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

Ventura County Health Care System Oversight Committee
Administrative Policies - December 11, 2025
Summary of Changes

| # | Title | Review Period | Summary of Changes |
|---|---|---|---|
| 1 | L.CHEM 2.24 Thyroid-Stimulating Hormone - Ultra II (TSH3ULII) | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 2 | L.CHEM 3.10 Control Tolerance Limits | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 3 | L.CHEM 3.11 Chemistry Quality Control Program | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 4 | L.CHEM 3.12 Quality Control | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 5 | L.CHEM 3.13 24 Hour Urine Handling Requirements | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 6 | L.CHEM 3.14 Sweat Chloride | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 7 | L.CHEM 3.15 Linearity Study | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 8 | L.CHEM 3.16 New Lot to Lot Crossover | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 9 | L.CHEM 3.17 Procalcitonin | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 10 | L.CHEM 3.18 Water Quality | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 11 | L.CHEM 3.19 Therapeutic Drugs- Collection Times | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 12 | L.CHEM 3.2 OSMOLALITY | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 13 | L.CHEM 3.20 Specimen Carryover | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 14 | L.CHEM 3.21 Parallel Testing on Siemens Vista | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 15 | L.CHEM 3.22 Verification of Qualitative Cut-off Values | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 16 | L.CHEM 3.23 Control Range Verification | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 17 | L.CHEM 3.24 iPTH Outside Lab Testing | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 18 | L.CHEM 3.25 Critical Results - Chemistry Department | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 19 | L.CHEM 3.3 Corrected Calcium Calculation | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 20 | L.CHEM 3.4 HCG (Urine) Qualitative | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 21 | L.CHEM 3.5 Plasma Ketones | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 22 | L.CHEM 3.6 Neonatal Urine Drug Screen | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 23 | L.CHEM 3.7 pH Body Fluids | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 24 | L.CHEM 3.8 Specimen Aliquoting Procedure | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |
| 25 | L.CHEM 3.9 Lipemic Specimens | Bienniel | Migrated from binder to PolicyStat. Reviewed. No changes. |

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# L.CHEM 2.24 Thyroid-Stimulating Hormone - Ultra II (TSH3ULII)



## Policy

**Thyroid-Stimulating Hormone- TSH3- Ultra II (TSH3ULII)**

The ADVIA Centaur® TSH3-Ultra II (TSH3ULII) assay is for in vitro diagnostic use in the quantitative determination of thyroid-stimulating hormone (TSH, thyrotropin) in human serum and plasma (EDTA and lithium heparin) using the ADVIA Centaur® XP and ADVIA Centaur® XPT systems. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.

**Summary and Explanation**

Thyroid-stimulating hormone is a glycoprotein with 2 non-covalently bound subunits. The alpha subunit is similar to those of follicle-stimulating hormone (FSH), human chorionic gonadotropin (hCG), and luteinizing hormone (LH).[1-4]

The beta subunit of TSH is unique, which results in the specific biochemical and immunological properties of this hormone.

TSH is synthesized and secreted by the anterior pituitary in response to a negative feedback mechanism involving concentrations of $FT_3$ (free $T_3$) and $FT_4$ (free $T_4$). Additionally, the hypothalamic tripeptide, thyrotropin-releasing hormone (TRH), directly stimulates TSH production.

TSH interacts with specific cell receptors on the thyroid cell surface and exerts 2 main actions. The first action is to stimulate cell reproduction and hypertrophy. Secondly, TSH stimulates the thyroid gland to synthesize and secrete $T_3$ and $T_4$.

The ability to quantitate circulating levels of TSH is important in evaluating thyroid function. It is especially useful in the differential diagnosis of primary (thyroid) from secondary (pituitary) and tertiary (hypothalamus) hypothyroidism. In primary hypothyroidism, TSH levels are significantly elevated, while in secondary and

tertiary hypothyroidism, TSH levels are low.
TRH stimulation differentiates secondary and tertiary hypothyroidism by observing the change in patient TSH levels. Typically, the TSH response to TRH stimulation is absent in cases of secondary hypothyroidism, and normal to exaggerated in tertiary hypothyroidism.
Historically, TRH stimulation has been used to confirm primary hyperthyroidism, indicated by elevated $T_3$ and $T_4$ levels and low or undetectable TSH levels. TSH assays with increased sensitivity and specificity provide a primary diagnostic tool to differentiate hyperthyroid from euthyroid patients.

# Principle of the Test

This assay is a third-generation assay that employs FITC-labeled mouse monoclonal anti-TSH antibody and mouse monoclonal anti-fluorescein antibody linked to paramagnetic particles, an FITC-labeled anti-TSH capture mouse monoclonal antibody, and a tracer consisting of a proprietary acridinium ester and an anti-TSH mouse monoclonal antibody conjugated to bovine serum albumin (BSA) for chemiluminescent detection. A direct relationship exists between the amount of TSH present in the patient sample and the amount of relative light units (RLUs) detected by the system.

# Reagents

| Material Description | Storage | Stability |
|---|---|---|
| **TSH3ULII ReadyPack® primary reagent pack**[a, b] Lite Reagent<br>6.0 mL/reagent pack BSA conjugated to mouse monoclonal anti-TSH antibody (~0.3 µg/mL) labeled with acridinium ester in buffer; mouse IgG; BSA; Bovine Gamma Globulin (BGG); goat serum; sodium azide (<0.1%); surfactant; preservatives<br>**Solid Phase**<br>21.0 mL/reagent pack FITC-labeled mouse monoclonal anti-TSH antibody and mouse monoclonal anti-fluorescein antibody linked to paramagnetic particles (~85 µg/mL) in buffer; BSA; BGG; goat serum; sodium azide (<0.1%); surfactant; preservatives.<br>**Ancillary Well Reagent**<br>6.0 mL/reagent pack FITC conjugated to mouse monoclonal anti-TSH antibody (~3 µg/mL); BSA; BGG; goat serum; sodium azide (<0.1%); surfactant; preservatives. | Unopened at 2–8°C<br>On board | Until expiration date on product<br>60 days |
| **CAL 3A**[a]<br>2.0 mL/vial After reconstitution, TSH (human); buffer; equine serum; sodium azide (<0.1%); surfactant; preservatives. | Lyophilized at 2–8°C<br>Reconstituted at 2–8°C<br>Reconstituted at room temperature | Until expiration date on product<br>28 days<br>4 hours. |
| **ADVIA Centaur Wash 1**[a, c]<br>2 x 1500 mL/pack Phosphate-buffered saline; sodium azide (<0.1%); surfactant. | Unopened at 2-25°C<br>On board | Until expiration date on product<br>1 month |
| **ADVIA Centaur Wash 1**[a, c]<br>2 x 2500 mL/pack Phosphate-buffered saline; sodium azide | Unopened at 2-25°C | Until expiration date on product |

| | | |
|---|---|---|
| (<0.1%); surfactant. | On board | 1 month |

[a] Store in an upright position.

[b] Prevent exposure to sunlight and heat.

[c] Refer to Materials Required but Not Provided

# Risk and Safety

For in vitro diagnostic use.
For Professional Use.
**CAUTION**
Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.
Safety data sheets (SDS) available on siemens-healthineers.com.
H412 P273, P501 Harmful to aquatic life with long lasting effects.
Avoid release to the environment. Dispose of contents and container in accordance with all local, regional, and national regulations.
Contains: Sodium azide (CAL 3A).
Contains: gentamicin sulfate. May produce an allergic reaction (CAL 3A).


**Warning! Potential Biohazard**
Contains human source material.
No known test method can ensure that products derived from human source materials will not transmit infection. These materials should be handled using good laboratory practices and universal precautions.[5-7]
**CAUTION**
This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.
Contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent buildup of azides.
Disposal into drain systems must be in compliance with prevailing regulatory requirements.
Dispose of hazardous or biologically contaminated materials according to the practices of your institution.
Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.



