intense than a 25 mIU/ml urine sample and that the Control (C) and Reference (R) regions meet minimum intensity specifications.

2. **Borderline**: Result is indeterminate, repeat in 48-72 hours.

3. **Negative**: The instrument will automatically determine the Test (T) region is less intense than the 25 mIU/ml hCG concentration levels that the device can detect, and confirms that the Control (C) and Reference (R) regions meet minimum intensity specifications.

4. **Invalid**: The instrument will automatically determine is a procedural error or test reagent deterioration had occurred by confirming that the Reference (R) and control (C) meet minimum intensity requirements. If not, the user will be advised to repeat the test and to contact local technical support if the problem persists.

Reference Interval

hCG	Negative (Non-Pregnant)

REFERENCES:

- Clinitek Status Connect Plus operator manual, Siemens Multistix 10SG package Insert 6/10, CLINITEST hCG Pregnancy Test package insert 6/15.

CROSS REFERENCE:
Daily Temperature Log

SUBJECT:	SECTION:
WAIVED & POINT OF CARE TESTING - COMPETENCY AND QUALITY	*Care of Patients (TX)* **Page 1 of 6**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

To ensure that all Waived and Point of Care Testing (POCT) at Sierra View Medical Center (SVMC) and Sierra View Community Health (SVCH) Clinic is performed consistently according to established policy for the maximum benefit of patients and care providers.

DEFINITIONS:

1. **Waived Test:** As defined by Clinical Laboratory Improvement Amendment of 1988 (CLIA'88), waived tests are simple tests with a low risk for an incorrect result. They include certain tests listed in the CLIA regulations, tests cleared by the Federal Drug Administration (FDA) for home use, and tests approved for waiver by the FDA using the CLIA criteria. Sites performing only waived testing must have a CLIA certificate and follow the manufacturer's instructions; other CLIA requirements do not apply to these sites.

2. **Point of Care Test (POCT)**: "Point-of-care testing" is a phrase used to describe the location where testing is performed, such as at the bedside or near the site of patient care. While some point-of-care tests are approved for a CLIA waiver, advances in technology that enhance the rapidity of testing are allowing more complex, non-waived testing to be performed at or near the site of patient care.

3. **Regulatory Compliance**: CLIA '88 set standards to improve the quality of testing in all laboratories, passed by Congress in 1988. According to CLIA, all sites where testing is performed must be registered with the Centers for Medicare and Medicaid Services (CMS) and must hold a certificate of accreditation. The agency that provides the accreditation must have deemed status equivalent either to that of CMS or The Joint Commission (TJC).

POLICY:

All waived and point of care tests used to provide information for screening, diagnosis, prevention or treatment of any disease or impairment shall meet all regulatory requirements as required by the Centers for Disease Control (CDC) under CLIA and TJC. The accountability to monitor regulatory compliance of the program is the responsibility of the Medical Director, who delegates implementation and on-going monitoring to the Education Department.

AFFECTED AREAS/PERSONNEL: *ALL PATIENT CARE AREAS*

PROCEDURE:

A. Waived Test complexity categorization depends on method and device used and is manufacturer specific. All such information will be maintained by the Education Department. Waived Tests performed include the following:

   1. Fecal Occult Blood - fecal occult slides currently granted as waived tests under CLIA

2. Finger Stick Blood Glucose Meter/Glucometer - glucose monitoring equipment currently granted as waived tests under CLIA

3. Gastric Occult Blood - gastric occult slides currently granted as waived tests under CLIA

4. Automated Urine Dipstick

5. Rapid detection of Influenza A & B

6. Rapid detection of Respiratory Syncytial Virus (RSV)

7. Rapid Detection of Group A Streptococcus

8. Hemoglobin A1C

B. Responsibilities for Waived and Point Of Care Testing:

1. The Vice President of Patient Care Services and Education Department as designee, is responsible for the overall coordination and supervision of the Waived Point of Care Testing (POCT) program, as delegated by the Medical Director of the nursing CLIA, including:

   a. Waived or POCT patient testing performed at SVMC and SVCH for screening or diagnostic purposes

   b. Waived or POCT products, reagents and equipment

   c. Authority to withdraw waived or POCT testing from an area that has a history of noncompliance

   d. New POCT or waived tests or testing methods – these will be submitted to the Vice President of Patient Care Services for evaluation and approval

C. Quality Control Documentation Review

1. Educators will oversee:

   a. Operational quality management of point of care testing

   b. Competence of operators

   c. Appropriateness of testing

   d. Reporting noncompliance issues to managers for resolution

   e. Proficiency testing

f. Training competency assessment

g. Result reporting

D. The CLIA Medical Director, in collaboration with the Education Department, is responsible for:

1. Policy review and approval before initial use of any test used for patient testing

2. Policy review and approval at least every two years and any time changes in procedures occur

E. Training and Competency:

1. Colorblind evaluation will be assessed during pre-employment physical. Directors will be notified accordingly.

2. All operators will read the policy and procedure on as part of training. Operators performing tests shall receive appropriate training to perform the tests and will demonstrate competence prior to independent testing.

3. The Education Department provides oversight of training and competency validation.

4. Completed competency validation is tracked electronically in the learning management system and competency forms will be filed in the employee's unit specific competency files.

5. Student nurses and nursing faculty are required to successfully complete the POCT training prior to performing POCT. Nursing faculty must show proof of valid California Registered Nurse License and have a documented competency.

a. The Education Department is responsible for training nursing faculty following SVMC's policies and procedures regarding POCT and validating competency on an annual basis. Completed competency forms will be kept in the Education Department.

b. The Education Department will work in conjunction with nursing faculty to develop, maintain and support a productive learning environment for student nurses.

F. Quality Management / Quality Control methods are outlined in individual policies / procedures for POCTs performed.

1. The quality management program for point of care testing ensures quality throughout the pre-analytic, analytic and post-analytic phases of testing, including:

a. Patient identification and preparation

b. Specimen collection, identification and processing

c. Accurate result reporting

2. Quality control procedures are designed to ensure the most accurate results possible from Point of Care Testing.

a. Manufacturer's recommendations are followed as applicable

G. Records Management:

1. Quality control records will be contained within the Education Department information system.

a. Paper records will be printed, reviewed and available for minimum of three years.

b. Issues identified will be addressed in collaboration between the Education Department and the nursing unit directors and clinical managers.

2. Proficiency testing records will be housed in Education Department.

3. Performance improvement activities will be housed in the Education Department.

a. This will include quality monitors, annual reviews and notations of equipment and process improvements.

b. Reports will be submitted to the Patient Care Services Council monthly and to Patient Care Services Cabinet, Performance Improvement Patient Safety and Rad/Path committees on a quarterly basis.

4. Records of equipment maintenance will be housed in the Bio-Medical Department.

5. Records of personnel competency will be housed in employee competency folders and tracked electronically in the learning management system.

6. Room temperature monitoring logs will be retained within the clinics.

H. Monitoring Process

1. The Health Educator will review quality control results monthly for Point of Care Testing, maintain accurate data collection for quality and compliance.

Results are reported to the Patient Care Services Council monthly and to Patient Care Services Cabinet, Performance Improvement Patient Safety and Rad/Path committees on a quarterly basis.

2. Corrective action taken will be documented.

I. Proficiency Testing

1. Proficiency testing is performed to assess:

   a. the accuracy of an instrument relative to an accepted reference

   b. the point of care testing process

2. Nursing department staff will participate in proficiency testing as requested.

3. Education Department will retain Proficiency Testing results.

   a. Inaccurate testing results will be submitted to Nursing Directors for investigation and corrective action plan, which may include remediation if deemed appropriate

   b. Documentation of corrective action plan will be maintained in the Education Department

J. 96-Hour Contingency Plan for Emergency: SVMC maintains, at a minimum, a 96-hour supply of all waived & point of care reagents to ensure self-sufficiency for performing tests in compliance with the SVMC Utilities Disruption Matrix.

REFERENCES:

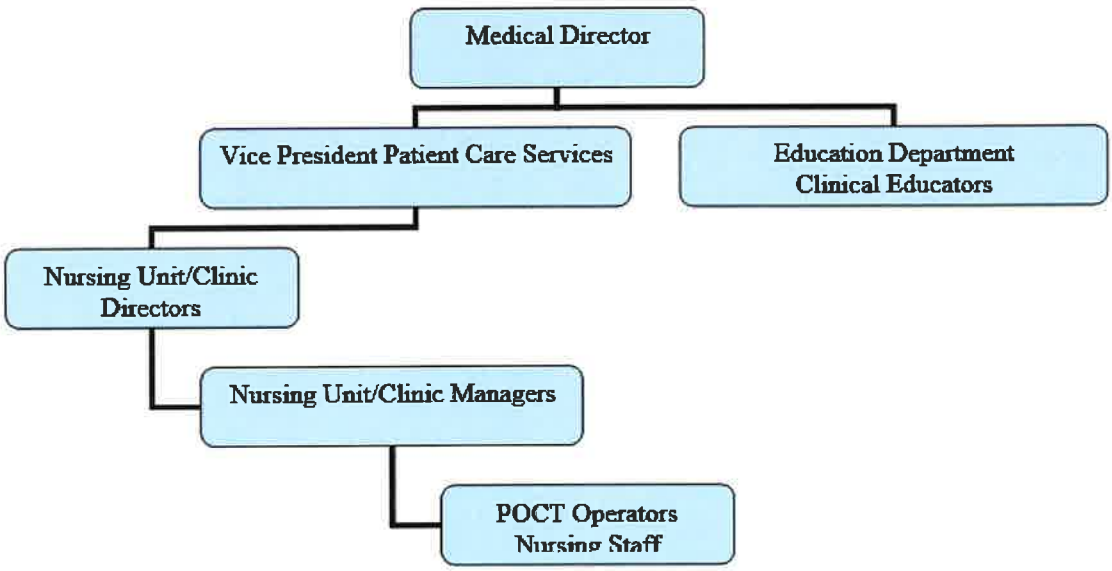
- Centers for Disease Control CLIA Amendments (2019). Retrieved on 05/29/20 at http://wwwn.cdc.gov/clia/Resources/Test Complexities.aspx.
- Centers for Disease Control CLIA Waived Tests (2005). Retrieved on 5/29/2020 at https://www.cdc.gov/labquality/waived-tests.html
- The Joint Commission (2020). Hospital accreditation standards. Joint Commission Resources. Oak Brook, IL.

CROSS REFERENCES:

- Waived and Point of Care Testing - Fecal Occult Blood Testing Policy & Procedure
- Waived and Point of Care Testing - Gastroccult Blood Testing Policy & Procedure

- Waived and Point of Care Testing - Glucose Meter (FSBG) Testing Policy & Procedure
- Clinitek Status Connect Urine Analyzer
- Clinitek Status Connect Plus Procedure
- Influenza A + B (BD Veritor System)
- Rapid Detection of Respiratory Syncytial Virus (RSV)
- Rapid Group A Strep (BD Veritor System)
- Hemoglobin A1C

Waived & Point of Care Testing Organizational Chart



SUBJECT: **WAIVED & POINT OF CARE TESTING GASTRIC OCCULT BLOOD**	SECTION: **Page 1 of 3**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

To establish the procedure to be followed for the use of testing for the presence of gastric occult blood.

POLICY:

1. Gastric blood slides will be used for point of care of gastric occult blood.
2. Nursing personnel performing gastric occult blood testing will be trained utilizing this policy and procedure and complete a competency prior to performance. Training will include reading Waived and Point of Care Testing – Gastric Occult Blood policy.
3. Nursing personnel will have competency validated annually.
4. Education Department will maintain records of all individuals who have completed training and competency validation.
5. Quality Control procedures will be completed with each patient test performed.
6. Quality control results will be documented on the Point of Care Occult Blood Worksheet.
7. Universal precautions will be observed throughout the patient testing procedure.

AFFECTED PERSONNEL/AREAS: *REGISTERED NURSES, LICENSES VOCATIONAL NURSES, TRAVELERS*

PROCEDURE:

PATIENT TESTING:

1. Collect materials needed for testing. Check expiration dates of slide and developer solution prior to use.
   - Gastric Occult Slides
   - Occult Blood Worksheet
   - Brand-specific Developer
   - Applicator Sticks
   - Product Instructions
   - Gloves, other applicable PPE
2. Appropriately fill out the Point of Care Occult Blood Worksheet by entering Meditech User ID, Lot# and Expiration of the slide/card prior to specimen collection. Place patient label to top of worksheet.
3. Collect a gastric sample on one end of the applicator stick or with gloved finger. Apply one drop of gastric sample to pH test circle and one drop to occult blood test area.
4. Apply two (2) drops of developer directly over the sample in the occult blood test area.

IMPORTANT NOTE: Some gastric samples may be highly colored and appear as blue or green on the

test area.
Test results should only be regarded as positive if additional blue is formed after developer is added.

5. Read gastric occult blood results within 60 seconds. The development of any trace of blue color in the occult blood test area is regarded as a positive result. Record results on patient record and Point of Care Occult Blood Worksheet.

6. Add one (1) drop of developer between the positive and negative Performance Monitor areas.

7. Interpret the Performance Monitor results.

8. In the unlikely event that the Performance Control Area does not react as expected after application of the developer, the test results should be regarded as invalid. **DO NOT REPORT RESULTS**. Repeat the test with a new slide.

9. After specimen is collected, results are interpreted, Performance Control is performed and Occult Blood Worksheet completed, an order for "Occult Blood, Gastric" (OBG) is placed in Meditech and all information on the Point of Care Occult Blood Worksheet is entered into appropriate fields. The RN or LVN is responsible for performing tests and completing Point of Care Occult Blood Worksheet. The unit clerk may enter the order and all necessary information from the Worksheet into Meditech.

10. Once the order has been placed in Meditech, the printed specimen labels will be stapled to the completed Point of Care Occult Blood Worksheet and placed in the designated area on the nursing unit for laboratory to pick up.

REPORTING RESULTS:

1. Report as POSITIVE or NEGATIVE and document in the patient record as well as the Occult Blood Worksheet.

QUALITY CONTROL:

1. The function and stability of the guiac paper and developer will be tested using the Performance Monitor feature located on the slide.

2. Quality control is performed and recorded on the Point of Care Occult Blood Worksheet with every patient test **AFTER** interpreting results.

STORAGE REQUIREMENTS:

1. Do not refrigerate or freeze slides or developer solutions. Store at controlled room temperature in original packaging. Protect from heat and light.

a. Electronic thermostat's are located in the supply storage locations. Staff are responsible for ensuring required temperature levels for equipment and supplies are maintained, documenting on the daily monitoring log. Link to print log is located under policy Cross References.

2. Do not store with volatile chemicals (e.g., iodine, chlorine, bromine, or ammonia).

3. The slides and developer, stored as recommended, will remain stable until the expiration dates, which appear on each slide and developer bottle. Do not use slides or developer after expiration date.

4. Developer should be protected from heat and light and the bottle kept tightly capped when not in use. It is flammable and subject to evaporation.

LIMITATIONS OF PROCEDURE:

Many factors can influence the results obtained from the gastric occult blood test. For further information refer to package insert.

REFERENCES:

- Package Instruction Insert

CROSS REFERENCES:

- Waived & Point of Care Testing Competency & Quality Policy
- Daily Temperature Log

SUBJECT:	SECTION:
WAIVED AND POINT OF CARE TESTING - GLUCOSE METER (FSBG) TESTING	*Care of the Patients (TX)* **Page** 1 **of** 10

PURPOSE:

To define and describe the policy and process to safely obtain a finger stick blood glucose (FSBG) result, in coordination with instructions provided with NOVA StatStrip ® Glucometer, and in compliance with Clinical Laboratory Improvement Amendment of 1988 (CLIA'88) guidelines and procedure guidelines based on manufacturer's instructions.

DEFINITIONS:

1. Glucose meter/Glucometer: handheld instrument used to test a finger stick blood sample and rapidly obtain a glucose level.

2. Certified instructors: those individuals who have a documented competency validated by the CLIA Medical Director/designee.

POLICY:

A. Only competent staff will perform FSBG testing.

B. Only individuals who are designated as "certified instructors" will teach formalized training sessions.

C. All staff expected to operate the NOVA glucometer will receive formalized competency training upon hire/during orientation and competency validation during orientation, at six (6) months after hire and annually with annual orientation.

D. Training will include reading *Waived and Point of Care Testing (POCT) - Glucose Meter (FSBG) Testing Policy* and all items in noted in Procedure, below.

E. Each operator will be given an operator identification number after training is completed.

F. Education Department will maintain records of all individuals who have completed training and competency validation.

G. Annual competency validation will be required to retain assigned operator Identification (ID) and continue to use the NOVA StatStrip® Glucose Meter for patient testing.

H. Quality control measures are completed each day that the machine might be used by an operator and stored in the memory of the glucose meter. If a quality control has not been completed within 24 hours, the meter prompts the operator to perform a quality control prior to use and does not allow the operator to perform a patient test until a quality control is completed.

I. Educator assigned will review data generated from the glucometers via the NovaNet system. This Quality data will be reviewed to identify any deviations from processes and/or policies required for waived testing/POCT. Identified issues will be addressed collaboratively by the Patient Care Services Council and the Education Department. Data review will include:

1. Patient tests
2. Quality control tests
3. User reports
4. Critical glucose values
5. Correct patient identification
6. Documentation

J. Quality Management data will be reported to the CLIA Medical Director and Patient Care Services Cabinet on a quarterly basis.

K. Proficiency testing will be performed three times per year to assess the accuracy of an instrument relative to an accepted reference and to test competence of validated operators.

L. Technical support is available for nursing staff by contacting the Biomedical Department at ext.4764 Monday thru Friday, 0800-1630. After hours, technical support is available by contacting the Nursing House Supervisor to contact the biomedical staff on-call.

M. Extra glucometers will be stored in the Biomedical Department.

AFFECTED AREAS/PERSONNEL: *ALL RN'S & LVN'S (INCLUDING TRAVELERS), MATERIALS MANAGEMENT, , LABORATORY, BIOMEDICAL, MEDICAL ASSISTANTS*

EQUIPMENT AND SUPPLIES:

NOVA StatStrip® Glucose Meter

Test strips

Quality Control solutions (level 1 = low, level 3 = high)

Clean disposable gloves

Alcohol swabs, lancets, Band-Aids

PROCEDURE:

A. Once new hire completes training, Education staff will input their operator ID into NOVA StatStrip® Glucose Meter information system.

B. Only those operators that have been certified through training and competency completion are able to access the meter. The meter "locks out" any unauthorized user.
See *Waived and Point of Care Testing – Competency and Quality Policy*.

C. Maintenance of meter and supplies:

1. Obtain new reagents (strips and control solutions) from Materials Management.

2. Date all vials with expiration date (month/day/year) and initials when opened (6 months from date opened for test strips, 3 months from date opened for control solutions)

3. Perform quality control with both Level 1 (low) and Level 3 (high) control solutions every 24 hours on any day that machine may be used for patient care (see procedure below)

4. Clean of the meter per manufacturer's instructions (see procedure below)

5. Change meter battery (see procedure below)

6. Meter docking (see procedure below)

7. Technical support available (see below)

D. Meter operation:

1. Perform quality control every 24 hours.

   a. If quality controls fail, repeat test on meter only once, then remove failing meter and send to Biomedical

2. Patient identification:

   a. Check patient ID prior to performing test using two identifiers (name and date of birth or medical record number)

   b. Enter patient ID using the meter scanner. (If scanner does not work, manually enter patient account number.)

3. Perform patient test

4. Retrieve patient results from meter

5. Document glucose result in patient's electronic medical record.

6. Document critical values and physician notification in the "Critical Test Result Reporting" assessment in the patient's electronic medical record, unless reporting directly to the physician (i.e. Emergency Department and Post Anesthesia Care Unit)

E. NOVA StatStrip® Glucose Meter

1. The acceptable temperature range for using the meter is 59-104°F (15-40°C). Do not place the meter near a heat source.

Meter should be held level when applying control or patient samples.

F. Test Strips

1. StatStrip Glucose Test Strips need be stored at 15 to 30°C. Do not refrigerate. Keep away from heat and direct sunlight. Store the test strips in an unopened vial are stable until manufacturer's expiration date indicated on vial.

2. Test strips expire 6 months after the opening date or the manufacturer's expiration date indicated on the vial, whichever comes first. When opened, vials must be dated with the **expiration** date, including month/day/year. Expired test strips must be discarded.

G. Level 1 (low) & Level 3 (high) Control Solutions

1. StatStrip Glucose Control Solutions at 15 to 30° C. Do not refrigerate. Solutions in an unopened bottle are stable until manufacturer's expiration date indicated on bottle.

2. Solutions expire 3 months after opening date. When opened, vials must be dated with the **expiration** date, including month/day/year. Expired solutions must be discarded.

H. Temperature Monitoring

1. Electronic thermostat's are located in the supply storage locations. Staff are responsible for ensuring required temperature levels for equipment and supplies are maintained, documenting on the daily monitoring log. Link to print log is located under policy Cross References.

PROCEDURE:

A. QUALITY CONTROL

1. The Quality Control will be performed every 24 hours. This process is completed by testing both Level 1 (low) and Level 3 (high) control solutions. (See "Attachment A" for specific process)

2. If either Level 1 (low) or Level (3) control fails, the operator may press the "Comment" key on the screen options as applicable. Then the quality control procedure must be repeated **ONLY ONCE**. If the control fails again, the operator is to remove the glucose meter from the nursing unit and send to the Biomedical Department for repair and replacement.

3. With each Quality Control, the meter will be cleaned appropriately (see "Maintenance of Glucose Meter" section). The glucose meter will then be placed in the Docking/Charging stations for downloading and uploading of information and charging of the battery when not in use.

B. PATIENT TESTING

1. All testing will be performed in accordance with Universal Precautions for the handling of blood and body fluids.

2. Actual performance of the glucose test will be performed as outlined on "Attachment B".

3. Upon diagnosis of hypoglycemia or hyperglycemia, the treatment will be based on hospital policy and/or physician's orders.

4. The blood glucose value will be documented under the, "Bedside Glucose", assessment in the patient's electronic medical record. Normal glucose reference range is 70 – 110 mg/dL.

5. Unexpected or unusual test results will be correlated with the patient's clinical symptoms to determine appropriate treatment actions. Please refer to the "Hypoglycemic Reaction: Immediate Treatment of" policy and Insulin Sliding Scale or Diabetic ketoacidosis (DKA) protocols for specific actions.

C. CRITICAL VALUES AND REPORTING:

1. The meter's reportable values range from 10- 600 mg/dl. If the numeric value of a patient's result is less than 10 mg/dl, this will be reported as "LO" and results of above 600 mg/dl will be reported as "HI" and a confirmation will need to be obtained from the clinical laboratory.

2. All critical values will require the operator to repeat the test once. Additionally, the operator may enter a note by pressing "Comment" and choosing from the available options.

3. Clinical laboratory confirmation of glucose values will need to be obtained (as ordered by physician, standing order and/or specific protocol i.e. DKA) if and/or when:

   - A new physician order
   - No numeric glucose values are displayed on the glucometer, "HI" or "LO" is the only displayed result
   - Initial or first time critical glucose value the patient has had on the glucometer since their current admission. For example: Patient blood sugar changes from 200's to 460. If the blood sugar remains the same, all subsequent blood glucose values do not need to be clinical laboratory confirmed.
   - Critical value changes as a result of treatment and/or condition. For example: During this admission, the patient had a blood glucose value above 400's (that was confirmed by lab initially) and now has a blood glucose reading of 38.

4. Report to the physician within 1 hour all critical glucose values that is reported from laboratory as a "Red Category" alert, as defined in the following policies: "Critical Results of Tests and Diagnostic Procedures, Reporting of"; "Critical Results (Pediatric/Neonate Specific) of Tests and Diagnostic Procedures, Reporting of".

   - Critical glucose values for adult patients (ages 13-years and above): <50 mg/dl or >400 mg/dl
   - Critical glucose values for pediatric patients (Ages 2-months to 13-years): <40 mg/dl or >400mg/dl
   - Critical glucose values for neonate patients (ages 0 to 2-months): <40 mg/dl or >250 mg/dl

5. Documenting critical values and physician notification in the "Critical Test Result Reporting" assessment in the patient's electronic medical record, unless reporting directly to the physician (i.e. Emergency Department and Post Anesthesia Care Unit).

6. If the patient requires immediate treatment for a critical glucose value, treatment will not be delayed for the laboratory confirmation test. The nurse will provide the treatment as specified by physician order and/or hospital policy.

MAINTENANCE OF GLUCOSE METER:

A. Cleaning the Glucose Meter

1. Meters will be cleaned after each patient use.

2. For "Special Contact Precaution" patients, those on isolation for possible Clostridia difficile or Noro virus, meters will be taken into patient rooms in clear specimen bags. Once out of the room, the meter will be cleaned as outlined below per manufacturer's instructions.

3. The meters should never be immersed in any cleaning agent. Always apply the cleaning agent to a soft cloth or use a cleaning wipe to clean the meter surface. Once complete, immediately dry thoroughly.

4. Meters may be cleaned by any of the following agents:
   - 10% bleach (sodium hypochlorite) Example: Clostridium difficile
   - Commercial surface decontamination preparations approved for use in our facility and included on the Environmental Protection Agency (EPA) Lists D and N.
   - Avoid harsh solvents such as benzene and strong acids

B. Docking the Glucose Meter

1. Place glucose meter in the Docking/Charging Station daily following quality control and whenever the meter is not in use for battery charging.

C. Validation of New Meters

1. The following are the criteria for validation of new meters before they can be used for patient glucose testing:

   - Be within range with the commercial quality control material

D. Changing the Battery

1. If you have a spare fully charged battery, it can be changed to allow for continuous operation. Press the Power Button to place the meter into Sleep Mode. This allows the operator approximately 20 seconds to change the battery without losing time/date settings.

2. Push down on the two cover latches to release the cover. Take the battery cover off the back of the meter.

3. Push up on the battery latch. Remove the drained battery. Replace with a fully charged battery. Replace the battery cover. Place the drained battery into the Charging Station.

4. Dock the meter.

QUALITY MANAGEMENT PROGRAM:

A. The Quality Management Program is a collaborative effort between the Education Department and the Nursing Division. The program ensures quality throughout the pre-analytic, analytic and post-analytic phases of testing, including patient identification and preparation specimen collection, identification and processing; and accurate result reporting. Bi-monthly monitoring of glucose testing is required based on the vulnerability analysis of the program. The Education Department is responsible for monitoring quality indicators bi-monthly (see below).

B. Results are reported to Nursing Management Council bi-monthly for follow-up and counseling of nursing staff as necessary. Quality Management data is reported to the CLIA Medical Director, Nursing Management Council and the Performance Improvement Department on a quarterly basis.

1. Pre-analytic indicators:

- Reagents dated with expiration date
- Validated operators have documented competency
- Quality control performance
- Meter cleaning performance

2. Analytic indicators:

- Valid patient identification entered
- Critical glucose values have laboratory confirmation

3. Post-analytic indicator:

- Glucose values are documented correctly in patient record
- Physician notification of critical values is recorded in the patient medical record

LIMITATIONS OF PROCEDURE:

A. If a significant difference between the bedside and lab results is observed, the patient's glucose should be monitored by the lab.

B. Sodium, lithium, and ammonium heparin are the recommended anticoagulants for use with the StatStrip Glucose Meter.

1. Depending on the amount of heparin used in the collection syringe and whether it is filled to capacity with blood, the concentrations of heparin may be 20 I.U. per mL to over 100 I.U. per mL. When liquid heparin is present in excess, it may cause dilution errors.

2. A lyophilized lithium heparin giving a final concentration in blood of not more than 20 I.U. per mL is acceptable.

- EDTA, citrate, oxalate, and sodium fluoride are not recommended for use.
- Glucose Interferences:
- The StatStrip Glucose Meter exhibits no interference from the following substances up to the following concentration levels:

Tested Interfering Substances	**Tested Concentration Level**
Acetaminophen	10.0 mg/dL
Ascorbic Acid	10.0 mg/dL
Bilirubin	15.0 mg/dL
Cholesterol	500.0 mg/dL
Creatinine	6.0 mg/dL
Dopamine	10.0 mg/dL
Ephedrine	0.9 mg/dL
D(+) Galactose	350.0 mg/dL
Hematocrit (RBC)	30% - 60%
Ibuprofen	48.0 mg/dL
L-Dopa	100.0 mg/dL
D(+) Maltose Monohydrate	240.0 mg/dL
D(+) Maltotetraose	240.0 mg/dL
D(+) Maltotetriose	240.0 mg/dL
Methyl-Dopa	1.0 mg/dL
Oxygen	All Concentrations
Salicylate	30.0 mg/dL
Tetracycline	30.0 mg/dL
Tolazamide	15.0 mg/dL
Tolbutamide	45.0 mg/dL
Triglycerides	750.0 mg/dL
Uric Acid	20.0 mg/dL

C. The following conditions can cause erroneous results:

- The test strips were used after the "Use By" date on the vial.

- The strips were not stored in the vial with the cap tightly sealed.
- The strip was not filled on the first touch of blood and was applied to the blood again.
- In situations of decreased peripheral blood flow, finger stick blood testing may not be appropriate, as it may not reflect the true physiological state. Examples include, but are not limited to, severe dehydration caused by diabetic ketoacidosis or the hyperglycemic hyperosmolar non-ketotic state, hypotension, shock or peripheral vascular disease.
- Capillary samples must be obtained from free flowing blood. Excessive milking or squeezing of the puncture site may produce erroneous results.
- Glucose results <10 mg/dL or >600 mg/dL are outside the linearity range and should not be considered accurate.
- Test results are best when obtained within an operating relative humidity of 10-90 (non-condensing). Testing outside these ranges may produce inaccurate results.

REFERENCES:

- The Joint Commission Standards on Waived Testing WT.04.01.01, Element of Performance (EP) (2020)
- Nova Biomedical StatStrip Operator's Manual (2018)

CROSS REFERENCES:

- Waived and Point of Care Testing – Competency and Quality
- Reporting of Critical Results of Tests and Diagnostic Procedures Policy
- Reporting of Critical Results (Pediatric/Neonate Specific) of Tests and Diagnostic Procedures Policy
- Daily Temperature Log

SUBJECT:	SECTION:
WAIVED AND POINT OF CARE TESTING - HEMOGLOBIN A1C (AFINION2)	**Page 1 of 5**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

To define and describe the policy and process to safely obtain a hemoglobin A1C level in coordination with instructions provided with the Afinion2 analyzer, and in compliance with Clinical Laboratory Improvement Amendment of 1988 (CLIA '88) guidelines and procedure guidelines based on manufacturer's instructions.

POLICY:

A. Personnel performing hemoglobin A1C testing will be trained utilizing this policy and procedure and complete a competency prior to performance. Training will include reading Waived and Point of Care Testing – Hemoglobin A1C Testing policy.

B. Personnel will have competency validated annually.

C. Education Department will maintain records of all individuals who have completed training and competency validation.

D. Quality control procedures will be completed daily (on days of testing) and with each new shipment of Afinion test kits, with each new lot number of Afinion test kits.

E. Proficiency testing will be performed three times per year to assess the accuracy of an instrument relative to an accepted reference and to test competence of validated operators.

F. Standard precautions will be observed throughout the patient testing procedure.

AFFECTED PERSONNEL/AREAS: *MEDICAL ASSISTANTS, BIOMEDICAL PERSONNEL*

EQUIPMENT:

- Afinion2 analyzer
- Afinion test cartridge
- Lancet
- Alcohol prep pad
- Gloves
- Cotton ball/gauze 2x2
- Bandaid

PROCEDURE:

A. Upon receipt of an order, a capillary blood specimen will be collected and tested to determine the patient's hemoglobin A1C level.