# Specimen Collection and Handling

Serum and plasma (EDTA and lithium heparin) are the recommended specimen types for this assay. The handling and storage information provided here is based on data or references maintained by the manufacturer. It is the responsibility of the individual laboratory to use all available references and/or its own studies when establishing alternate stability criteria to meet specific needs.
Collecting the Specimen

- Observe universal precautions when collecting specimens. Handle all specimens as if they are capable of transmitting disease.[7]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[8]
- Follow the instructions provided with your specimen collection device for use and processing.[9]

- Allow blood specimens to clot completely before centrifugation.[10]
- Keep tubes capped at all times.[10]

## Specimen Storage and Stability

- Separated samples are stable for up to 24 hours at room temperature, and for up to 2 days at 2–8°C.
- Separated serum and EDTA plasma samples are stable at ≤ -20°C for up to 30 days. Separated lithium heparin plasma samples are stable at ≤ -20°C for up to 14 days. Freeze samples only once. Do not store in a frost-free freezer. Thoroughly mix thawed samples and centrifuge them before using.
- Store all reagents in an upright position, away from light. Do not use products beyond the expiration date printed on the product labeling or beyond the in-use stability interval.

For information about product storage and stability, refer to Reagents.
Transporting the Specimen
Package and label specimens for shipment in compliance with applicable federal and international regulations covering the transport of clinical specimens and etiological agents.

# Procedure

## Materials

The following materials are provided:

| REF | Contents | Number of Tests |
|---|---|---|
| 11208702 | 5 ReadyPack primary reagent packs containing TSH3ULII Lite Reagent, Solid Phase, and Ancillary Well Reagent<br>ADVIA Centaur TSH3ULII master curve card<br>2 vials CAL 3A low calibrator CAL L<br>2 vials CAL 3A high calibrator CAL H<br>ADVIA Centaur CAL 3A calibrator assigned value cards and barcode labels CAL LOT VAL | 500 |

## Materials Required but Not Provided

The following materials are required to perform this assay, but are not provided:

| REF | Description |
|---|---|
| | ADVIA Centaur XP system[a]<br>ADVIA Centaur XPT system |
| 01137199<br>(112351) | ADVIA Centaur Wash 1 (wash) WASH 1 |
| 03773025 | ADVIA Centaur Wash 1 (wash) WASH 1 |

[a] Additional system fluids are required to operate the system: ADVIA Centaur Acid Reagent, ADVIA Centaur Base Reagent, and ADVIA Centaur Cleaning Solution.

## Optional Materials

The following materials may be used to perform this assay, but are not provided:

| REF | Description |
|---|---|
| 11208875 | ADVIA Centaur TSH3ULII MCM (master curve material) |



# Test Steps

This assay requires 100 µL of sample for a single determination. This volume does not include the unusable volume in the sample container or the additional volume required when performing duplicates or other tests on the same sample. For a complete list of appropriate sample containers and information about determining the minimum required volume, refer to the system on line help.
Do not use samples with apparent contamination. Before placing samples on the system, ensure that samples are free of:

- Bubbles or foam.
- Fibrin or other particulate matter.
- Remove particulates by centrifugation according to CLSI guidance and the collection device manufacturer's recommendations.[10]

**Assay Procedure**

The system automatically performs the following steps:

1. Dispenses 100 µL of sample into a cuvette.
2. Dispenses 50 µL of Ancillary Reagent and 50 µL of Lite Reagent, then incubates for 2.75 minutes at 37°C.
3. Dispenses 200 µL of Solid Phase then incubates for 5.5 minutes at 37°C.
4. Performs a wash sequence using ADVIA Centaur Wash 1.
5. Dispenses 300 µL each of ADVIA Centaur Acid Reagent and ADVIA Centaur Base Reagent to initiate the chemiluminescent reaction.

6. Reports results.

# Calibration

**Master Curve Definition**
Before initiating calibration on each new lot of reagent, enter the assay master curve values by scanning the master curve card. For information about defining the master curve, refer to the system on line help.

**Performing Calibration**
For calibration of the assay, use the calibrators provided with each kit.
**Note:** Calibrators provided in an assay kit must only be used with the reagent lot provided in the same kit.

**Calibration Frequency**
Perform a calibration if one or more of the following conditions exist:

- At the end of the 14-day calibration interval.
- When changing lot numbers of primary reagent packs.
- When indicated by quality control results.
- After major maintenance or service, if indicated by quality control results.

Follow government regulations or accreditation requirements for calibration frequency. Individual laboratory quality control programs and procedures may require more frequent calibration.



**Preparing the Calibrators**
Reconstitute the materials using the following steps:

1. Add 2.0 mL of reagent water into each vial. Replace cap.
2. Let the vials stand for 15–20 minutes at room temperature to allow the lyophilized material to dissolve.
3. Gently mix and invert the vials to ensure homogeneity of the material.
4. Use within the stability limits specified in Reagents and discard any remaining material.

**Calibration Procedure**
Perform the procedure using the following steps:

1. Ensure that the appropriate master curve and calibrator assigned values are entered on the system. For information about defining the master curve and entering calibrator values, refer to the system on line help.
2. Load the required reagents for the assay.
3. Schedule the calibrators.
4. Label sample containers with bar code labels: one container for each level. Place the bar code labels on the sample containers with the readable characters oriented vertically.
   **Note:** Bar code labels are lot-specific. Do not use bar code labels from one lot of calibrators with any other lot of calibrators.
5. Gently mix and dispense a sufficient volume of each level into the appropriate sample container. Avoid bubbles. The required sample volume for testing depends on several factors. For information about sample volume requirements, refer to the system on line help.

system and verified using the ADVIA Centaur TSH3ULII assay on the ADVIA Centaur XP system in accordance with CLSI Document EP28-A3c.[15]
Samples were assayed for TSH, $FT_3$, and $FT_4$ and considered normal if their values were within acceptable ranges. Samples were also screened for the presence of thyroid autoantibodies.[16]
The reference interval was determined by calculating the 2.5th and 97.5th percentiles of the distribution of values.

# Reference Interval

TSH reference ranges for pediatric, adolescent, and adult samples are:

- Infants (1-23 months): 0.87 – 6.15 µIU/mL (mIU/L)
- Pediatric (2 - 12 years): 0.67 – 4.16 µIU/mL (mIU/L)
- Adolescent (13 - 20 years): 0.48 – 4.17 µIU/mL (mIU/L)
- Adult (≥ 18 years): 0.55–4.78 µIU/mL (mIU/L)

Refer to test IFU for further information.

# Method Limitations



**The following information pertains to limitations of the assay:**

- **This assay has not been validated for testing samples from newborns.**
- **Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. This assay is designed to minimize interference from heterophilic antibodies.11,12**
- Do not use samples that contain fluorescein. Fluorescein levels > 0.24 µg/mL may decrease results in this assay. Evidence suggests that patients undergoing retinal fluorescein angiography can retain amounts of fluorescein in the body for up to 48–72 hours post-treatment.
- **In the cases of patients with renal insufficiency, including many diabetics, retention could be much longer. Such samples can produce falsely depressed values when tested with this assay, and should not be tested. Testing of samples spiked with a theoretical maximum level of fluorescein (250 µg/mL) used in these patients have resulted in TSH levels < 0.06 µIU/mL instead of the true value of 27.99 µIU/mL.13**
- **As with any immuno-recognition measurement of a peptide, extremely rare genetic variants may exhibit varying degrees of detection.14**

# Measuring Interval (AMR)

- **0.010–150.000 µIU/mL (mIU/L)**
- **The lower limit of the measuring interval is defined by the limit of quantitation (LoQ). Report results below the measuring interval as <0.010 mIU/L.**

# Reportable Range

The reportable range of the ADVIA Centaur TSH3-ULII assay is from the Limit of Quantitation (LoQ)

[0.010 µIU/mL (mIU/L)] to 150 µIU/mL (mIU/L).

**Dilutions**

- Patient samples with TSH levels greater than 150 µIU/mL (mIU/L) must be diluted and retested to obtain accurate results.
- For automatic dilutions, ensure that ADVIA Centaur Multi-Diluent 1 is loaded and set the system parameters as follows:
- Dilution point: ≥ 150 µIU/mL (mIU/L)
- Instrument Dilution factor: 2, 5
- TSH concentration with a concentration above the measuring interval will report as > 150 mIU/L
- For detailed information about automatic dilutions, refer to the IFU or online help system.