B. Turn analyzer on and open cuvette holder so you may insert the microcuvette.

C. Gather supplies: lancet, microcuvette (confirm in date), alcohol prep pad, cotton ball or gauze and bandaid

D. Clean the finger with alcohol prep pad and allow to dry.

E. Warm patient's finger and using your thumb, lightly press the finger from the top of the knuckle towards the tip. This stimulates the blood flow towards the sampling point.

F. Use lancet to obtain specimen from the side of the fingertip, not the center. While applying light pressure towards the fingertip, puncture the finger with lancet.

G. Wipe away the first 2 or 3 drops of blood.

H. Re-apply light pressure towards the fingertip until another drop of blood appears.

I. When the blood drop is large enough, fill the microcuvette in one continuous process. Do NOT refill.

J. Wipe off excess blood from the outside of the microcuvette with a clean, lint-free wipe, being careful not to touch the open end of the microcuvette, which could result in blood being drawn out of the microcuvette.

K. Look for air bubbles in the filled microcuvette. If present, discard the microcuvette and fill a new microcuvette from a new drop of blood. Small bubbles around the edge can be ignored.

L. Place the filled microcuvette in the cuvette holder. This must be performed within ten minutes after filling the microcuvette.

M. Gently slide the cuvette holder to the measuring position.

N. After 15-60 seconds, the hemoglobin value of the sample is displayed. The result will remain on the display as long as the cuvette holders is in the measuring position. When operating on battery power, the analyzer will automatically turn off after approximately 5 minutes.

O. Document result in the electronic health record.

P. Remove microcuvette and dispose of in sharps container.

QUALITY CONTROL

A. The Hemocue Hb 201 analyzer has an internal quality control, the "selftest". Every time the analyzer is turned on, it will automatically verify the performance of the optronic unit of the analyzer. This test is performed every second hour if the analyzer remains switched on. Upon

passing the "selftest", the display will show the Hemocue symbol and three flashing dashes, indicating the analyzer is ready to perform a measurement. An error code will be displayed if the "selftest" fails.

B. If an error code displays, turn off the analyzer and turn it on again after 30 seconds. Take a new microcuvette and repeat the measurement. If the problem continues, see specific error code Troubleshooting Guide in the manufacturer's instruction manual.

C. In addition to the automatic "selftest", a quality control using liquid control solutions will be performed on the days of testing. This process is completed by testing both Level 1 (low) and Level 3 (high) control solutions.

D. If either Level 1 (low) or Level 3 (high) fail, the quality control may be repeated ONLY ONCE. If the control fails a second time, the operator is to remove the device from the patient care area and send to the Biomedical Department for repair or replacement.

E. Quality control solutions should be stored in refrigerator at 2 to 8° C. Solutions in an unopened bottle are stable until manufacturer's expiration date indicated on bottle. After opening, the product is stable at 2 to 30° C for 30 days. When opened, the vials must be dated with the **expiration** date, including month/day/year. Expired solutions must be discarded.

MAINTENANCE OF HEMOCUE ANALYZER

A. STORAGE
   a. The analyzer is to be stored at room temperature (15-30° C).
   b. Individually packaged microcuvettes are to be stored at room temperature (15-30° C). Do not refrigerate. The microvettes are stable until the date printed on each package.
   c. Microcuvettes kept in a vial are to be stored at room temperature (15-30° C). Do not refrigerate. The expiration date of the microcuvettes in a sealed vial is printed on the vial. Once the seal is broken, the microcuvettes are stable for three months. Always keep the container properly closed. When opened, vials must be dated with the expiration date, including month/day/year. Expired microcuvettes must be discarded.
   d. Electronic thermostat's are located in the supply storage locations. Staff are responsible for ensuring required temperature levels for equipment and supplies are maintained, documenting on the daily monitoring log. Link to print log is located under policy Cross References.

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B. CLEANING
   a. The cuvette holder and optronic unit should be cleaned after each day of use or as needed.
   b. Check that the analyzer is turned off.
   c. Remove the cuvette holder away from the analyzer.
   d. Clean cuvette holder with alcohol or mild soap solution. Ensure the holder is completely dry before being replaced.

e. Clean the optronic unit with alcohol or mild soap solution. This should be done daily and when directed to do so in the Troubleshooting Guide or as needed.
f. To clean the optronic unit, push the Hemocue cleaner swab (or cotton tip swab moistened with alcohol) into the opening of the cuvette holder. Move from side to side 5-10 times. If the swab is stained, repeat with a new swab. No further cleaning is required if the swab remains clean.
g. Wait 15 minutes before replacing the cuvette holder and using the analyzer.

C. BATTERY
   a. If AC power is available, plug the supplied power adapter into the power inlet at the back of the analyzer.
   b. If no power is available, insert the 4 type AA batteries 1.5 V into the battery compartment.
   c. If the battery symbol appears on the display, the batteries are running low on power. The analyzer will continue to give accurate results, but the batteries should be replaced as soon as possible.

LIMITATIONS OF PROCEDURE:

A. Measuring range of the analyzer is 0-25.6 g/dL Results above 25.6 g/dL will be displayed as HHH. Values above 23.5 g/dL must be confirmed using a suitable laboratory method.

B. The Hemocue Hb 201 analyzer is only to be used together with Hemocue Hb201 microcuvettes.

C. Sulfhemoglobin is not measured with this method.

D. The Hemocue Hb 201 analyzer exhibits no interference from the following substances up to the following concentration levels:

Tested Interfering Substances	Tested Concentration Level
Acetaminophen	20 mg/dL
Ascorbic acid	3 mg/dL
Conjugated bilirubin	40 mg/dL
Unconjugated bilirubin	20 mg/dL
Creatinine	30 mg/dL
Ibuprofen	40 mg/dL
Leukocytes	600 x 10^9/L
Lipemia	Intralipid 4000 mg/L
	Triglycerides 1000 mg/dL
Salicylic acid	50 mg/dL
Tetracycline	20 mg/dL
Trombocytes	2100 x 10^9 L
Urea	500 mg/dL
Uric acid	20 mg/dL

REFERENCES:

HemoCue AB (n.d.) *Hemocue Hb 201 Operating Manual.*

Joint Commission. (2021). Standards on Waived Testing WT.03.01.01, WT.04.01.01, WT.05.01.01

CROSS REFERENCES:

Waived and Point of Care Testing – Competency and Quality

Daily Temperature Log

~~Responsibility for Review and Maintenance of Policy:~~ **~~Director Clinical Informatics/Education~~**	~~Original Creation Date:~~ **~~No Date Set~~**
~~Senior Management Team Review and Approval:~~ **~~Not Approved Yet~~**	~~Last Periodic Review Date~~ **~~No Review Date~~**
~~Board of Directors Review and Approval:~~ **~~Not Approved Yet~~**	~~Date Revised:~~ **~~05/28/2021~~**

SUBJECT:	SECTION:
WAIVED & POINT OF CARE TESTING - INFLUENZA A+B (BD VERITOR SYSTEM)	*Waived Testing* **Page 1 of 13**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

INTENDED USE:

The BD Veritor™ System for Rapid Detection of Flu A+B is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasopharyngeal wash aspirate and swab in transport media samples from symptomatic patients. The BD Veritor System for Rapid Detection of Flu A+B is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. A negative test is presumptive and it is recommended that these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. The test is not intended to detect influenza C antigens.

SUMMARY AND EXPLANATION:

Influenza illness classically presents with sudden onset of fever, chills, headache, myalgias, and a non-productive cough. Epidemics of influenza typically occur during winter months with estimated 114,000 hospitalizations[1] and 36,000 deaths[2] per year in the U.S. Influenza viruses can also cause pandemics, during which rates of illness and death from influenza-related complications can increase dramatically. Patients who present with suspected influenza may benefit from treatment with an antiviral agent especially if given within the first 48 hours of onset of illness. It is important to rapidly distinguish influenza A from influenza B in order to allow physicians a choice in selective antiviral intervention. Moreover, it is important to determine if influenza A or B is causing symptomatic disease in a particular institution (e.g., nursing home) or community, so that appropriate preventative intervention can be taken for susceptible individuals. It is therefore important to not only rapidly determine whether influenza is present, but also which type of influenza virus is present as severity and treatment can be different.[3] Diagnostic tests available for influenza include rapid immunoassay, immunofluorescence assay, polymerase chain reaction (PCR), serology, and viral culture.[4-11] Immunofluorescence assays entail staining of specimens immobilized on microscope slides using fluorescent-labeled antibodies for observation by fluorescence microscopy.[6,12,13] Culture methods employ initial viral isolation in cell culture, followed by hemadsorption inhibition, immunofluorescence, or neutralization assays to confirm the presence of the influenza virus.[13-15]

The BD Veritor System for Rapid Detection of Flu A+B is a chromatographic immunoassay to detect influenza A or B nucleoprotein antigens from respiratory specimens of symptomatic patients with a time to result of 10 minutes. The speed and simplified workflow of the BD Veritor System for Rapid Detection of Flu A+B makes it applicable as a "STAT" influenza A and B antigen detection test providing relevant information to assist with the diagnosis of influenza.

AFFECTED PERSONNEL/AREAS: *SVMC LABORATORY CLINICAL LAB SCIENTISTS (CLS), URGENT CARE RNs, ER TECHNICIANS, SIERRA VIEW COMMUNITY HEALTH CENTER (SVCHC) MEDICAL ASSISTANTS (MA)*

PROCEDURE:

The BD Veritor System for Rapid Detection of Flu A+B is a chromatographic assay to qualitatively detect influenza A and B viral antigens in samples processed from respiratory specimens. When specimens are processed and added to the test device, influenza A or B viral antigens bind to anti-influenza antibodies conjugated to detector particles in the A + B test strip. The antigen-conjugate complex migrates across the test strip to the reaction area and is captured by the line of antibody on the membrane. A positive result for influenza A is determined by the BD Veritor System Reader when antigen-conjugate is deposited at the Test "A" position and the Control "C" position on the BD Veritor System Flu A+B assay device. A positive result for influenza B is determined by the BD Veritor System Reader when antigen-conjugate is deposited at the Test "B" position and the Control "C" position in the BD Veritor System Flu A+B assay device.

REAGENTS:

The following components are included in the **BD Veritor** System for Rapid Detection of Flu A+B kit:

BD Veritor System Flu A+B Devices	30 devices	Foil pouched device containing one reactive strip. Each strip has two test lines of monoclonal antibody specific to either Flu A or Flu B influenza viral antigen and murine monoclonal control line antibodies.
RV Reagent C	30 tubes with 100 µL reagent	Detergent with < 0.1% sodium azide
300 µL Pipette	30 each	Transfer pipette
Control A+/B- Swab	1 each	Flu A Positive and Flu B Negative Control Swab, influenza A antigen (inactive recombinant nucleoprotein) with < 0.1% sodium azide
Control B+/A- Swab	1 each	Flu A Negative and Flu B Positive Control Swab, influenza B antigen (inactive recombinant nucleoprotein) with < 0.1% sodium azide

MATERIALS REQUIRED BUT NOT PROVIDED:

- BD Veritor System Reader (Cat. No 256055)
- Timer
- Vortex mixer
- Transport media (see ***Specimen Collection and Handling***)
- Distilled or deionized water
- Tube rack for specimen testing

WARNINGS AND PRECAUTIONS:

- For in vitro Diagnostic Use.
- Test results are not meant to be visually determined. All test results must be determined using the BD Veritor System Reader.
- If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to the state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.
- Pathogenic microorganisms, including hepatitis viruses, Human Immunodeficiency Virus and novel influenza viruses, may be present in clinical specimens. "Standard Precautions"16-19 and institutional guidelines should be followed in handling, storing and disposing of all specimens and all items contaminated with blood and other body fluids.
- Dispose of used BD Veritor System test devices as biohazardous waste in accordance with federal, state and local requirements.
- Reagents contain sodium azide, which is harmful if inhaled, swallowed or exposed to skin. Contact with acids produces very toxic gas. If there is contact with skin, wash immediately with plenty of water. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.
- Do not use kit components beyond the expiration date.
- Do not reuse the BD Veritor System test device.
- Do not use the kit if the Control A+/B- swab and Control B+/A- swab do not yield appropriate results.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- To avoid erroneous results, specimens must be processed as indicated in the assay procedure section.
- FluMist® is made from attenuated live flu virus and although the concentration tested (1%) was non-interfering, it is possible when tested with higher concentrations that an influenza A and/or influenza B false positive may occur.
- Specific training or guidance is recommended if operators are not experienced with specimen collection and handling procedures.

STORAGE AND HANDLING:

- Kits may be stored at 2–30°C. DO NOT FREEZE.
- Reagents and devices must be at room temperature (15–30°C) when used for testing.
- Electronic thermostat's are located in the supply storage locations. Staff are responsible for ensuring required temperature levels for equipment and supplies are maintained, documenting on the daily monitoring log. Link to print log is located under policy Cross References.

SPECIMEN COLLECTION AND HANDLING:

Specimen Collection and Preparation

- Acceptable specimens for testing with the BD Veritor System for Rapid Detection of Flu A+B include nasopharyngeal (NP) washes, aspirates and swab specimens in transport media. It is essential that correct specimen collection and preparation methods be followed. Specimens obtained early in the course of the illness will contain the highest viral titers.
- Inadequate specimen collection, improper specimen handling and/or transport may yield a false negative result; therefore, training in specimen collection is highly recommended due to the importance of specimen quality to accurate test results.

Specimen Transport Media

The following transport media have been tested and found to be compatible using moderate positive samples with the BD Veritor System for Rapid Detection of Flu A+B:

- Modified Amies Medium (liquid) ESwab
- Liquid Stuart Medium
- Amies
- Bartel ViraTrans™
- BD Universal Transport
- Hank's Balanced Salt Solution
- M4
- M4-RT
- M5
- M6
- Normal Saline
- Phosphate Buffered Saline
- Samples in these transport media can be stored at 2-8°C for up to 72 hours.
- Other transport media may be utilized if an appropriate validation exercise is performed.

NOTE: *Media containing lactalbumin (i.e., 0.5% or 1.0%) or any other transport media containing*

lactalbumin may not be compatible with the BD Veritor System for Rapid Detection of Flu A+B.

SPECIMEN TRANSPORT AND STORAGE:

Freshly collected specimens should be processed within 1 hour. If necessary, specimens may be stored at 2–8°C for up to 72 hours. It is essential that correct specimen collection and preparation methods be followed. Do not centrifuge specimens prior to use, as the removal of cellular material may adversely affect test sensitivity.

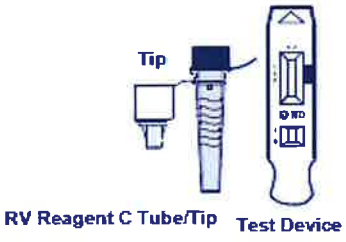
Procedure for Nasopharyngeal Swabs in Transport Media

- For NP swab specimens in transport media, a minimal volume of transport media (1 mL) is recommended.
- Process specimens as described in TEST PROCEDURE.

TEST PROCEDURE:

NOTE: *Reagents, specimens and devices must be at room temperature (15–30°C) for testing. Thoroughly mix all specimens prior to removal of an aliquot for processing. Do not centrifuge specimens.*

1. For each patient specimen and control swab, remove one **RV Reagent C** tube/tip and one BD Veritor System Flu A+B device from its foil pouch immediately before testing.
2. Label one BD Veritor System device and one **RV Reagent C** tube for each specimen and control to be tested.
3. Place the labeled **RV Reagent C** tube(s) in the designated area of the tube rack.