# Interferences

**Hemolysis, Icterus, Lipemia (HIL)**
Interference testing was performed using the ADVIA Centaur XP system in accordance with CLSI Document EP07-ed3.[21]
The following substances do not interfere with the assay when present in serum at the concentrations indicated. Bias due to these substances does not exceed 10% at a TSH concentration of approximately 0.900 µIU/mL (mIU/L) and 8.000 µIU/mL (mIU/L).



| ***Substance*** | ***Substance Test Concentration*** |
|---|---|
| Hemoglobin | 500 mg/dL (5.00 g/L) |
| Bilirubin, conjugated | 40 mg/dL (474 µmol/L) |
| Bilirubin, unconjugated | 40 mg/dL (684 µmol/L) |
| Lipemia (Intralipid) | 1000 mg/dL (11.3 mmol/L) |

**Other Substances**

**Interference testing was performed using the ADVIA Centaur XP system in accordance with CLSI Document EP07-ed3.21**
Refer to IFU for other interfering and non-interfering substances.

**Cross-Reactivity**
Cross-reactivity was determined using the ADVIA Centaur XP system in accordance with CLSI Document EP07-ed3.[21] Cross-reactivity of samples spiked with various substances does not exceed 5% at TSH concentrations of approximately 0.400 µIU/mL (mIU/L), 5.00 µIU/mL (mIU/L), 17.00 µIU/mL (mIU/L), and 90.00 µIU/mL (mIU/L).

| Substance | Substance Test Concentration |
|---|---|
| hCG | 200000 mIU/mL |
| FSH | 1500 mIU/mL |
| LH | 600 mIU/mL |

**Technical Assistance**
**For customer support, contact your local technical support provider or distributor. siemens-healthineers.com**

# References


1. Chen IW, Sperling MI. Thyroxine. In: Kaplan LA, Pesce AJ, eds. Clinical Chemistry: Theory, Analysis, Correlation. 2nd ed. St. Louis, MO: CV Mosby; 1989:952–961.
2. Fernandez-Ulloa M, Maxon HR. Thyroid. In: Kaplan LA, Pesce AJ, eds. Clinical Chemistry: Theory, Analysis, Correlation. 2nd ed. St. Louis, MO: CV Mosby; 1989:620–637.
3. Watts NB, Keffer JH. Practical Endocrine Diagnosis. 3rd ed. Philadelphia, PA: Lea and Febiger; 1982:1–27, 77–96.
4. Chattoraj SC, Watts NB. Endocrinology. In: Tietz NW, ed. Fundamentals of Clinical Chemistry. 3rd ed. Philadelphia, PA: WB Saunders; 1986:550–551.
5. US Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories. 5th ed. Washington, DC: US Government Printing Office; December 2009.
6. World Health Organization. Laboratory Biosafety Manual. 3rd ed. Geneva: World Health Organization; 2004.
7. Clinical and Laboratory Standards Institute. Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document M29-A4.
8. Clinical and Laboratory Standards Institute. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Sixth Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2007. CLSI Document GP41-A6.
9. Clinical and Laboratory Standards Institute. Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard—Sixth Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document GP39-A6.
10. Clinical and Laboratory Standards Institute. Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document GP44-A4.
11. Kricka LJ. Human anti-animal antibody interferences in immunological assays. Clin Chem. 1999;45(7):942–956.
12. Vaidya HC, Beatty BG. Eliminating interference from heterophilic antibodies in a two-site immunoassay for creatine kinase MB by using F(ab')2 conjugate and polyclonal mouse IgG. Clin Chem. 1992;38(9):1737–1742.
13. Inloes R, Clark D, Drobnies A. Interference of fluorescein, used in retinal angiography, with certain clinical laboratory tests. Clin Chem. 1987;33(11):2126–2127.
14. Drees JC, Stone JA, Reamer CR, et al. Falsely undetectable TSH in a cohort of South Asian euthyroid patients. J Clin Endocrinol Metab. 2014; 99(4):1171–1179.
15. Clinical and Laboratory Standards Institute. Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document EP28-A3c.
16. Kratzsch J, Schubert G, Pulzer F, et al. Reference intervals for TSH and thyroid hormones are mainly

affected by age, body mass index and number of blood leucocytes, but hardly by gender and thyroid autoantibodies during the first decades of life. Clin Biochem [serial online]. 2008;41(13):1091–1098, doi: 10.1016/j.clinbiochem.2008.04.007.

17. Horn PS, Pesce AJ. Reference Intervals: A User's Guide, Washington, DC: AACC Press; 2005.
18. Clinical and Laboratory Standards Institute. Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2012. CLSI Document EP17-A2.
19. Clinical and Laboratory Standards Institute. Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document EP05-A3.
20. Clinical and Laboratory Standards Institute. Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2018. CLSI Document EP09c-ed3.
21. Clinical and Laboratory Standards Institute. Interference Testing in Clinical Chemistry; Approved Guideline—Third Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2018. CLSI Document EP07-ed3.
22. Clinical and Laboratory Standards Institute. Evaluation of Linearity of Quantitative Measurement Procedures; Approved Guideline—Second Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2020. CLSI Document EP06-ed2.



## All Revision Dates

10/3/2025

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 8/7/2025 |

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| Next Review | 10/3/2027 | | |

# L.CHEM 3.10 Control Tolerance Limits



# Policy

**Control Tolerance Limits**

Results of all controls must be verified for acceptability before reporting patient results. Patient data can be released even if quality control results fall outside pre established statistical limits, provided that patient care is not compromised. These data should be reviewed for such considerations as biological variation, medical usefulness of the test, and type and magnitude of the rule violation.

# Procedure

1. Repeat any controls that exceed the posted +/- 2 SD.
2. If the repeat analysis is within +/- 2 SD, accept the control result and report the patient result.
3. If the repeat analysis is not within +/- 2 SD, but within +/- 3 SD, accept the result as an outlier. Report patient results.
4. If the repeat analysis is outside of +/- 3 SD, follow the out of control corrective action flow chart.
5. If the repeat analysis is still outside of +/- 3 SD after following the flow chart, bring to the attention of the Chemistry Supervisor or person designated in charge. **DO NOT REPORT OUT PATIENT RESULTS UNLESS INSTRUCTED TO DO SO.**
6. Enter the original and repeat results that are within +/- 3 SD into the computer and make comments as to the corrective action taken for the out of control results.
7. Controls are checked for trends and shifts when result is entered into the computer.
8. When obtaining a Rule 7 or Rule 8 flag, enter appropriate comment into the computer to bring to the attention of the Chemistry Supervisor.

## All Revision Dates

10/3/2025

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 7/31/2025 |

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# L.CHEM 3.11 Chemistry Quality Control Program



## Policy

**Chemistry Quality Control Program**

The purpose of the Chemistry Department Quality Control program is to assure that all test results are as precise, accurate and reliable as is possible within the confines of the instrumentation and procedures utilized for obtaining these results. In all cases, manufacturer's recommendations will be followed as to the type of controls required and the frequency at which they are run.

- Function verification and preventive maintenance will follow manufacturer's requirements.
- A schedule is provided for each instrument and is kept next to the instrument.
- All preventive maintenance and function checks will be documented on the appropriate schedule.
- Following is a general overview, by instrument of controls to be used and the frequency at which they must be run:

**Siemens Dimension Vista**

- Two levels of controls are run once every twenty-four hours for each analyte being measured.
- Check the posted control list for current controls in use and their location.
- Current Means and Standard deviations are maintained in the computer and on the analyzers.

**ALL OTHERS**

- Two levels of controls are run once every twenty-four hours for each analyte being measured.
- Check the posted list for current controls in use and their location.
- Current Means and Standard deviations are maintained in the computer.

The Control Tolerance Limits protocol is used to evaluate all QC results before patient results can be released. An Out of Control Corrective Action Flow Chart is used to resolve "Out of Control" issues.

The QC Program is reviewed daily or on the next routine working day by the Chemistry Supervisor or a backup appointed in the supervisor's absence. See the Protocol for Evaluating Quality Control Data Policy. Summary Reviews are evaluated monthly for comparability of results between different instruments and for established mean and SD versus observed. QC data is submitted monthly for inter laboratory comparison and evaluated upon return.

## All Revision Dates

10/3/2025

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|---|---|---|
| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
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| Owner | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services |
| Policy Area | Laboratory Services - Chemistry |

# L.CHEM 3.12 Quality Control



# Policy

**Quality Control**

It is the policy of the Ventura County Medical Center (VCMC) Laboratory to provide optimal patient specimen result integrity throughout the pre-analytical (patient identification and preparation; specimen collection, identification, preservation, transportation), analytical (specimen processing) and post-analytical (result reporting) processes.

# Pre-Analytical

Instructions for patient preparation and specimen collection are provided in the Laboratory Directory, available at all nursing stations and clinics. These instructions are also available in the Phlebotomy Manual and in the appropriate department manuals.
The Office/Phlebotomy Supervisor and Department Supervisors are responsible for maintaining these procedures.

# Analytical and Post-Analytical

All laboratory results are subject to variations that may interfere with data evaluation and interpretation. Variations can be both within and outside the control of the technologist. The laboratory must be able to evaluate and recognize the extent of any analytical variation and determine its clinical significance.

The Quality Control programs are designed to monitor the variance of the systems. The foundation for the program is the analysis of pre-assayed controls at specified intervals. If the controls satisfy the statistical analyses, the reagents and instrumentation are determined to be "in-control". If, however, the

control results fail the statistical analyses, the reagent and/or instrumentation is "out-of-control" and patient results are withheld (and repeated) until the problem is corrected. Augmenting these controls is Proficiency Testing samples, patient delta checks, and test linearity parameters.

# Procedure

## Testing steps

All quality control specimens are tested in the same manner as patient specimens, and by the same testing personnel that test patient samples.
Standards, controls and linearity studies for individual tests will be performed according to instructions in the Department's Manual. The tolerance limits and corrective action protocol are described in each manual.
Tests processed on multiple instruments or methodologies have comparability studies performed according to instructions in the Department's Manual.
Patient test results are monitored with both delta checks for consistency and absolute value limits for possible dilution and/or critical values. Additionally Department Supervisors or a designee reviews the daily Patient Exception Reports for appropriate actions and notifications.

## Documentation and Evaluation



The results of all Quality Control testing are recorded and initialed by the technologist performing the test. Upon computer entry, the system automatically runs the preset Multi-Rules. Any results that fall outside of the range, as a result of clerical or analytical error, are immediately flagged. The procedures following an out-of-control result will also be documented and initialed. The records are reviewed and noted each day by the appropriate Department Supervisor or designee. The records are maintained for three years.

## Inter-Laboratory Comparison

The laboratory participates in inter laboratory comparison programs for most of the analytes. The specimens are integrated into the routine workload and analyzed by the same personnel and methods used for patient samples. All comparison results are reviewed by the Department Supervisor in consultation with the Laboratory Manager.
**CHM.10500, 14800**

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10/3/2025

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 7/31/2025 |

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# L.CHEM 3.13 24 Hour Urine Handling Requirements



## Policy

**Urine 24 Hour Handling Requirements**

## 24 Hour Urine Handling Requirements

| TEST | PRESERVATIVE | SPECIAL INSTRUCTIONS |
|---|---|---|
| Amylase | Refrigerate During Collection | |
| Calcium | Refrigerate During Collection | Acidify to pH < 2 after Collection *** |
| Creatinine | Refrigerate During Collection | |
| Electrolytes | Refrigerate During Collection | Acidify to pH < 2 after Collection *** |
| Magnesium | Refrigerate During Collection | Acidify to pH < 2 after Collection *** |
| Phosphorus | Refrigerate During Collection | |
| Protein | Refrigerate During Collection | |
| Urea Nitrogen | Refrigerate During Collection | |
| Uric Acid | Refrigerate During Collection | |

## 24 Hour Urine Send Out Handling Requirements

| TEST | PRESERVATIVE | SPECIAL INSTRUCTIONS |
|---|---|---|
| Catecholamines | Refrigerate During Collection | Acidify to pH < 2 after Collection *** - Give patient special diet list. |
| Citric Acid | Refrigerate During | Acidify to pH < 2 after Collection *** |

| | | |
|---|---|---|
| (Citrate) | Collection | |
| 5-HIAA | Refrigerate During Collection | Abstain from medications, OTC drugs, Herbal drugs for 72 hours. |
| 17 OH Corticosteroids | Refrigerate During Collection | 10 grams Boric Acid tablets |
| 17 Ketosteroids | Refrigerate During Collection | Acidify to pH < 2 after Collection *** |
| Metanephrines | Refrigerate During Collection | NONE |
| Oxalate | Refrigerate During Collection | Acidify to pH < 2 after Collection *** |
| Porphobilinogen | Refrigerate During Collection | Protect From Light |
| Porphyrins | Refrigerate During Collection | Protect From Light |
| VMA and/or HVA | Refrigerate During Collection | NONE |

- *** Adjust pH using HCL (6N) as needed.

Date Prepared: 10/25/2007



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10/3/2025

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| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 8/6/2025 |

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# L.CHEM 3.14 Sweat Chloride



## Policy

**Sweat Chloride**

## Principle

Sweat chloride analysis provides laboratory confirmation of the clinical diagnosis of cystic fibrosis. Patients with cystic fibrosis have a normal sweat rate with an increased concentration of sweat chloride. The quantitative determination of chloride concentration in sweat is a three step procedure involving stimulation of the sweat gland by pilocarpine iontophoresis and collection of induced sweat into a micro-bore capillary tubing. These first two steps utilize the Wescor Macroduct Sweat Collection System. The third step involves quantitative analysis of the chloride concentration in the collected sweat utilizing a Labconco Digital Chloridometer.

## Specimen Collection and Handling

Specimen requirement; 20 µL of sweat.

* The minimum volume of sweat collected to insure proper sweat rate is 15 µL (CHM.30000). The minimum volume required to perform the analysis is 20 µL.

## Reagents

- Pilogel iontophoretic discs
- Chloridometer Acid Reagent
- Chloride Standard, 100 mEq/L

- Silver wire
- Macroduct Sweat Collection kit

# Procedure

## Disinfection of Equipment

- The induction electrodes and wires are cleaned with alcohol wipes before and after each patient use. The entire surface of the electrode must be wiped thoroughly.
- The induction electrode straps and the Macroduct straps are disinfected after each patient use.
- Soak straps in 70% Isopropyl alcohol for 1 - 5 minutes.
- Rinse the soaked straps thoroughly 2 to 3 times in de-ionized water.
- Allow to air dry before next use.
- The sweat collection devise is one time use only.
- All other reusable equipment such as scissors, nippers, and sweat dispensers should be rinsed with distilled or deionized water and dried with each use to ensure they are not contaminated with sweat.
- The procedure for disinfection of the sweat chloride equipment is reviewed biennally by the Laboratory Medical Director, and/or designee to assure continued effectiveness (CHM.29150).



## Sweat Stimulation and Collection

- Assemble the Macroduct Sweat Collection System and perform the iontophoresis for sweat stimulation. Use the Wescor Instruction Manual for complete details, including instructional photos, of this procedure. Always follow the manufacturer's listed recommendations. To minimize sample evaporation or contamination (CHM.29200), emphasis is placed on the following steps:
- Wash the patient's skin stimulation site thoroughly first with alcohol and then De-ionized water to remove any accumulated sweat before the stimulation. Also wash with De-I water after the stimulation to remove any pilocarpine and thoroughly dry before placing the collection coil on the site.
- Avoid touching the stimulation site and the collecting surface of the coil.
- Attach the collection device on the stimulation site with firm strap pressure. Recheck for firm attachment once sweat appears in the coil.
- Do not remove the collection device from the patient's extremity before separating the coil from the main body. Doing so may result in a loss of sweat sample.
- Clean the nipper device and the sweat dispensing needle with an alcohol wipe before and after using, to avoid any contamination with sweat sample.
- **NOTE:** The electrodes used for stimulation must be placed only on the patient's lower arm or upper leg that is free from any rashes or diffuse inflammation (CHM.29300), and **never in a position that would cause the current to cross the patient's trunk** (CHM.29500).
- If the patient should exhibit an allergic reaction to the pilocarpine, such as urticaria (hives),

redness and swelling or burns exhibited by redness and blistering, discontinue the stimulation and notify the Pathologist immediately (CHM.30300). The stimulation must be performed for 5 minutes and not longer using the manufacturer's (Wescor) battery powered device. This equipment is checked annually by the Biomed Dept. (CHM.29600).