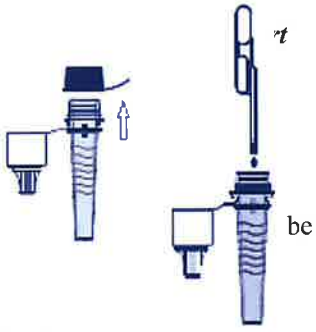


4. Process the specimen or control as directed below:

> ***For NP washes, aspirates and swab specimens in media:***

a. Vortex or thoroughly mix specimen. Do not centrifuge.

b. Remove and discard the cap from the **RV Reagent C** tube corresponding to the sample to tested.



c. Using the transfer pipette, transfer 300 µL of specimen into the **RV Reagent C** tube. Discard pipette after use.

> ***For Kit Swab Controls:***

a. Remove and discard the cap from the **RV Reagent C** tube corresponding to the sample to be tested.

b. Using the transfer pipette add 300 µL of distilled or deionized water to the **RV Reagent C** tube.

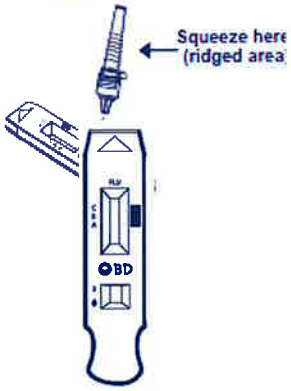
c. Insert the control swab into the tube and vigorously plunge the swab up and down in the fluid for a minimum of 15 seconds.

d. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

5. Press the attached tip firmly onto the **RV Reagent C** tube containing the processed specimen or control (threading/twisting not required). ***NOTE:*** *Do not use tips from any other product, including other products from BD or other manufacturers.*

6. Vortex or mix thoroughly.

7. Invert the **RV Reagent C** tube and hold the tube vertically (approximately one inch above the BD Veritor System Flu A+B device sample well). Holding the tube at the ridged area, squeeze gently allowing three (3) drops of the processed sample to be dispensed into the sample well of the appropriately labeled BD Veritor System Flu A+B device. ***NOTE:*** *Squeezing the tube too close to the tip may cause leakage.*



8. After adding the sample, allow the test to run for 10 minutes before inserting into the reader.

9. When the test is ready, insert the BD Veritor System Flu A+B device into the BD Veritor System Reader. (The BD Veritor System Reader should be powered-on prior to use and will indicate when it is ready for insertion of the BD Veritor System device.)

10. Follow the reader on-screen prompts to complete the procedure and obtain the test result.

ALTERNATIVE TEST PROCEDURE: Testing Influenza A+B & RSV on same swab

Use of BD Veritor System for rapid detection of **influenza A+B** (CAT# 256041) and BD Veritor System for rapid detection of **RSV** (CAT# 256042) from a single NP wash, aspirate or swab specimen in transport media.

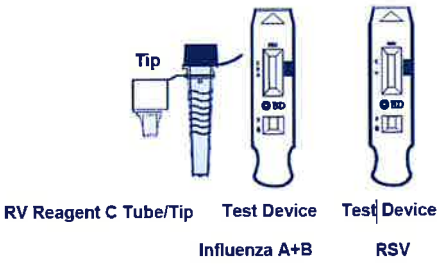
Use this procedure if both influenza A+B and RSV are to be tested from a single patient.

IMPORTANT NOTE: *The sample to be tested in the RSV kit must be from a patient less than 20 years of age as indicated in the BD Veritor RSV clinical package insert. The processed sample should be tested within 15 minutes.*

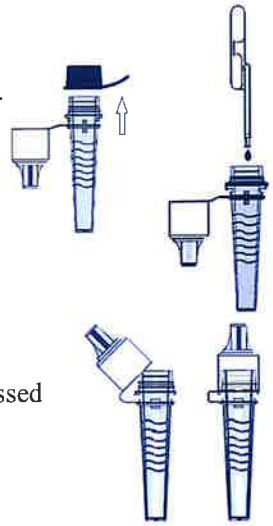
NOTE: *Reagents, specimens and devices must be at room temperature (15-30°C) for testing. Thoroughly mix all specimens prior to removal of an aliqot for processing. Do not centrifuge specimens.*

NOTE: *The BD Veritor System for Rapid Detection of RSV (CAT# 256042) is required for this procedure.*

1. For each patient specimen and control swab, remove one **RV Reagent C** tube/tip and one BD Veritor Flu A+B device and one BD Veritor System RSV device from its foil pouch immediately before testing.
2. Label the BD Veritor System devices and one **RV Reagent C** tube for each specimen and control to be tested.



3. Place the labeled **RV Reagent C** tube(s) in the designated area of the tube rack.
4. Vortex or thoroughly mix specimen. Do not centrifuge.
5. Remove and discard the cap from the **RV Reagent C** tube corresponding to the sample to be tested.
6. Using the transfer pipette, transfer 300 µL of specimen into the **RV Reagent C** tube. Discard pipette after use.
7. Press the attached tip firmly onto the **RV Reagent C** tube containing the processed specimen or control (threading/twisting not required).



NOTE: *Do not use tips from any other product, including other products from BD or other manufacturers.*

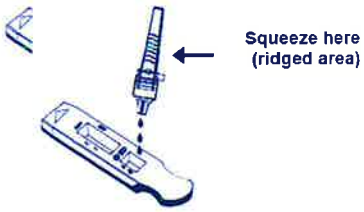
8. Vortex or mix thoroughly.

9. Invert the RV Reagent C tube and hold the tube vertically (approximately one inch above the BD Veritor System Flu A+B device sample well). Holding the tube at the ridged area, squeeze gently allowing three (3) drops of the processed sample to be dispensed into the sample well of the appropriately labeled BD Veritor System Flu A+B device.

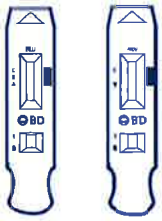
NOTE: *Squeezing the tube too close to the tip may cause leakage.*

10. Immediately continue to test for RSV. Invert the RV Reagent C tube and hold the tube vertically (approximately one inch above the BD Veritor System RSV device sample well). Holding the tube at the ridged area, squeeze gently allowing three (3) drops of the processed sample to be dispensed into the sampl well of the appropriately labeled BD Veritor System Flu A+B device.

NOTE: Squeezing the tube too close to the tip may cause leakage.



11. After adding the sample, allow the test to run for 10 minutes before inserting into the reader.



12. When the test is ready, insert the BD Veritor System Flu A+B device into the BD Veritor System Reader. (the BD Veritor System Reader should be powered on prior to use and will indicate when it is ready for insertion of the BD Veritor System device.)

13. Follow the reader on-screen prompts to complete the procedure and obtain the test result.

14. Immediately after the Flu A+B test result is obtained and recorded, insert the BD Veritor System RSV device into the BD Veritor System Reader.

Follow the reader on-screen prompts to complete the procedure and obtain the test result.

COMPETENCY ASSESSMENT

1. All Operators must read the procedure manual and complete the training and competency record during the initial training. Competency is assessed at orientation and annually using at least two of the following methods:
    i. Performing a test on a blind specimen
    ii. Lead CLS observation of routine work
    iii. Each user's quality control performance is monitored
    iv. Written testing specific to the method
2. Only approved operators are allowed to perform the test and report results.
3. Competency validation is tracked electronically in the learning management system. Competency forms are kept in employee competency files.

QUALITY CONTROL:

Each BD Veritor System Flu A+B device contains both positive and negative **internal/procedural controls:**

1. The internal positive control validates the immunological integrity of the device, proper reagent function, and assures that the correct test procedure was followed.

2. The membrane area surrounding test lines functions as a background check on the assay device.

These positive and negative internal/procedural controls are evaluated by the BD Veritor System Reader after insertion of the BD Veritor System test device. The BD Veritor System Reader will prompt the operator should a quality issue occur. Failure of the internal/procedural controls will generate an invalid test result.

External Positive and Negative Controls:

Swab controls (Flu A positive/B negative and Flu B positive/A negative) are supplied with each kit. These controls provide additional quality control material to demonstrate positive or negative assay results using the BD Veritor System Reader and BD Veritor System test device. BD recommends that positive and negative controls be run once for:

Run external controls with each shipment and/or monthly.

Run external controls with new operator.

NOTE: *If the kit controls do not perform as expected, do not test patient specimens. Contact BD Technical Services at 1-800-638-8663.*

INTERPRETATION OF RESULTS:

The BD Veritor System Reader instrument (purchased separately) must be used for all interpretation of test results. Operators should not attempt to interpret assay results directly from the test strip contained within the BD Veritor System Flu A+B assay device.

Reader Display	Interpretation
FLU A: + FLU B: -	Positive Test for Flu A (influenza A antigen present)
FLU A: - FLU B: +	Positive Test for Flu B (influenza B antigen present)
FLU A: - FLU B: -	Negative Test for Flu A and Flu B (no antigen detected)
RESULT INVALID	Result Invalid
CONTROL INVALID	Control line error

> *Invalid Test:* If the test is invalid, the BD Veritor System Reader will display a "RESULT INVALID" or "CONTROL INVALID" result and the test or control must then be repeated.

REPORTING OF RESULTS:

Positive Test: Positive for the presence of influenza A or influenza B antigen. A positive result may occur in the absence of viable virus.

Negative Test: Negative for the presence of influenza A and influenza B antigen. Infection due to influenza cannot be ruled-out because the antigen present in the sample may be below the detection limit of the test. A negative test is presumptive and it is recommended that these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay.

Invalid Test: Test result is inconclusive. Do not report results. Repeat the test.

LIMITATIONS OF THE PROCEDURE:

- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
- The contents of this kit are to be used for the qualitative detection of influenza type A and B antigens from NP wash, aspirate and swab in transport media specimens.
- The BD Veritor System for Rapid Detection of Flu A+B is capable of detecting both viable and non-viable influenza particles. The BD Veritor System for Rapid Detection of Flu A+B performance depends on antigen load and may not correlate with other diagnostic methods performed on the same specimen.
- Results from the BD Veritor System for Rapid Detection of Flu A+B test should be correlated with the clinical history, epidemiological data and other data available to the clinician evaluating the patient.
- A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly; therefore, a negative test result does not eliminate the possibility of influenza A or influenza B infection, and

should be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay.

- Positive test results do not rule out co-infections with other pathogens.
- Positive test results do not identify specific influenza A virus subtypes.
- Negative test results are not intended to rule out other non-influenza viral or bacterial infections.
- Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children.
- Positive and negative predictive values are highly dependent on prevalence rates. Positive test results are more likely to represent false positive results during periods of little/no influenza activity when disease prevalence is low. False negative test results are more likely during peak influenza activity when prevalence of disease is high.
- This device has been evaluated for use with human specimen material only.
- Monoclonal antibodies may fail to detect, or detect with less sensitivity, influenza A viruses that have undergone minor amino acid changes in the target epitope region.
- The analytical reactivity of this device has not been established for avian or swine origin influenza strains other than those included in the "strain reactivity" tables in the product package insert.
- The performance characteristics of this test with specimens from humans infected with H5N1 or other avian influenza viruses are unknown.
- The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection.
- The BD Veritor System Reader reports dual positive influenza A and influenza B results as "Result Invalid." Specimens generating a "Result Invalid" should be retested. Upon retesting, if the specimen produces a "Result Invalid" the user may want to consider other methods to determine whether the sample is positive or negative for influenza virus.\

INTERFERING SUBSTANCES:
Various substances were evaluated with the BD Veritor System for Rapid Detection of Flu A+B test. These substances included whole blood (2%) and various medications. No interference was noted with this assay for any of the substances tested.

Substance	Concentration
4-Acetamidophenol	10 mg/mL
Acetylsalicylic acid	20 mg/mL
Albuterol	0.083 mg/mL

Substance	Concentration
Loratidine	100 ng/mL
Menthol Throat Lozenges	10 mg/mL
Mometasone	500 ng/mL

Amantadine Hydrochloride	500 ng/mL
Ayr Saline Nasal Gel	10 mg/mL
Beclomethasone	500 ng/mL
Budesonide	500 ng/mL
Chlorpheniramine maleate	5 mg/mL
Dexamethasone	10 mg/mL
Dextromethorphan	10 mg/mL
Diphenhydramine HCl	5 mg/mL
Fexofenadine	500 ng/mL
FluMist	1%
Flunisolide	500 ng/mL
Fluticasone	500 ng/mL
Four OTC nasal sprays	10 %
Four OTC throat drops	25 %
Guaiacol Glyceryl Ether	20 mg/mL
Homeopathic Allergy Medicine	10 mg/mL
Ibuprofen	10 mg/mL

Mupirocin	500 ng/mL
Oseltamivir	500 ng/mL
Oxymetazoline	0.05 mg/mL
Phenylephrine	1 mg/mL
Pseudoephedrine HCl	20 mg/mL
Purified Mucin Protein	1 mg/mL
Ribavirin	500 ng/mL
Rimantadine	500 ng/mL
Three OTC mouthwashes	5 %
Tobramycin	500 ng/mL
Triamcinolone	500 ng/mL
Whole Blood	2%
Zanamivir	1 mg/mL

Of the 44 substances tested in this study, none exhibited interfering reactions when tested with influenza A and influenza B positive samples. Based on the data, the substances tested at the indicated concentration levels did not interfere with the BD Veritor System for Rapid Detection of Flu A+B test.

AVAILABILITY:

Cat. No.	**Description**
256041	BD Veritor™ System for Rapid Detection of Flu A+B, 30 tests

256055 BD Veritor™ System Reader

256051 BD Veritor™ System Flu A+B Control Swab Set, 10 pairs of swabs

REFERENCES:

- Simonsen L., Fukuda K, Schonberger LB, Cox NJ. Impact of influenza epidemics on hospitalizations. J. Infect. Dis. 2000; 181:831-7
- Thompson WW, Shay DK, Weintraub E, et al. Mortality associated with influenza and respiratory syncytial virus in the United States. JAMA 2003: 289: 179-86

- **Technical Information:** In the United States, contact BD Technical Service and Support at 800-638-8663 or www.bd.com/ds.
- Becton, Dickinson and Company, 7 Loveton Circle Sparks, MD 21152 USA
- EC REP Benex Limited, Pottery Road, Dun Laoghaire, Co. Dublin, Ireland
- FluMist is a registered trademark of MedImmune, LLC.
- ViraTrans is a trademark of Trinity Biotech, PLC.
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CROSS REFERENCE:

Daily Temperature Log

SUBJECT: **WAIVED & POINT OF CARE TEST - RAPID DETECTION OF RESPIRATORY SYNCYTIAL VIRUS (RSV)**	SECTION: *Waived Testing* **Page 1 of 12**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

INTENDED USE:

The BD Veritor™ System for Rapid Detection of Respiratory Syncytial Virus (RSV) is a chromatographic immunoassay with an instrumented read for the direct and qualitative detection of RSV fusion protein from a direct nasopharyngeal swab from patients suspected of having a viral respiratory infection. This test is intended for *in vitro* diagnostic use to aid in the diagnosis of RSV infections in infants and pediatric patients under the age of 6 years. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by viral cell culture or an alternative method, such as a FDA-cleared molecular assay. The test is intended for professional and laboratory use. It is to be used in conjunction with the BD Veritor System Reader.

SUMMARY AND EXPLANATION:

Viral respiratory tract infections are responsible for widespread disease. Respiratory syncytial virus is a leading cause of lower respiratory tract infections (LRI) in young children in both the developed and developing worlds. Worldwide, it is estimated that RSV is responsible for greater than 30 million cases of LRI in children under 5 years of age each year.[1,2] RSV has also been implicated in severe respiratory infections in the elderly and immunocompromised patients.[3,4] RSV has been identified as causing 20% of "influenza-like" illness in people 15–44 years of age and is responsible for greater than 17,000 deaths per year in the United States, almost 80% of which occur in adults over age 65.[5,6]

The BD Veritor System for Rapid Detection of RSV (also referred to as the BD Veritor System and BD Veritor System RSV) is a chromatographic immunoassay to detect RSV fusion protein extracted from nasopharyngeal swab specimens from symptomatic patients.