- **Do not attempt stimulation on a patient receiving oxygen by an open delivery system. This could cause an explosion** (CHM.29700).
- Make sure the collection device is placed over the exact area of stimulation (the area under the red electrode). It is important that the stimulation area and collection area are equivalent (CHM.29800).
- Once the induction is complete perform the collection phase. Use the Wescor Instruction Manual for complete details of this part of the procedure. Use only the Wescor Macroduct collection device provided with the kit. No other devices are acceptable (CHM.29850).
- The collection period must be for a minimum of, but no longer than, 30 minutes (CHM.29900).
- Once the sample is obtained, it must be placed immediately into a plastic microcup with lid and labeled with the patient's identification label (CHM.30200). The minimum volume of sweat collected to insure proper sweat rate is 15 µL (CHM.30000), however 20 µL or more is required for analysis. Samples that are less than 20 µL must be rejected and **not pooled** for analysis (CHM.30100). If there is a significant delay between collection and analysis, appropriate storage conditions must be followed:
- Sweat collected in macroduct is stable at refrigeration or room temperature for up to 72 hours in a 0.2 mL microcentrifuge tube with a tight fitting cap. (CHM.30250) Proceed immediately to the analysis portion of the procedure. The analysis should be run in duplicate if enough sample is collected.
- If an insufficient volume is obtained after two attempts, it must be reported in the computer and in the Sweat Chloride Log Book. Reschedule the patient for another appointment in two weeks. Inform the patient to drink sufficient water in order to be well hydrated before the next appointment.
- The incidence of insufficient sweat samples is monitored and recorded on a form (Annual Insufficient Sweat Rate). The annual insufficient sweat rate should not exceed 5% (CHM.30150).

# Chloride Analysis

- Place Titration switch in Standby and Range switch to Low. Using the Brinkmann Dispenser, pipet 4.0 ml of Acid Reagent into each of three vials labeled patient, normal control and abnormal control.
- Pipette 20 µL of the collected patient sweat sample, normal level control and abnormal level control into the appropriate vials of Acid Reagent. If there is adequate patient sample to run in duplicate, then do so and report the average of the two results.
- Place each vial in turn in holder, raise holder, and depress the Titration switch to Start.
- Use the values obtained to calculate the patient's chloride and control results in mEq/L, using the formula provided.

**Calculation:** $\frac{\text{Patient (Control) Value}}{\text{Standard (Avg Value)}} \text{ X } 100 \text{ mEq/L} = \text{Sweat Cl}^- \text{ mEq/L}$

# Calibration

Frequency: Calibration must be done each time a new patient sweat sample is to be analyzed.

1. Set the toggle switch on the rear of the instrument to the Standard position (down). Place the Titration switch in Standby and the Range switch to Low.
2. Using the Brinkmann Dispenser, pipet 4.0 ml Acid Reagent into each of two vials. These serve as blanks.
3. Place each vial in turn on the vial holder, raise the holder and depress the Titration switch to start.
4. Calculate the average of the two blank determinations and enter that number on the Blank thumbwheel switch.
5. Using the Brinkmann Dispenser, pipet 4.0 ml of Acid Reagent into each of two vials and pipet 20 µL of 100 mEq/L Standard into each vial.
6. Place each standard vial in turn in the vial holder, raise the holder and depress the Titration switch to Start.
7. Calculate the average of the two standard determinations and use this value in the formula to calculate sweat chloride control and patient results.



# Quality Assurance

Daily maintenance is performed per schedule and per manufacturer's recommendations. Maintenance includes the disinfection of the equipment. See the Disinfection Procedure below. The schedule is reviewed monthly by the Chemistry Dept. Supervisor.
See the Labconco Digital Chloridometer Instruction Manual and the Wescor Macroduct Collection System Manual for details of these procedures.
Three levels of controls, normal and abnormal low and abnormal high, are run along with each patient tested (CHM.30600). Established ± 2 SD ranges are posted. New lots of un-assayed controls are run concurrently with the old established lot to obtain new ranges before they are put in use. For assayed controls, the lab must verify the acceptability ranges supplied by the manufacturer. (CHM.30650)
The analytical method has been validated by this laboratory and includes studies of accuracy, precision, and linearity to determine the upper and lower limits of the analytical measurement range (CHM.30400). Linearity check is performed every six months.

# Results

Conductivity is a non-selective method for sweat analysis that has its own unique set of reference intervals. When sweat conductivity is expressed as units of Aqueous sodium chloride solution, the values are approximately 15 mmol/L higher than when chloride is measured directly. A patient having a sweat conductivity greater than equal to 50 mmol/L should be referred to a specialized cystic fibrosis center for a quantitative analysis of sweat chloride with or without sweat sodium.

# Reference Values

- 29 or less mEq/L : Negative
- A range of 30 – 59 mEq/L: Intermediate
- 60 mEq/L or greater: Consistent with CF
- The Cystic Fibrosis Foundation reference intervals for chloride (Farrell PM et al 2007) are:

| Test | Result | Interpretation |
|---|---|---|
| Sweat Chloride | <30 mmol/L | Newborns with a positive newborn screen: CF unlikely |
| Sweat Chloride | 30-59 mmol/L | All populations: intermediate range- need further study to establish or rule out a CF diagnosis |
| Sweat Chloride | ≥60 mmo/L | All populations: indicative of CF for individuals presenting consistent with CF, or a positive family history |

# Limitation of Procedure

Sweat electrolyte concentration is related to sweat rate. At low sweat rates, sweat electrolyte concentration decreases. The average sweat rate must exceed 1 gm/m2 per minute. The minimum acceptable sample size to assure proper rate is 15 µL collected in 30 minutes (CHM30000). If collection is less than this then patient sweat induction must be repeated. Multiple insufficient samples may not be pooled for analysis (CHM.30100).
Patient must be older than 48 hours before performing the testing to assure that proper sweat stimulation and collection takes place (CHM.29100).

- Lower Limit of Reportable Results: Results less than 10 mEq/L will be reported as < 10 mEq/L (CHM.30550).
- Upper Limit of Reportable Results: Results greater than 160 mEq/L will not be reported, because chloride results > 160 mEq/L are not physiologically possible. The patient must be retested. Results must be less than or equal to 160 mEq/L of chloride. (CHM.30900).

To ensure proficiency with collection and analysis two CLS personnel are certified to perform sweat chloride testing. Testing is divided equally between these two personnel in order to provide a sufficient number of collections and analyses to remain proficient (CHM.31000).

# References


1. Sweat Testing: Sample Collection and Quantitative Analysis; Approved Guideline, NNCLS Document C34-A, December 1994.
2. Macroduct Sweat Collection System Instruction Manual, Wescor Inc., M2551-4, 1995.
3. Digital Chloridometer Instruction Manual, Labconco Corp., 1997.
4. Wescor Product Bulletin, Disinfection Options for Macroduct and Nanoduct Straps, 10 October 2005, DOC-00291A.doc.

5. Farrell PM, et al. Diagnosis of Cystic Fibrosis: Consensus Guidelines from the Cystic Fibrosis Foundation. J. Pediatr. February 2017;181S; S4-15.
6. Clinical and Laboratory Standards Institute (CLSI). Sweat Testing: Sample Collection and Quantitative Analysis; Approved Guideline-Third Edition, CLSI document C34-A3 (ISBN 1-56238-713-8. Clinical and Laboratory Standards Institute, 940 West Valley Road, Wayne, PA, 19087-1898, USA, 2009.
7. CHM.30700, CHM.30900, CHM.30100, CHM.29100, CHM.30550, CHM.31000

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## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 8/2/2025 |

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# L.CHEM 3.15 Linearity Study



# Policy

**Linearity**

# Purpose

Linearity studies are performed to determine the linear reportable range for an analyte. The linearity for each analyte is assessed by checking the performance of recovery throughout the manufacturer's stated range of the testing system. This is done using a set of standards containing varying levels of an analyte in high enough and low enough concentrations so as to span the entire range of the test system.

Linearities are performed when:

- A new analyzer, analyte or method is introduced into the laboratory, or
- An analyzer is replaced.
- Linearities may also be performed for troubleshooting purposes when quality control is unacceptable and deviations from acceptable data cannot be explained, or
- Major analyzer repair or replacement of components has taken place.
- Linearities are performed on assays that do not have 3 or more point calibration.
- Also applies to Osmolality, Sodium, Potassium, Chloride and Sweat chloride.

# Procedure

1. Linearity studies will be performed as part of the procedure "Evaluation of Automated Test Methods" in order to determine linear reportable range. For each analyte, a set of linearity standards will be tested in the same manner as patient samples.

2. Testing should be performed in triplicate, and at a minimum, in duplicate, when performed within a single run. If one value deviates greatly from the others due to random error, it may be removed from the data analysis and repeated.
3. The test results will be graphed and statistically analyzed as described below under "Evaluation of Linearity Study Data."
4. Once a linearity study has been performed to determine the linear reportable range for a test method, it may be repeated as recommended by the manufacturer (i.e.: following relocation of the instrument or after major maintenance) or calibration verification may be performed in accordance with CLIA guidelines, to verify continued acceptable performance of calibration and stated reportable range of the analyzer or analyte.

# Evaluation of Linearity Study Data

The data from the linearity study will be recorded on a linearity study sheet or programmed or downloaded into an available software program. Some manufacturers of linearity standards provide online data entry with real time comparison with peer group data and the capability to download linear regression graphs.

Values are plotted as observed values (Y axis) vs. expected values (X axis). Examine the raw data for obvious errors. If an analytical or technical problem is found, repeat the testing. Assessment will be made by evaluating the data and statistics using the following guidelines.



# Accuracy and Precision

Review the linearity data for acceptable accuracy and precision. Ideally, endpoint assays should be within 10% of the standard's stated value or peer group comparison value, but at a minimum, manufacturer's stated tolerance limits should be met. Coefficient of Variation, which is a measure of precision, and is the standard deviation expressed as a percentage of the mean, ideally should also be less than 10%, or at a minimum, remain within the threshold of the manufacturer's stated acceptable performance. It is ultimately the responsibility of the laboratory director to determine acceptability of this data and the validity of analyzer results with respect to accuracy and precision.

**SLOPE AND Y-INTERCEPT**

- Two key statistical values in determining linearity are:
- Slope: Equal to 1.0
    - Acceptable Range: 0.9-1.1
- If the slope is outside the acceptable range; examine the results of the highest standard first. It is possible that the test is nonlinear at its highest value.

**Y-intercept:**

- Ideally, the Y-intercept is equal to zero. For enzyme determinations and other assays with results in high numerical values, the Y—intercept may be much higher with no clinical significance. The Y—intercept for assays with low numerical values should be 0.0 + /— 1.0.

# Reportable Range

A reportable range will be established for each analyte tested. The upper limit of the reportable range will be set at the concentration of the highest standard tested which exhibited acceptable results for linearity, accuracy and precision. This concentration, however, may not exceed the manufacturer's stated linear range.

For analytes which have a lower limit of linearity, the lower limit of the reportable range will be set at the lowest standard tested which exhibits acceptable results, however, this concentration may not exceed the manufacturer's lower limit. Patient samples with · concentrations which exceed the reportable range will be diluted with the appropriate diluents and retested, when the analyzer provides this capability. Samples with concentrations which are lower than the reportable range will be reported as "Less than (the lower limit)".

# Calibration Verification

Calibration verification is necessary to verify that an analyte's calibration is still valid, and confirms that testing provides continued accurate results throughout the previously established reportable range.

If calibration of an analyte or test system is performed every six months, utilizing three or more calibrators across a majority of the reportable range, then calibration verification is automatically met, and the laboratory does not need to perform further verification.

For analyzers and analytes that are not calibrated with a minimum of three calibrators verifying the low, midpoint and high end of the reportable range, calibration verification must be performed to substantiate the continued accuracy of the monitors throughout the reportable range, after initial validation studies are performed with the setup of the analyzer.



**Calibration verification is performed every six months**, as stated in current CLIA regulations. Calibration verification should also be performed under the following conditions:

1. Whenever major maintenance is performed or a critical component part of an analyzer has been replaced
2. Whenever reagent lots are completely changed (unless it has been stated and shown that these lot changes do not affect test results, as with manufacturer's instructions and guidelines in package inserts and analyzer specific manuals)
3. When control values are found to be continually unacceptable, as with shifts and trends in Levy-Jennings graphs over a period of time.

To perform calibration verification, low, midpoint and high level standards are tested in the same manner as patient samples. Evaluation of this analysis is achieved through use of slope, intercept, correlation coefficient or manufacturer established guidelines for acceptability criteria.

Each laboratory and its director should establish its own acceptance criteria for calibration verification. When acceptable performance is met, the calibration has been verified. If calibration verification is found to be unacceptable, the instrument must be re-calibrated and all corrective action must be documented.

Assays with less than three point calibration. The linearities can be performed by the Siemens Vista analyzer. Once the Linearity is completed, it should be reviewed, accepted and printed by Clinical Laboratory Scientist.

# Vista Analyzer Linearity

**Ordering Linearity Study on Siemens Vista Analyzer**

The linearity study is not available for nephlometric methods. When a linearity study is ordered, the system creates five levels and orders two replicate per level. Calibrator vials on board are used to prepare the intermediate levels (25%, 50%,75%). To order a linearity study from cups, low and high calibrator or water and high calibrator can be used, depending on the methods used to perform the study. The dialog box for order of calibrator levels/cups.

For Dimension Vista 500/1500 system operators, skip Step 2 and proceed to Step 3.

1. Press the **Advanced** icon, then the Calibration icon. From the **Calibration** menu, select Calibrations by lot.
2. Use the twin selector to designate left or right instrument.
3. Highlight a method. From the Order menu, select **Order Linearity Study**.
4. Verify that the information on the screen is correct. Use the drop-down menu to verify that the Calibrator lot id correct, then press OK to start the study.

**Linearity Study Using a Cup**

Use this procedure for calibrating methods that require calibrator to be supplied in a cup.

1. Press the Advanced icon, then the Calibration icon. From the Calibration menu, select Calibrations by lot
2. Highlight a method. From the Order menu, select **Order Linearity Study**.
3. Verify that the information on the screen is correct. Use the drop-down menu to verify that the calibrator lot is correct.
4. Check the Use Cups box.
5. Pipet calibrator from the correct lot into a cup
6. Placed the cup in an adapter into position 1 on the rack. For additional cups, use the positions in ascending order. Be sure to use the number of calibration levels and cups as specified in the method IFU.
7. Scan the rack barcode and verify the information on the screen.
8. Press **OK** and load the rack on the instrument.

**Review a Linearity Study**

An alert message appears when the linearity study is complete. To accept the study, follow this procedure.

1. From the Calibration menu, select **Calibration by Lot**. Select the appropriate method.

2. Review the displayed data. To see more detail, select the **Show details** option.
3. To acknowledge the study, select the **Mark Linearity as Reviewed** option in the lower Actions menu

After the study is acknowledged, a report is printed.

| **Linearities for Vista A** | | **Linearities for Vista B** | |
|---|---|---|---|
| **Assay** | **Calibrator** | **Assay** | **Calibrator** |
| Acetaminophen | DRUG 2 | Albumin | CHEM 4 |
| Albumin | CHEM 4 | Alkaline Phosphatse (ALPI) | ALPI |
| Alkaline Phosphatse (ALPI) | ALPI | AMMONIA | CHEM 3 |
| AMYLASE | ENZ1 | AMYLASE | ENZ1 |
| AST | ENZ 2 | AST | ENZ 2 |
| ALTI | ENZ 2 | ALTI | ENZ 2 |
| BUN | CHEM 1 | BUN | CHEM 1 |
| CALCIUM | CHEM 1 | CALCIUM | CHEM 1 |
| CHOLESTEROL | CHEM 1 | CHOLESTEROL | CHEM 1 |
| CKI | ENZ 6 | CKI | ENZ 6 |
| CO2 | CHEM 3 | CO2 | CHEM 3 |
| CREATININE | CHEM 1 | CREATININE | CHEM1 |
| DBIL | BILI | DBIL | BILI |
| ETHANOL | CHEM 3 | ETHANOL | CHEM 3 |
| GLUCOSE | CHEM 1 | GLUCOSE | CHEM 1 |
| HDLC | LIPID | HDLC | LIPID |
| LACTIC ACID | CHEM 1 | IRON | IRON |
| LDLC | LIPID | LACTIC ACID | CHEM 1 |
| LDH(LDI) | ENZ 5 | LDLC | LIPID |
| Magnesium | CHEM 1 | LDH(LDI) | ENZ 5 |
| PHOS | CHEM 2 | MAGNESIUM | CHEM 1 |
| Salicylate | CHEM 2 | PHOS | CHEM 2 |
| TBIL | BILI | TIBC | TIBC |
| Total Protein | CHEM 4 | TBIL | BILI |
| TRIG | CHEM 2 | Total Protein | CHEM 2 |
| Uric Acid | CHEM 1 | TRIG | CHEM 1 |
| Sodium (NA) | Verichem | Uric Acid | CHEM 1 |
| Potassium (K) | Verichem | Sodium (NA) | Verichem |
| Chloride | Verichem | Potassium (K) | Verichem |

| | | | |
|---|---|---|---|
| | | Chloride | Verichem |

# Osmolality Linearity

**Linearity**: Osmolality linearity is can be performed by assaying in duplicate the standards provided by Osmolality Linearity set.