PRINCIPLES OF THE PROCEDURE:

The BD Veritor System for Rapid Detection of RSV is a chromatographic assay to qualitatively detect RSV fusion protein in samples processed from nasopharyngeal specimens. When specimens are processed and added to the test device, RSV antigen binds to anti-RSV antibodies conjugated to detector particles in the RSV test strip. The antigen-conjugate complex migrates across the test strip to the reaction area and is captured by the line of RSV antibody on the membrane. A positive result for RSV is determined by the BD Veritor System Reader (purchased separately) when antigen-conjugate is deposited at the Test "T" position and the Control "C" position on the BD Veritor System RSV assay device.

AFFECTED AREAS/PERSONNEL: *SVMC LAB CLINICAL LAB SCIENTISTS (CLS), SIERRA VIEW COMMUNITY HEALTH CENTER (SVCHC) MEDICAL ASSISTANTS*

REAGENTS:

The following components are included in the BD Veritor System for Rapid Detection of Flu A+B kit:

BD Veritor System RSV Devices	30 devices	Foil pouched device containing one reactive strip. Each strip has one test line of monoclonal antibody specific to RSV viral antigen and murine monoclonal control line antibodies.
RV Reagent D	30 tubes with 400 µL reagent	Detergent with < 0.1% sodium azide (preservative)
Flexibile minitip flocked swab	30 each	Swab for nasopharyngeal collection
RSV Positive Control Swab	1 each	RSV Positive Control Swab, RSV antigen (noninfectious cell lysate) with <0.1% sodium azide (preservative)
RSV Negative Control Swab	1 each	RSV Negative Control Swab, RSV antigen (detergent-treated non-infected cells) with <0.1% sodium azide (preservative)

MATERIALS REQUIRED BUT NOT PROVIDED:

- BD Veritor System Reader (Cat. No. 256055)
- Timer
- Tube rack for specimen testing

WARNINGS AND PRECAUTIONS:

- For *in vitro* Diagnostic Use.
- Test results are not meant to be visually determined. *All test results must be determined using the BD Veritor System Reader.*
- The RSV Positive Control Swab and the positive control line on the BD Veritor System for Rapid Detection of RSV device have been prepared from RSV-infected tissue culture cells which have been inactivated by detergent treatment and sonication then subsequently tested by bioassay procedures.
- Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus may be present in clinical specimens. "Standard Precautions"[10-13] and institutional guidelines should be followed in handling, storing and disposing of all specimens and all items contaminated with blood and other body fluids.
- Dispose of used BD Veritor System test devices as biohazardous waste in accordance with federal, state and local requirements.
- Reagents contain sodium azide, which is harmful if inhaled, swallowed or exposed to skin. Contact with acids produces very toxic gas. If there is contact with skin, wash immediately with plenty of water. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides.

On disposal, flush with a large volume of water to prevent azide build-up.

- Use the flocked swabs provided with the kit for specimen collection.
- Other than the flocked swabs that are used for specimen collection, kit components should not make contact with the patient.
- Do not use kit components beyond the expiration date.
- Do not reuse the BD Veritor System test device.
- Do not use the kit if the Control RSV Positive Swab and Control RSV Negative Swab do not yield appropriate results.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- To avoid erroneous results, specimens must be processed as indicated in the assay procedure section.
- Proper specimen collection, storage and transport are critical to the performance of this test.
- Specific training or guidance is recommended if operators are not experienced with specimen collection and handling procedures.

STORAGE AND HANDLING:

- Kits may be stored at 2–30°C. DO NOT FREEZE.
- Reagents and devices must be at room temperature (15–30 °C) when used for testing.
- Electronic thermostat's are located in the supply storage locations. Staff are responsible for ensuring required temperature levels for equipment and supplies are maintained, documenting on the daily monitoring log. Link to print log is located under policy Cross References.

SPECIMEN COLLECTION AND HANDLING:

Specimen Collection and Preparation

- The acceptable specimen for test with the BD Veritor System for Rapid Detection of RSV is a nasopharyngeal (NP) swab.
- It is essential that correct specimen collection and preparation methods be followed.
- Specimens obtained early in the course of the illness will contain the highest viral titers.
- Inadequate specimen collection or improper specimen handling and/or transport may yield a false negative result; therefore, training in specimen collection is highly recommended due to the importance of specimen quality for generating accurate test results.

Specimen Transport and Storage:

- Freshly collected specimens should be processed and tested within one hour.
- It is essential that correct specimen collection and preparation methods be followed.

1. The BD Veritor System RSV Kit includes swabs with a flocked nylon tip for nasopharyngeal specimen collection.

2. Insert the swab into one nostril of the patient, reaching the surface of the posterior nasopharynx.

3. Rotate the swab over the surface of the posterior nasopharynx.

4. Withdraw the swab from the nasal cavity. The sample is now ready for processing using the BD Veritor System Kit.

NOTE: *THE DO'S AND DON'TS OF SAMPLE COLLECTION:*

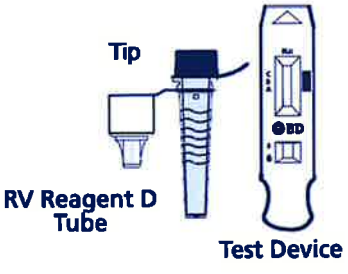
- *Do collect sample as soon as possible after onset of symptoms*
- *Do test sample immediately*
- *BD recommends flocked swabs which are provided in the BD Veritor System RSV Kit*
- *Do not use cotton tips and wooden shafts*
- *Do not use calcium alginate swabs*

TEST PROCEDURE FOR NASOPHARYNGEAL SWABS:

NOTE: *Reagents, specimens and devices must be at room temperature (15–30 °C) for testing.*

Prepare for Testing

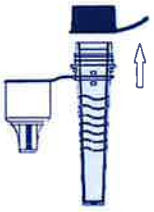
1. For each patient specimen and control swab, remove one **RV Reagent D** tube/tip and one BD Veritor System RSV device from its foil pouch immediately before testing.



2. Label one BD Veritor System device and one **RV Reagent D** tube for each specimen and control to be tested.

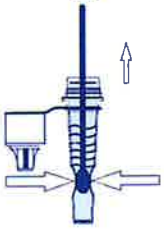
3. Place the labeled **RV Reagent D** tube(s) in the designated area of the tube rack.

Prepare the Sample



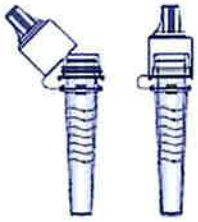
1. Remove and discard the cap from the **RV Reagent D** tube corresponding to the sample to be tested.

2. Insert the patient swab all the way down into the **RV Reagent D** tube and swirl along the inside wall **3** times.



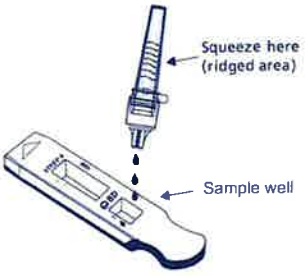
3. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

Run the Test



1. Press the attached tips firmly (until it snaps in place) onto the **RV Reagent D** tube containing the processed specimen (threading/twisting_ not required).

   NOTE: *Do not use tips from any other product, including those from BD or other manufacturers.*



2. Vortex for mix thoroughly by swirling or flicking the bottom of the

tube.

3. Invert the **RV Reagent D** tube, and hold the tube vertically (approximately one inch above the BD Veritor System RSV device sample well). Holding the tube at the ridged area, squeeze gently allowing three **(3)** drops of the processed sample to be dispensed into the sample well of the appropriately labeled BD Veritor System RSV device.

   NOTE: *Be sure not to add more than the required number of drops. 6 or more drops may cause erroneous results.*

   NOTE: *Squeezing the tube close to the tip may cause leakage.*

4. After adding the sample, allow the test to run for **10** minutes before inserting into the Reader.

Analyze the Results

1. The BD Veritor System Reader should be powered-on prior to use and will indicate when it is ready for insertion of the BD Veritor System device.
2. When the test is ready, insert the BD Veritor System RSV device into the BD Veritor System Reader.
3. Follow the Reader on-screen prompts to complete the procedure and obtain test result.

INTERPRETATION OF RESULTS:

The BD Veritor System Reader (purchased separately) must be used for all interpretation of test results. Operators should not attempt to interpret assay results visually directly from the test strip contained within the BD Veritor System RSV assay device.

Reader Display	Interpretation
RSV: +	Positive Test for RSV (RSV antigen present)
RSV: –	Negative Test for RSV (no RSV antigen detected)
CONTROL INVALID	Test Invalid. Repeat the test.

Invalid Test: If the test is invalid, the BD Veritor System Reader will display a "CONTROL INVALID" result and the test or control must then be repeated. If the "CONTROL INVALID" reading recurs, contact BD Technical Support.

REPORTING OF RESULTS:

Positive Test: Positive for the presence of RSV antigen. A positive result may occur in the absence of viable virus.

Negative Test: Negative for the presence of RSV antigen. Infection due to RSV cannot be ruled-out because the antigen present in the sample may be below the detection limit of the test. A negative test is presumptive and it is recommended that these results be confirmed by viral cell culture or an FDA-cleared RSV molecular assay.

Invalid Test: Do not report results. Repeat the test.

OPTIONAL TEST PROCEDURE:

- Testing for RSV and INFLUENZA A+B using a single NP swab.
- For patients under the age of 6.

  NOTE: *The BD Veritor System for Rapid Detection of Flu A+B (CAT# 256045) is required for this procedure in addition to the BD Veritor System for Rapid Detection of RSV (CAT # 256038).*
- This alternative procedure allows for use of the remaining processed sample from Step 5 above to test for Influenza A+B.
- When using this optional test procedure, the sample may be used up to 15 minutes after initial processing.

1. Collect NP swab from the patient and follow Steps 1-8 of the test procedure above as instructed for RSV.

2. Using the sample from Step 8, continue the test procedure using the test device for Flu A+B.

3. Refer to the product insert for BD Veritor System for Rapid Detection of Flu A+B (CAT # 256045) for the test procedure and full description of the BD Veritor Flu A+B test.

4. Follow the Reader on-screen prompts to complete the procedure and obtain test results. Refer to the product insert for the BD Veritor System Flu A+B POC kit (CAT # 256045) for result interpretation.

QUALITY CONTROL:

External Positive and Negative Controls:

Swab controls (RSV + and RSV -) are supplied with each kit. These controls provide quality control material to assess that the test reagent and the BD Veritor System Reader perform as expected. BD recommends that positive and negative controls be run:

- Each new kit lot and/or monthly
- New operator

Test Procedure for Kit Swab Controls:

1. Remove and discard the cap from the **RV Reagent D** tube corresponding to the sample to be tested.

2. Insert the control swab into the tube and vigorously plunge the swab up and down in the fluid for a minimum of 15 seconds.

3. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

4. Continue processing the swab according to the TEST PROCEDURE FOR NASOPHARYNGEAL SWABS above, beginning at Step 7.

NOTE: *If the kit controls do not perform as expected, do not test patient specimens. Contact BD Technical Services at 1-800-638-8663.*

Additionally, each of the BD Veritor System RSV devices contains both positive and negative **internal/procedural controls**:

1. The internal positive control validates the immunological integrity of the device, proper reagent function, and assures that the correct test procedure was followed.

2. The membrane area surrounding test lines functions as a background check on the assay device. These positive and negative internal/procedural controls are evaluated by the BD Veritor System Reader after insertion of the BD Veritor System test device. The BD Veritor System Reader will prompt the operator should a quality issue occur. Failure of the internal/procedural controls will generate an invalid test result.

NOTE: *The internal control does not assess that the sample was properly collected.*

COMPETENCY ASSESSMENT

1. All operators must read the procedure and complete the training and competency record during the initial training. Competency is assessed at orientation and annually using at least two of the following methods:

    i. Performing a test on a blind specimen
    ii. Lead CLS observation of routine work

iii. Each user's quality control performance is monitored
iv. Written testing specific to the method

2. Only approved operators are allowed to perform the test and report results.
3. Competency validation is tracked electronically in the learning management system. Competency forms are placed in employee competency files.

LIMITATIONS OF THE PROCEDURE:

- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
- The contents of this kit are to be used for the qualitative detection of RSV antigens from nasopharyngeal swabs.
- The BD Veritor System for Rapid Detection of RSV is capable of detecting both viable and non-viable RSV particles. The BD Veritor System for Rapid Detection of RSV performance depends on antigen load and may not correlate with other diagnostic methods performed on the same specimen.
- Results from the BD Veritor System for Rapid Detection of RSV test should be correlated with the clinical history, epidemiological data and other data available to the clinician evaluating the patient.
- A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly; therefore, a negative test result does not eliminate the possibility of RSV infection, and should be confirmed by viral cell culture or an FDA-cleared RSV molecular assay.
- Positive test results do not rule out co-infections with other pathogens.
- Negative test results are not intended to rule in other non-RSV viral or bacterial infections.
- Positive and negative predictive values are highly dependent on prevalence rates. Positive test results are more likely to represent false positive results during periods of little/no RSV activity when disease prevalence is low. False negative test results are more likely during peak RSV activity when prevalence of disease is high.
- This device has been evaluated for use with human specimen material only.
- Monoclonal antibodies may fail to detect, or detect with less sensitivity, RSV viruses that have undergone minor amino acid changes in the target epitope region.
- The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection.
- The validity of the BD Veritor System for Rapid Detection of RSV test has not been proven for identification/confirmation of tissue culture isolates and should not be used in this capacity.

- Therapeutic anti-RSV monoclonal antibodies may interfere with the BD Veritor System for Rapid Detection of RSV.
- Performance characteristics have not been established for use with patients older than 5 years of age or for immunocompromised patients.

INTERFERING SUBSTANCES:

Various substances were evaluated for potential inference with the BD Veritor System for Rapid Detection of RSV test. These substances included whole blood (2%) and various medications. No interference was noted with this assay for any of the substances at the concentrations tested.

Substance	Concentration
Ary Saline Nasal Gel	10 mg/mL
4-Acetamidophenol	10 mg/mL
Acetylsalicylic acid	20 mg/mL
Albuterol	0.083 mg/mL
Amantadine Hydrochloride	500 ng/mL
Beclomethasone	500 ng/mL
Budesonide	500 ng/mL
Chlorpheniramine maleate	5 mg/mL
Dexamethasone	10 mg/mL
Dextromethorphan	10 mg/mL
Diphenhydramine HCl	5 mg/mL
Fexofenadine	500 ng/mL
FluMist	1% v/v
Flunisolide	500 ng/mL
Fluicasone	500 ng/mL

Substance	Concentration
Menthol Throat Lozenges	5% w/v
Mometasone	500 ng/mL
Mupirocin	500 ng/mL
Oseltamivir	500ng/mL
Oxymetazoline	0.05 mg/mL
Phenylephrine	1 mg/mL
Pseudoephedrine HCl	20 mg/mL
Purified Mucin Protein	1 mg/mL
Ribavirin	500 ng/mL
Rimantadine	500 ng/mL
Synagis	4 µg/mL
Tobramycin	500 ng/mL
Triamcinolone	500 ng/mL
Zanamivir	1 mg/mL
Four OTC nasal sprays	10%

Guaicacol Glyceryl Ether	20 mg/mL
Homeopathic Allergy Medicine	10 mg/mL
Ibprofen	10 mg/mL
Loratidine	100 ng/mL

Four OTC throat drops	12.5%
Four OTC mouthwashes	5%
Whole blood	2%

TECHNICAL SUPPORT:

For questions, or to report a problem, please call **Technical Support** at **1-800-638-8663**. Test system problems may also be reported to the FDA using the MedWatch reporting system (phone: 1-800-FDA-1088; fax: 1-800-FDA-1078; or http://www.fda.gov/medwatch).

AVAILABILITY:

Cat. No.	**Description**
256038	BD Veritor™ System for Rapid Detection of RSV, 30 test kit
256055	BD Veritor™ System Reader
256061	BD Veritor™ System RSV Control Swab Set

REFERENCES:

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- Clinical and Laboratory Standards Institute. Approved Guideline M29-A3. Protection of laboratory workers from occupationally acquired infections, 3rd ed., CLSI 2005. Wayne, PA.
- Garner JS, Hospital Infection Control Practices Advisory Committee, U. S. Department of Health and Human Services, Center for Disease Control and Prevention. Guideline for isolation precautions in hospitals. Infect Control Hospit Epidemiol 1996;17:53-80.

CROSS REFERENCE

Daily Temperature Log

SUBJECT:	SECTION:
WAIVED & POINT OF CARE TESTING - RAPID GROUP A STREP (BD VERITOR SYSTEM)	*Waived Testing* **Page 1 of 10**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

INTENDED USE:

The BD Veritor™ System for Rapid Detection of Group A Strep test is a rapid chromatographic immunoassay for the direct and qualitative detection of Group A *Streptococcus* antigen from throat swabs of symptomatic patients. It is intended to be used in conjunction with the BD Veritor System Reader as an aid in the diagnosis of Group A Strep.

The BD Veritor System for Rapid Detection of Group A Strep test is intended for use in point-of-care or laboratory settings.

SUMMARY AND EXPLANATION:

Streptococcus pyogenes is a gram-positive coccus, which contains the Lancefield group A antigen that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis.[1] Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess.[2] Traditional identification procedures for group A streptococcal infection involve the isolation and identification of viable organisms using techniques that require 24 to 48 hours or longer.[3]

Rapid diagnosis and early antibiotic therapy of group A streptococcal infection appear to be the best means of preventing medical complications and reducing the spread of the disease.[4] The BD Veritor System for rapid detection of Group A Strep is a rapid test to qualitatively detect the presence of Strep A antigen in throat swab specimens from symptomatic patients, providing results within 5 minutes. The test utilizes antibodies specific for whole cell Lancefield group A *Streptococcus* to selectively detect Strep A antigen.

PRINCIPLES OF THE PROCEDURE:

The BD Veritor System for Rapid Detection of Group A Strep is a qualitative, lateral flow immunoassay for the detection of Strep A antigen in a throat swab. In this test, antibody specific to Strep A antigen is coated on the test line region of the assay device. During testing, the processed throat swab specimen reacts with an antibody to Strep A that is conjugated onto detector particles. The mixture migrates up the membrane and is captured by the line of antibody on the membrane. A positive result for Strep A is determined by the BD Veritor System Reader when antigen-conjugate is deposited at the Test "T" position and the Control "C" position on the BD Veritor System Strep A assay device.

AFFECTED AREAS/PERSONNEL: *URGENT CARE RNs AND EMERGENCY ROOM TECHNICIANS, SIERRA VIEW COMMUNITY HEALTH CENTER (SVCHC) MEDICAL ASSISTANTS.*

REAGENTS:

The following components are included in the BD Veritor System for Rapid Detection of Flu A+B kit:

BD Veritor System Group A Strep Devices	30 devices	Foil pouched device containing one reactive strip. Each strip has one test line of polyclonal antibody specific to Strep A antigen and negative control line of polyclonal antibody.
BD GAS Reagent 1	Bottle with 4 mL reagent	Dilute acetic acid solution
BD GAS Reagent 2	30 tubes with 200 µL reagent	Sodium nitrite, EDTA
Individually packaged swabs, sterile	30 each	Swab for throat specimen collection
Positive Control Swab	1 each	Strep A Positive Control Swab (purified Strep A antigen) with < 0.1% sodium azide
Negative Control Swab	1 each	Strep A Negative Control Swab with < 0.1% sodium azide

MATERIALS REQUIRED BUT NOT PROVIDED:

- BD Veritor System Reader (Cat. No. 256055)
- Timer
- Tube rack for specimen testing

WARNINGS AND PRECAUTIONS:

- For *in vitro* Diagnostic Use.
- Test results are not meant to be visually determined. *All test results must be determined using the BD Veritor System Reader.*
- Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus may be present in clinical specimens. "Standard Precautions"5-8 and institutional guidelines should be followed in handling, storing and disposing of all specimens and all items contaminated with blood and other body fluids.
- Dispose of used BD Veritor System test devices as bio hazardous waste in accordance with federal, state and local requirements.
- Reagents contain sodium azide, which is harmful if inhaled, swallowed or exposed to skin. Contact with acids produces very toxic gas. If there is contact with skin, wash immediately with plenty of water. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.
- Only use the swabs and reagents provided with the kit for specimen collection and preparation. Do not mix components from different kit lots.

- Other than the swabs that are used for specimen collection, kit components should not make contact with the patient.
- Do not use kit components beyond the expiration date.
- Do not reuse the device.
- Do not use the kit if the Positive Control Swab and Negative Control Swab do not yield appropriate results.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- To avoid erroneous results, specimens must be processed as indicated in the assay procedure section.
- Specific training or guidance is recommended if operators are not experienced with specimen collection and handling procedures.

CAUTION: GAS Reagent 1 *may cause skin, eye and respiratory tract irritation.* ***GAS Reagent 1*** *contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water. The combination of* ***GAS Reagent 1*** *and* ***GAS Reagent 2*** *generates nitrous acid which may cause skin, eye and respiratory tract irritation. If this solution contacts the skin or eye, flush with large volumes of water.*

GAS Reagent 2
WARNING

Hazard Statements

H302 Harmful if swallowed.

Precautionary Statements

P264 Wash thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P301 + P312 IF SWALLOWED: Call POISION CENTER or doctor/physician if you feel unwell.

P330 Rinse mouth.

P501 Dispose of contents/container in accordance with local/regional/international regulations.

STORAGE AND HANDLING:

- Kits may be stored at 2–30°C. DO NOT FREEZE.
- Reagents and devices must be at room temperature (15–30 °C) when used for testing.
- Electronic thermostat's are located in the supply storage locations. Staff are responsible for ensuring required temperature levels for equipment and supplies are maintained, documenting on the daily monitoring log. Link to print log is located under policy Cross References.

SPECIMEN COLLECTION AND HANDLING:

Specimen Transport and Storage

- Testing should ideally be performed immediately after the specimens have been collected. Swab specimens may be stored in clean, dry plastic tubes for up to 8 hours at room temperature or 72 hours at 2 – 8 °C.

Specimen Collection and Preparation

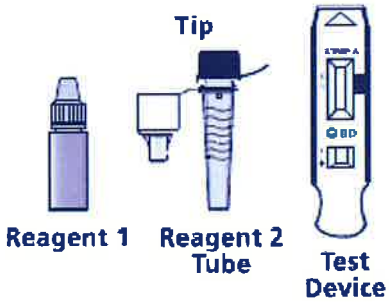
- Only use components provided in the kit.
- Collect the throat swab specimen with the sterile Rayon swab that is provided in the kit.
- Rayon swabs can also be transported with Modified Stuart's or Amies Liquid Medium.
  - Swab the posterior pharynx, tonsils and other inflamed areas.
  - Excess blood or mucus on the swab specimen may interfere with test performance.
  - Avoid touching the tongue, cheeks and teeth and any bleeding areas of the mouth with the swab when collecting specimens.[9]

TEST PROCEDURE:

NOTE: *Reagents, specimens and devices must be at room temperature (15–30 °C) for testing. The reader should be powered-on prior to use and will indicate when it is ready for insertion of the BD Veritor System Group A Strep device.*

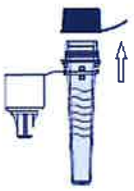
Prepare for Testing

1. For each patient specimen and control swab, take the bottle of **GAS Reagent 1** and one **GAS Reagent 2** tube/tip and one BD Veritor Group A Strep device from its foil pouch immediately before testing.
2. Label one BD Veritor System device and one **GAS Reagent 2** tube for each specimen and control to be tested.
3. Place the labeled **GAS Reagent 2** tube(s) in the designated area of the workstation or rack.



Prepare the Sample

1. Remove the cap from the **GAS Reagent 2** tube corresponding to the sample to be tested.



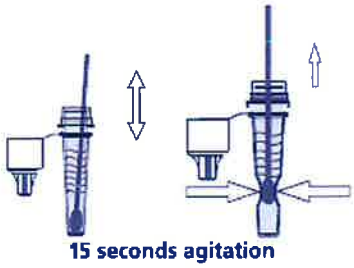
> Remove the cap from the **GAS Reagent 1** bottle and add 3 drops from the **GAS**

Reagent 1 bottle to the **GAS Reagent 2** tube.

— **GAS Reagent 2** contains a pH-sensitive dye which turns from blue to yellow to confirm the addition of **GAS Reagent 1**. A uniform yellow color indicates complete mixing of the reagent. If any blue color remains, mix the solution by gently swirling the tube.

2. Insert the specimen or control swab and incubate for **1-2** minutes, then plunge the swab up and down for a minimum of **15** seconds, scrubbing the inside of the tube with the swab. Avoid splashing.

3. Remove the swab while squeezing the sides of the tube to extract the liquid.



Run the Test

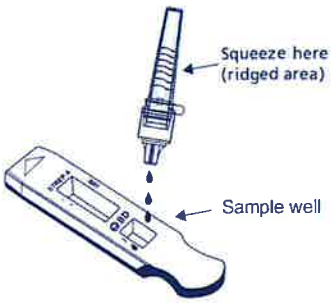
4. Snap fit the tip onto the tube containing the processed specimen or control (threading/twisting not required).

NOTE: Do not use tips from any other product, including those from BD or other manufacturers.

5. Invert the tube, holding it vertically (approximately one inch above the BD Veritor System Group A Strep device sample well).

6. Squeeze gently on the half of the tube away from the tip, allowing three (**3**) drops of the processed specimen to be dispensed into the sample well of the appropriately labeled BD Veritor System Group A Strep device.

NOTE: Squeezing the tube close to the tip may cause leakage.



7. After adding the sample, allow the test to run for **5** minutes and then insert the BD Veritor System Group A Strep device into the BD Veritor System Reader (purchased separately). The BD Veritor System Reader should be powered-on prior to use and will indicate when it is ready

for insertion of the BD Veritor System device.

Analyze the Results

8. When the test is ready, insert the BD Veritor System Group A Strep device into the BD Veritor System Reader. Follow the reader on-screen prompts to complete the procedure and obtain the test result.

INTERPRETATION OF RESULTS:

The BD Veritor System Reader must be used for all interpretation of test results. Due to the technologies incorporated in the BD Veritor System, operators should not attempt to interpret assay results visually from the test strip.

Reader Display	Interpretation
STREP: +	Positive Test for Strep A (Strep A antigen present)
STREP: –	Negative Test for Strep A (no antigen detected)
CONTROL INVALID	Control line error Contact BD

> *Invalid Test:* The BD Veritor System Reader will display a "CONTROL INVALID" result and the test must then be repeated. If "CONTROL INVALID" reading occurs, contact BD.

REPORTING OF RESULTS:

Positive Test: Positive for the presence of Strep A antigen. A positive result may occur in the absence of viable bacteria.

Negative Test: Negative for the presence of Strep A antigen. Infection due to Strep A cannot be ruled-out because the antigen present in the sample may be below the detection limit of the test. *Culture confirmation of negative samples is recommended.*

Invalid Test: Test result is inconclusive. Do not report results.

QUALITY CONTROL:

Each BD Veritor System Strep A device contains both positive and negative **internal/procedural controls**:

> The internal positive control validates the immunological integrity of the device, proper reagent function, and assures that the correct test procedure was followed.
> The membrane area surrounding test lines functions as a background check on the assay

device.

NOTE: *the internal control does not assess that the sample was properly collected.*

These positive and negative internal/procedural controls are evaluated by the BD Veritor System Reader after insertion of the BD Veritor System test device. The BD Veritor System Reader will prompt the operator should a quality issue occur. Failure of the internal/procedural controls will generate an invalid test result.

External Positive and Negative Controls:

Swab controls (Strep A Positive and Strep A Negative) are supplied with each kit. These swab controls should be used to ensure that the test reagents work properly and that the test procedure is performed correctly. For kit swab controls, process according to the test procedure on the previous page beginning at STEP 1.

- Run external controls monthly and/or each new shipment.
- New operators

NOTE: *If the kit controls do not perform as expected, do not test patient specimens. Contact BD Technical Services at 1-800-638-8663.*

COMPETENCY ASSESSMENT

1. All operators must read the procedure and complete the training and competency record during the initial training. Competency is assessed at orientation an annually using at least two of the following methods:

    a. Performing a test on a blind specimen
    b. Lead CLS observation of routine work
    c. Each user's quality control performance is monitored
    d. Written testing specific to the method

2. Only approved operators are allowed to perform test and report results.

3. Competency validation is tracked electronically in the learning management system. Competency forms are placed in employee competency files.

LIMITATIONS OF THE PROCEDURE:

- This test will only indicate the presence of Strep A antigen in the throat swab specimen from both viable and non-viable group A Streptococcus bacteria. It does not determine the qualitative concentration of Strep A antigen.
- Respiratory infections can be caused by Streptococci of serogroups other than A as well as other

pathogens. This test does not differentiate between carriers and infected individuals.

- Excess blood or mucus on the swab specimen may interfere with test performance.
- Avoid touching the tongue, cheeks, and teeth and any bleeding areas of the mouth with the swab when collecting specimens.
- False negative results can occur from inadequate or improper specimen collection, or from antigen levels that are below the limit of detection for this test.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- As recommended by the American Academy of Pediatrics, patients with symptoms and an antigen negative test should have a follow-up culture.
- The use of antibiotics or over-the-counter medications may suppress the growth of Group A Streptococcus in culture despite the presence of organisms detectable by rapid antigen tests.

INTERFERING SUBSTANCES:

Various substances were evaluated for potential inference with the BD Veritor System for Rapid Detection of Group A Strep test at concentrations comparable to or greater than levels that may be present in patient respiratory samples. Of the substances tested in this study, none exhibited interference when either Group A positive or Group A negative samples were tested with the BD Veritor System for Rapid Detection of Group A Strep test.

Substance	Concentration	Substance	Concentration
4-Acetamidophenol	10 mg/mL	Menthol Throat Lozenges	5% w/v
Acetylsalicylic acid	20 mg/mL	Mometasone	500 ng/mL
Albuterol	0.083 mg/mL	Mouthwash Listerine	5% w/v
Amantadine	500 ng/mL	Mouthwash Scope	5% w/v
Ascorbic acid chewable tablets	5% by weight	Mouthwash CVS	5% w/v
Beclomethasone	500 ng/mL	Mucin, salivary protein, purified	1 mg/mL
Benzocaine throat spray (Cepacol)	5% by volume	Nasal Spray	5% w/v
Blood, type A	2% (v/v)	Nasal Spray	5% w/v

Blood, type B	2% (v/v)
Blood, type A/B	2% (v/v)
Blood, type O	2% (v/v)
Budesonide	500 nm/mL
Chlorpheniramine maleate	5 mg/mL
Dexamethasone	10 mg/mL
Dextromethorphan	10 mg/mL
Dyclonine HCl lozenges (Sucrets)	5% w/v
Diphenhydramine HCl	5 mg/mL
Fexofenadine	500 ng/mL
FluMist	1% v/v
Fluicasone	500 ng/mL
Guaicacol Glyceryl Ether	20 mg/mL
Ibprofen	10 mg/mL
Loratidine	100 ng/mL

Nasal Spray	5% w/v
Oseltamivir	500ng/mL
Oxymetazoline	0.05 mg/mL
Phenol throat spray (Chloraseptic)	5% w/v
Phenylephrine	1 mg/mL
Pseudoephedrine HCl	20 mg/mL
Throat drops: CVS	5% w/v
Throat drops: Pedia Care	5% w/v
Throat drops: Triaminic	5% w/v
Tobramycin	500 ng/mL
Triamcinolone	500 ng/mL
Zanamivir	1 mg/mL
Zicam throat spray (Zn/benzalkonium chloride)	5% w/v
Zinc Lozenges	5% w/v

AVAILABILITY:

Cat. No.	**Description**
256040	BD Veritor™ System for Rapid Detection of Group A Strep, 30 tests
256055	BD Veritor™ System Reader
256049	BD Veritor™ System Group A Strep Control Swab Set, 10 pairs of swabs

REFERENCES:

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- Becton, Dickinson and Company, 7 Loveton Circle Sparks, MD 21152 USA
- Benex Limited, Pottery Road, Dun Laoghaire Co. Dublin, Ireland
- FluMist is a registered trademark of MedImmune, LLC.
- BD, BD Logo and BD Veritor are trademarks of Becton, Dickinson and Company. © 2014 BD.