**Intended Use**: Osmometer standards are sued to calibrate and/or check the performance of the osmometer. These standards should only be used in accordance with the osmometer that is being calibrated. Carefully snap off the topof the ampule. There may be sharp edges at breakpoint, and could result in injury if caution is not taken.

**Instruction for Use:**

1. Carefully snap off the top of the ampule.
2. Obtain samples with clean sample tips. The sample size will be based on the osmometer that is being used.

**Storage and Handling**

1. Dispose of any opened ampules at the end of the testing day. Do not refreeze. Unopened 2-30°C (36-86°F) refer to expiration date on the box for stability.



# Limitations

If there is visible evidence of microbial growth in the ampules, do not use the calibration standards. Erroneous results can occur from adverse shipping and/or storage conditions, used of expired materials, or sampling handling errors.

**Expected Values and Expected ranges**

The table below lists the nominal values and the corresponding expected ranges for the osmometer standards, assuming nominal instrument performance.

| Expected (Target) Values | Expected Range |
|---|---|
| 50 mOsm/kg $H_20$ | 48-52 mOsm/kg $H_20$ |
| 100 mOsm/kg $H_20$ | 98-102 mOsm/kg $H_20$ |
| 200 mOsm/kg $H_20$ | 198-202 mOsm/kg $H_20$ |
| 400 mOsm/kg $H_20$ | 398-402 mOsm/kg $H_20$ |
| 500 mOsm/kg $H_20$ | 497.5-502.5 mOsm/kg $H_20$ |
| 850 mOsm/kg $H_20$ | 845.75-854.25 mOsm/kg $H_20$ |
| 900 mOsm/kg $H_20$ | 895.5-904.5 mOsm/kg $H_20$ |
| 1000 mOsm/kg $H_20$ | 998-1005 mOsm/kg $H_20$ |
| 1500 mOsm/kg $H_20$ | 1492.5-1507.5 mOsm/kg $H_20$ |
| 2000 mOsm/kg $H_20$ | 1990-2010 mOsm/kg $H_20$ |
| 3000 mOsm/kg $H_20$ | 2985-3015 mOsm/kg $H_20$ |

# Interpretation of Results

Osmometer results are evaluated with respect to the total expected range, which combines the effects of the osmometer standard expected range and the instrument specifications. If results falls outside the total expected range, it may indicate unsatisfactory calibration, operator error, contamination of reagents, or fault performance of equipment.

The data should be submitted to the Chemistry supervisor for review, acceptance and statistical analysis.

**Sodium, Potassium, Chloride Linearity**: Perform the linearity using Verichem Linearity material. Analyzer Na, K, and Cl in duplicate for each standard. Submit the data to the Chemistry Supervisor, for review, acceptance and statistical analysis.

**Intended Use**: The Electrolyte Standard kit is a liquid in vitro diagnostic product intended for calibration or calibration verification of serum electrolyte tests systems.

**Instructions for Use**: Mix by inversion several times prior to use. Remove dome cap, invert and discard the first drop. Dispense amount required. Replace dome cap and promptly store unused portion at 2°C to 8 °C. Product is stable in original container until the expiration date indicated. Avoid prolonged exposure of standards to room temperature. Refrigerate promptly after each use. Do not remove dropper tip. Never transfer Verichem standards to another container. Keep from freezing.



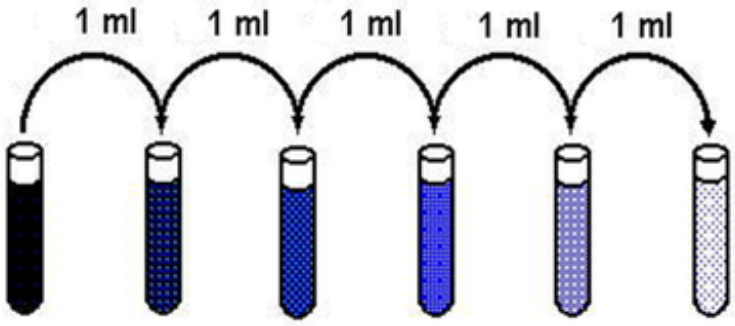
**Standard values:** Unless otherwise noted, these standard values are assigned by gravimetric procedure and indicate weight per volume composition using standard source materials of known purity.

| Analyte | Units | Level A | Level B | Level C | Level D | Level E |
|---|---|---|---|---|---|---|
| Sodium | mmol/L | 100 | 118 | 136 | 154 | 172 |
| Potassium | mmol/L | 1.75 | 4.50 | 7.25 | 10.00 | 12.75 |
| Chloride(Indirect ISE) | mmol/L | 60.0 | 88.5 | 117.0 | 145.5 | 174.0 |
| Chloride (Direct ISE)* | mmol/L | 59.7 | 85.9 | 112.2 | 138.5 | 164.8 |

- Direct ISE chloride target values were assigned using NIST Human serum Standard Reference Material No. 956d.

Linearities of other assays are performed by using College of American Pathologists (CAP) provided linearity material. Data are submitted to CAP for evaluation. Review and documentation of any corrective action as needed.

# Sweat Chloride Linearity




| | | | | | | |
|---|---|---|---|---|---|---|
| Standard | 2 mL | - | - | - | - | - |
| Deionized $H_2O$ | - | 1 mL | 1 mL | 1 mL | 1 mL | 1 mL |
| Dil factor | 1 | 2 | 4 | 8 | 16 | 32 |
| Expected Result | 200 | 100 | 50 | 25 | 12.5 | 6.25 |
| Actual Result | | | | | | |



## Materials

1. Chloridometer Chloride Standard
2. Chloridometer Acid Reagent
3. 1 ml pipet

## Procedure

1. Label 6 tubes with dilution factors: 1,2,4,8,16,32.
2. Add 2ml of standard to the tube labeled 1.
3. There should be no delay in the procedure as there will be rapid evaporation of the acid that will cause inaccurate results.
4. Add 1ml of Acid labeled 2,4,8,16,32.
5. Pipet 1ml of Standard from tube 1 to tube 2, then mix. Continue doing serial dilution up to tube 32. The last remaining aliquot of 1 ml may be discarded. This should leave a total of 1 ml in all of the tubes.
6. Perform sweat chloride analysis on all six tubes, repeated twice. Record results on Sweat Chloride Linearity result sheet and submit to supervisor for review.

# Centaur Linearity

**Ordering Linearity Study on Siemens Centaur XP Analyzer**

- A master curve material (MCM) is used to evaluate the Advia Centaur XP assay. It is intended to be run singly an unknown samples after a two-point calibration has been performed on the

system.

- Add reagent water into each master curve material vial using a volumetric pipet.
- Let the vials stand for 15-20 minutes at room temperature to allow the lyophilized material to dissolve.
- Gently swirl and invert the vials until homogeneous.
- Schedule the material curve material in the worklist. Order test in duplicate.
- Label sample cups with the appropriate labels for the MCM.
- Gently mix each vial and dispense into sample cups.
- Place the MCM from lowest to highest concentration on the system.
- Note: ensure that the assay reagents are loaded on the system.
- Start the system, if required.

**Evaluating the results**

The target ranges represent the acceptable results for the MCM tested singly as unknown samples. All levels are expected to be in the acceptable range. When evaluating MCM results that are outside of the acceptable range, use the same evaluation criteria used when evaluating patient and quality control results.



# Limitations

- The following information pertains to limitations of the MCMs:
- Do not pour the master curve material back into the vials after the testing because evaporation can occur, which may affect performance.
- Dispose of any material remaining in the sample cups after 8 hours.
- Do not refill master curve material sample cups when the contents are depleted. If required, dispense fresh master curve material.
- Linearities for Advia Centaur XP: **Alpha-Fetoprotein (AFP), Cortisol (COR), Cancer Antigen 27.29 (BR), Testosterone (TESTO), Carcinoembryonic antigen (CEA), Thyroxine (T4), Triiodothyronine (T3), and Thyroid stimulating hormone (TSH).**

**Recalibration**

If the calibration verification are unacceptable or outside the target ranges/ lot-specific value sheet for the expected values, the test is repeated with the calibration procedure. After repeating, the quality controls are run before any patient test are run.