CROSS REFERENCE:

Daily Temperature Log

SUBJECT:	SECTION:
WAIVED & POINT OF CARE TESTING - TESTING FOR FECAL OCCULT BLOOD	**Page 1 of 4**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

To establish the procedure to be followed for the use of testing for the presence of fecal occult blood.

POLICY:

1. Fecal blood slides will be used for point of care of fecal occult blood.
2. Personnel performing fecal occult blood testing will be trained utilizing this policy and procedure and complete a competency prior to performance. Training will include reading Waived and Point of Care Testing – Fecal Occult Blood policy.
3. Personnel will have competency validated annually.
4. Education Department will maintain records of all individuals who have completed training and competency validation.
5. Quality Control procedures will be completed with each patient test performed.
6. Quality control results will be documented on the Point of Care Occult Blood Worksheet.
7. Universal precautions will be observed throughout the patient testing procedure.

AFFECTED AREAS/PERSONNEL: *LABORATORY, RN, LVN, TRAVELERS, MEDICAL ASSISTANTS (MA)*

PROCEDURE:

PATIENT TESTING:

1. Collect materials needed for testing. Check expiration dates of slide and developer solution prior to use.
    a. Fecal Occult Slides
    b. Occult Blood Worksheet
    c. Brand specific Developer
    d. Applicator Sticks
    e. Product Instructions
    f. Gloves, other applicable PPE

2. Appropriately fill out the Point of Care Occult Blood Worksheet by entering Meditech User ID and the Lot# and Expiration date of the slide/card and developer prior to specimen collection. Place patient label to top of worksheet.

3. Collect a small fecal sample on one end of the applicator stick or with gloved finger. Apply a thin smear to left window.

4. Obtain a second sample from a different part of the stool. Apply a thin smear to right window. To increase the probability of detecting occult blood, separate samples should be taken from two different sections of each fecal specimen.

5. Close the cover.

6. Open the flap in the back of the slide and apply two drops of Developer to the Specimen Test Area paper directly over each smear.

7. Read results within 30 - 60 seconds.

    a. Any trace of blue on or at the edge of the smear is positive for occult blood.

    b. For color illustrations of test results, see INTERPRETING THE FECAL OCCULT TEST in the centerfold of the product instructions contained in the kit.

    c. Always develop the test and determine whether the fecal sample is positive or negative before developing the Performance Control Area feature. Do not apply developer to the Performance Control Area before interpreting results. Any blue originating from the Performance Control Area should be ignored when reading the specimen test results.

    d. Neither the intensity nor the shade of blue from the Performance Control Area should be used as a reference for the appearance of positive patient results.

8. Apply one drop only of Developer in the Performance Control Area.

9. Read results within 30 seconds.

    a. If the slide and developer are functional, a blue line will appear in the Performance Control Area.

    b. For color illustrations of Performance Control results, see INTERPRETING THE FECAL OCCULT TEST in the centerfold of the product instructions.

    c. Check "QC OK" box on Occult Blood Worksheet if blue line appears as expected.

    d. In the unlikely event that the Performance Control Area does not react as expected after application of the developer, the test results should be regarded as invalid. **DO NOT REPORT RESULTS.** Repeat the test with a new slide.

10. After specimen is collected, results are interpreted, Performance Control is performed and Point of Care Occult Blood Worksheet completed, an order for "Occult Blood, Stool" (OBS) is placed in Meditech and all information on the Point of Care Occult Blood Worksheet is entered into appropriate fields. The RN, LVN or MA is responsible for performing tests, recording patient results in the medical record and completing Point of Care Occult Blood Worksheet. The unit clerk may enter the order and all necessary information from the Worksheet into Meditech.

11. Once the order has been placed in Meditech, the printed specimen labels will be stapled to the completed Point of Care Occult Blood Worksheet and placed in the designated area on the nursing unit. The Laboratory Department will retain these worksheets.

REPORTING RESULTS:

1. Report as POSITIVE or NEGATIVE and document in the patient record as well as the Point of Care Occult Blood Worksheet.

QUALITY CONTROL:

1. The function and stability of the guiac paper and developer will be tested using the Performance Control Area feature located on the slide.

2. Quality control is performed and recorded on the Point of Care Occult Blood Worksheet with every patient test **AFTER** interpreting results.

STORAGE REQUIREMENTS:

1. Do not refrigerate or freeze slides or developer solutions. Store at controlled room temperature in original packaging. Protect from heat and light.

   a. Electronic thermostat's are located in the supply storage locations. Staff are responsible for ensuring required temperature levels for equipment and supplies are maintained, documenting on the daily monitoring log. Link to print log is located under policy Cross References.

2. Do not store with volatile chemicals (e.g., iodine, chlorine, bromine, or ammonia).

3. The slides and developer, stored as recommended, will remain stable until the expiration dates, which appear on each slide and developer bottle. Do not use slides or developer after expiration date.

4. Developer should be protected from heat and the bottle kept tightly capped when not in use. It is flammable and subject to evaporation.

LIMITATIONS OF PROCEDURE:

Many factors can influence the results obtained from the fecal occult blood test, such as obvious rectal bleeding, hematuria or menstruation. For further information refer to package insert.

REFERENCES:

- Package Instruction Insert

CROSS REFERENCES:

- Waived & Point of Care Testing Competency and Quality
- Daily Temperature Log

Senior Leadership Team	3/28/2023
Board of Director's Approval	
Bindusagar Reddy, MD, Chairman	3/28/2023

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SIERRA VIEW MEDICAL CENTER-
CONSENT AGENDA
March 28, 2023
BOARD OF DIRECTOR'S APPROVAL

The following Polices/Procedures/Protocols/Plans have been reviewed by Senior Leadership Team and are being submitted to the Board of Director's for approval:

	Pages	Action
Policies:		Approve ↓
1. Investigations and Government Search Warrants, Unannounced	1-4	
2. Medical Director Arrangement Policy	5-11	
3. Medical Staff Assignments	12-13	
4. Organized Health Care Arrangement	14-15	
5. Professional Practice Council Nursing Peer Review	16-20	
6. Sponsorships and Donations	21	
7. Voluntary Disclosure of Violations (Reportable Events)	22-24	
8. Waiver of Medicare Co-Payments and Deductibles/Offerings Benefits	25-26	
9. Annual Evaluation for the Effectiveness of the Environment of Care (EC), Emergency Operations Plan (EOP) & Life Safety (LS) Management Programs	27-41	

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SUBJECT: **INVESTIGATIONS AND GOVERNMENT SEARCH WARRANTS, UNANNOUNCED**	SECTION: **Page 1 of 4**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

To provide guidance and establish a process for appropriately responding to a government investigation or search warrant by federal, state or local law enforcement pursuant to a government investigation.

POLICY:

Sierra View Medical Center (SVMC) will cooperate with all law enforcement or government requests and investigations while protecting the legal rights of the organization and individual employees. In order to ensure those protections and the proper conduct of the investigation, the Compliance Officer (CO) or designee shall oversee and direct, to the extent possible, the response to a government search warrant. Searches by law enforcement or government agents are not allowed unless a search warrant is presented. Do not verbally or otherwise agree to allow a search in the absence of a search warrant.

Documents, computer files/media etc. related to the investigation shall not be destroyed, hidden or altered.

Any employee who participates or otherwise has knowledge that a government search warrant, investigation or audit has been executed that relates to SVMC should keep the matter confidential and refrain from discussing the written order or related events with any other individuals except those authorized by the CO or legal counsel.

DEFINITION:

Government investigation: May include, but is not limited to, investigation by the Office of the Inspector General of the United States Department of Health and Human Services, United States Attorney General's Office, the Federal Bureau of Investigation, the State Attorney General's Office, the Office of Civil Rights, State Medi-Cal Fraud Control Unit, or the District Attorney.

Search Warrant: Means a written court order that entitles law enforcement to search a defined area and seize property that is described in the search warrant or located in an area specifically identified as covered by the search warrant.

PROCEDURE:

If federal, state, or local authorities enter a SVMC facility to conduct a government investigation or presents a search warrant, employees shall take the following steps:

1. Escort the agents/investigators to a conference room or private office in order to minimize disruption to patients and/or caregivers.

2. Identify the agent in charge.

a. Ask for identification, such as a business card of the agent/investigator in charge which includes name, title, agency, and telephone number of agent.

b. Immediately contact the Administrator On-Call (AOC), CO and CEO and politely ask the agent/investigator to wait for one of these SVMC representatives to arrive. The AOC, CEO, CO, or designee will be the SVMC representative responsible to coordinate SVMC's response to the government investigation.

AOC -	Refer to house supervisor for number
Compliance Officer	(559) 791-3838
Chief Executive Officer	(559) 788-6100

Do not leave a voice mail or message. Rather make every possible effort to reach the AOC, CO and CEO on their cell phones. If unsuccessful, contact any senior leadership team member. Provide all the information collected in step #2 above.

IN THE CASE OF A SEARCH WARRANT

3. Follow the steps in #2 above. Ask for a copy of the search warrant, and any accompanying affidavit. The agents/investigators presenting the search warrant do not have an obligation to wait for the AOC, CEO, or CO or designee, but request this in any event.

4. Do not consent to the search or sign a form acknowledging consent. Politely decline. Consenting to the search and/or signing the form may jeopardize the ability of SVMC to challenge the legality of the search at a later time. **HOWEVER, NO EMPLOYEE SHOULD OBSTRUCT THE SEARCH IN ANY WAY.**

5. Notify the responsible director or manager of the entity or department to which the search warrant has been presented that agents are on the premises and have issued a search warrant and who else has been notified. The responsible director or manager should make every effort to be present at the site for the execution of the search warrant.

6. The responding AOC, CO, CEO or designee will take the following steps:

a. Contact the hospital's general counsel.

b. Carefully read the search warrant and confirm that the search warrant is signed by a judge. If there is a discrepancy, notify the agent in charge.

c. Ask for the name and phone number of the prosecutor, if not indicated on the documents provided.

d. Identify the essential employees that are knowledgeable and can assist in retrieving documents, computer information, etc.

e. Move all non-essential employees to another site for the length of the search. Exercise discretion to ensure that the facility continues to operate at an acceptable level.

f. Ensure that at least one employee accompanies the agents/investigators at all times.

g. The search warrant will describe, often in detail, the areas of the facility that the agents/ investigators have been authorized to search and the documents and other items authorized to seize. Give the agents/investigators access to the areas identified in the search warrant. If the agents/investigators want to inspect an area of the facility, or seize a document or object outside the scope of the warrant, do not prevent the agents/investigators from doing so, and do not argue with the agents/investigators about the scope of the warrant. Instead, state to the agent/investigator that the area, documents or items are not covered by the warrant and you are permitting the search under protest. If the search exceeds the scope of the warrant, SVMC may later challenge the legality of the search.

h. SVMC has no obligation to assist the agents/investigators in conducting the search. Should the agents/investigators inquire about the location of documents or objects, answer their questions truthfully. For example, unlocking a file cabinet upon request is reasonable, however, taking the agents/investigators on a tour of the facility, explaining operations, or the documents they have been authorized to seize is not required or recommended. It is the agents'/investigators' obligation to specify the documents or objects sought, and it is SVMC's obligation to not obstruct the agents/investigators access to such documents or objects covered in the search warrant.

i. Should the agents/investigators ask to see client/attorney privileged documents ask them to wait until SVMC attorneys arrive to speak with them about this issue. If the agents/investigators refuse to wait, make note of any such information reviewed or seized.

j. Should the agents wish to see patient medical records, or other confidential patients' records, remind them of the highly confidential nature of such information and request that they take precautions to preserve confidentiality. Make careful note of any such information seized.

k. Monitor/record the search without interfering with the agents (video recording is an option). Keep a detailed list of the areas searched, documents and objects removed. Ask to copy the documents before they are removed. SVMC does not have the right to stop the search; however, SVMC has the right to observe the search at all times and make a record of everything the agents/investigators have searched.

l. Advise employees that, during the search, questions may be asked of them regarding not only the documents or other items that are seized by the government, but also their and others' duties and responsibilities within the facility. Employees should be advised that they are not required to speak with the agents and that SVMC will provide counsel for the employees if they wish.

m. At the conclusion of the search, the agents/investigators are obligated to provide SVMC with an inventory of all documents seized.

n. In the event of media coverage, immediately notify the Director of Marketing.

7. EMPLOYEE RIGHTS FOR OFF-SITE VISITS OR CONTACTS BY GOVERNMENT AGENTS/INVESTIGATORS: *Employees are free to speak to government agents/investigators; however, are not required to submit to questioning.*

a. Individuals are free to talk to government agents/investigators if they wish, but also have the right to decline an interview or to postpone an interview until they have had an opportunity to seek legal counsel or other advice.

b. Only a government attorney working with an attorney representing the person to be interviewed can make promises binding the government.

c. If an employee chooses to be interviewed, he or she has the following rights:

i. To have an attorney or someone else present as a witness
ii. To take notes, including questions asked and responses
iii. To know the full identify of all persons who conduct the interview (name, position, and government agency)
iv. To end an interview at any time, without providing a reason
v. To decline to answer any questions

Employees who agree to be interviewed should always tell the government agent/investigator the truth, be completely accurate, and not guess or speculate. If employees do not know the answer to a question, stating such is acceptable.

Employees are requested to immediately report any off-site visits by government agents/investigators to the CO.

REFERENCES:

- HCCA Health Care Compliance Professional's Manual, 2021, Volume 1, pages 574 – 584.
- United States Sentencing Commission Guidelines Manual 2021: Appendix B (2021). Retrieved from https://www.ussc.gov/sites/default/files/pdf/guidelines-manual/2021/APPENDIX_B.pdf.

SUBJECT: **MEDICAL DIRECTOR ARRANGEMENT POLICY**	SECTION: **Page 1 of 7**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

The purpose of this policy is to ensure that:

A. All Medical Director Arrangements are undertaken only when Sierra View Medical Center (SVMC) has a legitimate need for a Physician to provide the type and quantity of medical director services contemplated to promote quality, cost-effective care or to fulfill other legitimate needs of Sierra View for a particular hospital department, program or service.

B. The remuneration[1] paid to a Physician pursuant to any Medical Director Arrangement is commercially reasonable and consistent with fair market value[2] for the medical director services furnished by the Physician.

C. All medical director services furnished by a Physician pursuant to a Medical Director Arrangement are adequately and contemporaneously documented by the Physician in a time log furnished by Sierra View Medical Center.

D. All Medical Director Arrangements comply with applicable laws and regulations, including the federal Anti-Kickback Statute and the Stark law.

E. Under no circumstances will a Medical Director Arrangement involve Sierra View paying remuneration to a Physician, directly or indirectly, with the intent to induce the Physician to refer patients to, or otherwise generate business for, Sierra View.

F. Sierra View only enters into a Medical Director Arrangement with a single Physician for each department, program or service where a medical director need exists.

This policy applies to "*Medical Director Arrangements*"[3] pursuant to which Sierra View Medical Center ("*Sierra View*") compensates a physician ("*Physician*"), or such Physician's medical group, for medical director services provided by such Physician. For purposes of this policy, a Physician means a physician that is licensed to practice medicine in California and a member of the Sierra View medical staff or entity in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for, Sierra View.

POLICY:

The procedure, outlined below, must be followed in connection with the development, renewal, or replacement of any Medical Director Arrangement. The procedures listed below must be documented on

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1 "*Remuneration*" means anything of value, including, but not limited to, cash, items or services.

2 "*Fair Market Value*" means the value in arms-length transactions, consistent with the compensation that would be included in a services agreement, as the result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party.

3 "*Medical Director Arrangement*" means an arrangement pursuant to which Sierra View provides remuneration to a Physician, or such Physician's medical group, for the performance of medico-administrative, consulting or other administrative services (not direct clinical patient care) in a hospital department, or for a particular Sierra View program or service.

the Medical Director Arrangement checklist by the Contract Administrator and kept with the medical director agreement.

AFFECTED PERSONNEL/AREAS: *ALL SVMC EMPLOYEES, MEDICAL STAFF*

PROCEDURE:

A. Identify the Need for the Services.

Sierra View must identify and describe the purpose and need for the medical director services, and why the medical director services are reasonably necessary for the efficient operation of the Sierra View department, program or service.

B. Identify the Specific Services to be Performed.

Sierra View must identify the specific medical director services for each Medical Director Arrangement that are both *bona fide* and needed for program development, improvement of healthcare services, patient safety, or the quality of care provided to patients.

C. Project the Number of Hours/Specific Services Required.

Sierra View must document that it has made an objective determination that the number of hours of medical director services that will be provided by the Physician each month are reasonably necessary to accomplish Sierra View's legitimate needs and are supported by the Fair Market Value Assessment.

D. Demonstrate the Qualifications of the Physician.

Sierra View may not enter into a Medical Director Arrangement unless Sierra View has determined that the Physician is qualified (*i.e.,* possesses the necessary skills, training and experience), and is capable of performing the medical director services.

E. Calculate Fair Market Value Compensation.

Sierra View may not enter into a Medical Director Arrangement unless Sierra View has determined and documented that the remuneration being offered to the Physician for the medical director services is commercially reasonable and does not exceed fair market value. In order to ensure that compensation paid to the Physician or to his or her medical group is consistently determined, compensation must be determined in accordance with the following guidelines for using compensation benchmark databases in determining fair market value.

1. Compensation paid pursuant to a Medical Director Arrangement cannot exceed the median compensation rate for a Physician's medical specialty as set forth using the sources detailed herein except that One Hundred Twenty-Five Dollars ($125.00) per hour will be the minimum compensation rate paid to a physician. The primary source for calculating the national median compensation (median annual hours times the median

hourly rate) is MDRanger ("*MDRanger*"). For purposes of this policy, the Directorship Compensation for a Physician's medical specialty as set forth in the most recent MDRanger database on Medical Director physician compensation is referred to as the "*MDRanger Administration Benchmark for Medical Direction*". Documentation must be placed in a master contract database (see paragraph K below) relating to each Medical Director Arrangement.

2. If the national median compensation using the MDRanger is lower than the proposed compensation, then the proposed compensation should be compared to the most recent Medical Directorship Compensation Report available on the Medical Group Management Association ("MGMA") website using the MGMA DataDive reporting function." The median is calculated using Hourly Rate Compensation and Total Hours Spent on Directorship per week. Documentation must be placed in a master contract database (see paragraph K below) relating to each Medical Director Arrangement identifying the specific medical specialty in the MGMA Directorship Compensation Report that is being utilized to determine the compensation paid pursuant to each such Medical Director Arrangement published by the MGMA.

3. If the national median compensation using the MDRanger and the MGMA national medians are lower than the proposed compensation, then the proposed compensation should be compared to the current MDRanger California Region annual payment and/or the median as calculated using Hourly Rate Compensation and Total Hours Spent on Directorship per Week by Geographic Section for the Western Section in the most recent Medical Directorship Compensation Report published by the Medical Group Management Association ("MGMA").

4. If the median compensation using the MDRanger and MGMA medians are lower than the proposed compensation or when an appropriate comparative is not available in MDRanger or MGMA, a third party appraiser should conduct a survey to determine an appropriate median for California. The independent third party appraiser will survey (hours per month and hourly rate) for the same Medical Director Service from five (5) comparable California Hospitals. This data will be used to determine a median and 75th percentile for hours per month and hourly rate. The FMV is to be less or equal to the product of the median hours per month and the median hourly rate.

5. Documentation must be placed in a master contract database (see paragraph K below) relating to each Medical Director Arrangement identifying the specific medical specialty and the source that is being utilized to determine the compensation paid pursuant to each such Medical Director Arrangement.

6. The sources above are to be utilized for determining the fair market value of the Physician's medical director services under the Medical Director Arrangement, regardless of whether the payment under the Medical Director Arrangement will be paid on an hourly, monthly or other basis.

7. If the proposed compensation is greater than the median, follow the steps in G. for approval of compensation over the median.

F. Approval for Compensation Over Monthly/Annual Median.

Where a Physician requests compensation higher than the median in the source for determining fair market value, one of the following must be documented before such compensation can be set forth in the Medical Director Arrangement:

1. The Physician's curriculum vitae must identify educational or professional experience, or other expertise sufficiently high to warrant the proposed compensation. .

2. An independent third party appraiser qualified to assess physician compensation provides an independent opinion that the Physician's educational or professional experience, or other expertise, warrants the proposed compensation.

3. Outside legal counsel with a specialty in health care law affirms that it is reasonable to utilize the proposed compensation under the circumstances.

4. Approval by CEO/President

G. Medical Director Arrangement Compensation Provisions.

The Medical Director Arrangement must identify the anticipated number of hours the Physician must spend on the medical director services each month, and the remuneration must be determined by multiplying the fair market value hourly rate by the projected number of hours identified in the Medical Director Arrangement, the Medical Director Arrangement must compensate the Physician for each hour of service rendered (up to a maximum per month, which maximum should be what Sierra View anticipates is reasonably needed for the legitimate business purposes of Sierra View). Under no circumstances will the Physician be paid greater compensation for the provision of a greater number of hours of medical director services than are contracted in the Medical Director Arrangement.

1. The Medical Director Arrangement must require the submission per the contracted time frame and approval of monthly time logs as a pre-condition to payment. A form time log should be attached to the written Medical Director Arrangement as an exhibit.

H. Certification From Physician's Medical Group Must Be Obtained.

If Sierra View enters into a Medical Director Arrangement with a Physician's medical group, prior to execution of that Medical Director Arrangement the medical group must furnish to Sierra View a written representation and warranty that (1) the compensation of each physician affiliated with the medical group, including without limitation, the Physician, (a) will be commercially reasonable and consistent with fair market value, and (b) will not vary with, reflect or relate to, directly or indirectly, the volume or value of patient referrals (actual or anticipated) to, or other business generated for, Sierra View, and (2) the medical group agrees to comply with all relevant claims submission and billing laws and regulations.

I. Other Terms of the Medical Director Arrangement.

1. The Medical Director Arrangement must be in writing (oral arrangements are prohibited), executed by both parties (no compensation will be paid until the written Medical Director Arrangement is signed by each party), and clearly describe each medical director service to be furnished by the Physician.

2. The term of the written Medical Director Arrangement must be for at least one year.

3. The Medical Director Arrangement must state that, in the event the Medical Director Arrangement is terminated during the first year of the term, neither Sierra View nor the Physician will enter into another similar arrangement with each other for the remainder of the first year of the intended term of the agreement other than on the same terms and conditions as specified in the Medical Director Arrangement.

4. The remuneration paid by Sierra View to the Physician may not vary (or be adjusted or renegotiated) in any manner based on the volume or value of any actual or expected referrals to, or business otherwise generated for, Sierra View by the Physician.

5. Neither the Physician nor, in the event of a Medical Director Arrangement with a medical group, any physician affiliated with such medical group, may be precluded or restricted in any manner from (a) establishing medical staff privileges at any other hospital or health care facility, (b) referring patients to or utilizing the services of any other hospital or health care facility, or (c) otherwise generating business for any other hospital or health care facility.

J. Creation and Maintenance of a Contract Database.

Sierra View will maintain a master contract database in which a copy of each duly executed Medical Director Arrangement will be maintained, together with the information used to determine that a need for the medical director services exist, the number of hours that are needed, and how the fair market value compensation was calculated.

K. Termination of the Medical Director Arrangement Prior to the Planned Date of Termination.

The CEO may terminate the Medical Director Arrangement for cause if any of the following events occur, but not limited to:

1. Non-compliance with applicable laws and regulations.
2. Failure to maintain licensure and Medical Staff privileges in good standing
3. Inadequate documentation of services.
4. Failure to meet performance expectations.
5. Failure to meet outcome metrics.
6. Failure to comply with the terms of the Medical Director agreement

L. Medical Director Time Log Documentation Guidelines

SVMC requires Medical Directors to accurately and legibly document services/activities provided on the Medical Director time log provided by SVMC. Services/activities must be in alignment with the administrative and/or other duties designated in the Medical Director's agreement.

1. The Medical Director must document the date of the service/activity, time spent and brief description of the service/activity. Further explanation may be requested, if an entry is unclear. Entries that do not meet documentation guidelines may be considered non-allowable for payment.
2. By signing the Medical Director time log, the Medical Director affirms and attests that the services/activities were performed.
3. The Medical Director must submit his/her time log on a monthly basis to the Service/Program leader per the terms of his/her medical director agreement.
4. Unless otherwise specified, payment for time logs submitted more than 30 days following the due date of 15 days after the end of the preceding month may not be honored.

REFERENCES:

- Anit-Kickback Statute (42 USC § 1320 a-7b(b)) https://www.law.cornell.edu/uscode/text/42/1320a-7b
- Stark Law (42 USC § 139nn) https://www.law.cornell.edu/uscode/text/42/1395nn

SUBJECT: **MEDICAL STAFF ASSIGNMENTS**	SECTION: ***Response and Assignment of Personnel*** **Page 1 of 2**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

POLICY:

Several teams of physicians will be needed to assist in the provision of definitive treatment and sorting. Assignments will be made after consideration of the physician's area of expertise.

AFFECTED PERSONNEL/AREAS:

GOVERNING BOARD, MEDICAL STAFF, ALL HOSPITAL EMPLOYEES, VOLUNTEERS, VENDORS

PROCEDURE:

1. Initial responsibility for Triage and Treatment will be the responsibility of the Emergency Department Physician. As the disaster response expands, Medical Control responsibilities will be assumed by the Chief of Staff or his/her designee.

2. Upon initiation and notification of the disaster response, all available physicians in the facility will report to the Emergency Department (ED).

3. The designated Medical Staff Unit Leader and the Chief of Staff or designee will implement a physician call-in from the Medical Staff Office after receiving a briefing on the status of the disaster situation and determining actual or potential medical care needs.

4. The designated Medical Staff Director will organize, prioritize, and assign physicians to areas where medical care is being delivered. See *Disaster Physician Assignments* and *Available Physician Log.*

5. Team assignments which will be needed include:

    a. Physician coverage for Immediate, Delayed, and Minimal Treatment areas. Orthopedic Surgeons should report to the ED.- ED Physician will designate assignments as necessary to cover all areas where care is delivered.

    b. Operating Room – Anesthesiologist, Surgeons.- evaluate and prioritize surgical candidates and perform surgical procedures as required.

    c. Radiology – for interpretation of X-rays and other diagnostics.

    d. Intensive Care and Med/Surg units- (provide medical care to patients on units if the attending physician isn't available. Assist with and provide care for disaster patients admitted to the units.

    e. Utilization Review – make rounds with the Nursing Unit Leader and review for discharge or potential transfer.

    f. Pathology – to assist with laboratory diagnostics, forensic issues, and pathological tissue diagnosis.

REFERENCES:

- Title 22: Section 70741, 70743, 70745, 70746
- The Joint Commission (2023) Hospital Accreditation Standards. EM.12.02.03

SUBJECT: **ORGANIZED HEALTH CARE ARRANGEMENT**	SECTION: **Page 1 of 2**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

This policy/procedure recognizes the establishment of an Organized Health Care Arrangement (OHCA) between Sierra View Medical Center (SVMC) and Sierra View Medical Staff. The HIPPA Privacy Rule permits multiple Covered Entities who provide care in a clinically integrated care setting, such as the hospital setting, to declare themselves an OHCA. The OHCA's purpose is to protect patient privacy while minimizing disruption to quality patient care.

POLICY:

Under the Health Insurance Portability and Accountability Act (HIPAA), privacy rule, an OHCA is an arrangement or relationship that allows two or more Covered Entities who participate in joint activities to share Protected Health Information (PHI) about their patients in order to manage and benefit their joint operations. OHCA's are arrangements involving clinical or operational integration among legally separate Covered Entities in which it is often necessary to share PHI for the joint management and operation of the OHCA. Participating Covered Entities hold themselves out to the public as a joint arrangement and participate jointly in utilization review, quality assessment, improvement, and payment activities. A common example of an OHCA is an inpatient or outpatient hospital setting where the hospital, medical staff and other health care providers, collectively provide treatment, share PHI and improve hospital quality and operations. These definitions are met between SVMC and the medical staff to permit entering into an OHCA.

OHCA's are an administrative tool and are specific to the HIPAA privacy rule to ease administrative burdens. An OHCA is not to be construed as evidence of a closer association such as an employment relationship or joint venture. Covered Entities participating in the OHCA remain separate Covered Entities for HIPAA privacy purposes, except for the acceptance of a Joint Notice of Privacy Practices developed and distributed to all patients by the hospital.

The greatest benefit of the OHCA is to the patients. HIPAA requires all providers provide a "Joint Notice of Privacy Practices" to each patient upon admission. The OHCA eliminates the burden of multiple notices by each physician treating the patient. One Joint Notice of Privacy Practices would be given to each SVMC patient and the single written acknowledgement of the patient will meet the HIPAA regulations.

The SVMC Joint Notice of Privacy Practices only pertains to the use and disclosure of SVMC patient protected health information related to care and treatment received at SVMC. The physicians in the OHCA must provide their own privacy notice for patients seen in their private offices.

AFFECTED AREAS/PERSONNEL: *ALL MEDICAL STAFF CREDENTIALED WITH SIERRA VIEW MEDICAL CENTER AND ALL EMPLOYEES*

SUBJECT: **ORGANIZED HEALTH CARE ARRANGEMENT**	SECTION: **Page 2 of 2**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PROCEDURE:

1. It is the policy of SVMC that an OHCA, as defined in 45 CFR 164.501, be established for uses and disclosures of PHI to carry out treatment, payment, or health care operations as specified in 45 CFR 164.506(C)(5).

2. Participants of the OHCA consist of all SVMC employees, all medical staff members and their representatives.

3. The participants have adopted a Joint Notice of Privacy Practices for the sharing of PHI contained in the SVMC designated record set as defined in 45 CFR 164.501.

4. Following recommendations and guidance from the Office of Civil Rights and Department of Health & Human Services, the Sierra View Medical Center Medical Staff Bylaws has declared an OHCA with Sierra View Medical Center to expedite the sharing of data for improvement of patient care and operations. A written designation of an OHCA is not required. However, the OHCA and Joint Notice of Privacy Practices will be reflected in the Medical Staff Bylaws and approved by the SVMC's Medical Staff Executive Committee.

5. As part of the credentialing process the medical staff will sign and acknowledge that they agree to be bound by the OHCA as they agree to be bound by the bylaws.

6. Implementation of a Joint Notice of Privacy Practices streamlines compliance with the Privacy Rule. Under the OHCA, it will not be necessary for a physician or Allied Health Professional to produce a Notice of Privacy Practices to patients on their first encounter in the hospital setting. It will be necessary for physicians to present their own Notice of Privacy Practices to patients on their first encounter in the physician's office setting.

7. Each OHCA participant is a separate entity and is responsible for their own HIPAA privacy compliance efforts. The agreement does not imply that OHCA participants are joined in one another's HIPAA privacy compliance, nor does it mean that any member is responsible for the violations of another participant.

REFERENCES:

- 45 CFR § 164.501, 164.506, 164.520, https://www.law.cornell.edu/cfr/text/45/164.501, https://www.law.cornell.edu/cfr/text/45/164.506, https://www.law.cornell.edu/cfr/text/45/164.520

CROSS REFERENCES:

- Notice of Privacy Practices
- Sierra View Medical Staff Bylaws 2022