# References

1. Siemens Master Curve Material 10994462 Rev. A, 2015-11, 10994433 Rev. A, 2015-05, 10994419 Rev. A, 2015-11, 10994459 Rev. B, 2014-08, 10699171 Rev. A, 2012-10
2. Advanced Instruments, Inc. Osmolality Linearity Set 3MAP05 Rev 8 3LP027 rev 10
3. Verichem Laboratories Electrolyte Standard Kit Rev 09 2015

4. Digital Chloridometer Instruction Manual, Labconco Corp., 1997.
5. Siemen's Dimension Vista System Operator's guide 2012-01, 6-31

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## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 8/2/2025 |

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| Next Review | 10/3/2027 |
| Owner | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services |
| Policy Area | Laboratory Services - Chemistry |

# L.CHEM 3.16 New Lot to Lot Crossover



## Policy

New Lot of Reagent- Lot to lot Crossover

## Purpose

Clinical laboratory reagents are exposed to many variables including changes in temperature during transportation and various storage conditions. The verification or parallel testing of new reagent lot numbers and/or shipments with current lot numbers is performed to ensure that, in spite of varying shipping and environmental conditions, no clinically significant differences in the results are obtained. The procedure outlines the reagent parallel testing requirements for quantitative, qualitative and semi-quantitative assays performed in the clinical laboratory. It also includes the selection of appropriate specimens for testing, frequency of testing and suggested methods for evaluation of results.

## Sample Preparation

1. The recommended number of samples is at least three patient samples (low, normal and high).
2. Ensure that instrument maintenance is up-to-date.
3. Patient samples should be used whenever possible.
4. If stored samples are used, ensure that the samples were stored appropriately.

## Frequency

1. Each time a new lot of reagent is received and before it is put into use by the laboratory.

# Procedure

Reagent lot crossovers on patient samples can be performed on the Dimension Vista System. Patient samples are processed using all on board reagent lots.

1. Press the Advanced Icon, then the Samples icon. Select Batch Test Mode Test Setup from the Menu.
2. Select Create or Modify Batch Mode Configuration from the Actions menu.
3. Enter Batch ID in the Batch ID field. Name it (1#)
4. Select "Sample Fluid Type" from the drop-down menu.
5. Select the method(s) to be processed.
6. If multiple replicates are needed select the method of choice and the number of times needed to be run.
7. Scan the Sample rack bar-code. The bar-code are listed in the display box for multiple sample racks. The sample rack barcodes can also be manually entered in the space provided.
8. Press Save Changes in the Actions menu.
9. Select Lot Crossover in the Batch Mode Menu.
10. Load the sample racks on the instrument.
11. When the batch mode is processed the sample ID is generated by Rack-position+sequence number. The same sequence number is added to the Batch ID to form the Patient ID filed.
12. As the results are completed, the Dimension Vista System displays the results on the result History screen. The results can also be viewed in the Test status screen. Print results for documentation.
13. Obtain the results for new lot and old lot, average mean and cumulative coefficient of variation (CV) from the printout. This will be used for calculating acceptability ratio.
14. The Acceptability ratio is calculated to determine if there is any significant difference in patient values between current lot and the new lot of reagent.
    - Acceptability Ratio : (New Lot result- Old Lot result)/(Average mean X Coefficient Variation)
        - The acceptability ratio should be **less than or equal to 1.**

Rationale: Multiplying the CV by the Average Mean provides a standard deviation (SD). Dividing the value into the difference of the two reagent means provides a standard deviation index (SDI) with which to measure the difference in results between the two reagents. Differences in results between successive lots of reagents should not be more than ±1 SDI.
COM.30450



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## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 8/2/2025 |

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# L.CHEM 3.17 Procalcitonin



# Policy

**Procalcitonin**

**METHOD**

VIDAS® B·R·A·H·M·S PCT (PCT) is an automated test for use on the instruments of the VIDAS family for the determination of human procalcitonin in human serum or plasma (lithium heparinate) using the ELFA (Enzyme-Linked Fluorescent Assay) technique. The VIDAS® B·R·A·H·M·S PCT (PCT) is intended for use in conjunction with other laboratory findings and clinical assessments to aid in the risk assessment of critically ill patients on their first day of ICU admission for progression to severe sepsis and septic shock.

# Principle

The assay principle combines a one-step immunoassay sandwich method with a final fluorescent detection (ELFA).

The Solid Phase Receptacle (SPR®), serves as the solid phase as well as the pipetting device. Reagents for the assay are ready-to-use and pre-dispensed in the sealed reagent strips.

All of the assay steps are performed automatically by the instrument. The sample is transferred into the wells containing anti-procalcitonin antibodies labeled with alkaline phosphatase (conjugate). The sample/conjugate mixture is cycled in and out of the SPR® several times. This operation enables the antigen to bind with the immunoglobulins fixed to the interior wall of the SPR® and the conjugate to form a sandwich. Unbound compounds are eliminated during washing steps.

Two detection steps are performed successively. During each step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-umbelliferone) the fluorescence of which is measured at 450 nm. The intensity of the fluorescence is proportional to the concentration of antigen present in the

sample.
At the end of the assay, results are automatically calculated by the instrument in relation to two calibration curves corresponding to the two detection steps. A fluorescence threshold value determines the calibration curve to be used for each sample. The results are then printed out.

# Reagents and Materials

***Reagents and Materials Provided***

Refrigerate 2-8°C Note: Do not freeze the reagent kit.

1. PCT Reagent Strips
2. PCT SPRs
3. PCT Calibrators (S1 & S2)
4. PCT Kit Controls (C1 and C2)

***Reagent Preparation and Storage***

1. PCT Calibrator - Reconstitute with 2 ml of distilled water. Wait 5 - 10 minutes and then mix. After reconstitution, the calibrator is stable for 8 hours at 2-8°C or until the expiration date of the kit at -25 ± 6°C. 5 freeze/thaw cycles are possible.
2. PCT Controls - Reconstitute with 2 ml of distilled water. Wait 5 -10 minutes and then mix. After reconstitution, the controls are stable for 8 hours at 2-8°C or until the expiration date of the kit at -25 ± 6°C. 5 freeze/thaw cycles are possible.



***Materials Required But Not Provided***

1. Calibrated pipette to dispense 2 mL and 200 µL.
2. Disposable pipette tips for pipette.
3. Powderless disposable gloves.

# Specimen Collection and Handling

- Collect Human Serum or Plasma with Lithium Heparin.
- For a given patient, the PCT assays must be performed on the same type of sample tube.
- Since EDTA causes a decrease in the values measured, plasma collected on EDTA should not be used (to test). Samples containing suspended fibrin particles or erythrocyte stroma should be centrifuged before testing.
- Sample preparation:
    - Dry tubes: wait for samples to coagulate and centrifuge according to the tube manufacturer's recommendations to eliminate fibrin.
    - Other tubes: follow the tube manufacturer's recommendations for use.
    - Frozen-stored samples: after thawing, all these samples must be clarified by centrifuging.
- Note: Blood sampling tube results may vary from one manufacturer to another depending on

the materials and additives use.

- It is the responsibility of each laboratory to validate the type of sample tube used and to follow the manufacturer's recommendations for use.
- The sera or plasma separated from the clot can be stored at 2-8°C in stoppered tubes for up to 48 hours; if longer storage is required, freeze at -25 ± 6°C. Six-month storage of frozen samples does not affect the quality of results. Three freeze/thaw cycles were validated.

# Procedure

## Test Steps

1. Remove the required reagents from the refrigerator.
2. Use one "PCT" strip and one "PCT" SPR for each sample, control or calibrator to be tested. Make sure the storage pouch has been carefully resealed after the required SPRs have been removed.
3. The test is identified by the "PCT" code on the instrument. The calibrators must be identified by "S1" and by "S2", and tested in duplicate. If the controls need to be tested, they should be identified by C1 and C2 and tested singly.
4. Mix the calibrators and/or controls using a vortex-type mixer.
5. For this test, the calibrator, control, and sample test portion is 200 µl.
6. Insert the "PCT" SPRs and strips into the appropriate position on the instrument. Check to make sure the color labels with the assay code on the SPRs and the Reagent Strips match.
7. Initiate the assay immediately. All the assay steps are performed automatically by the instrument.
8. Reclose the vials and return them to the required temperature after pipetting.
9. The assay will be completed within approximately 20 minutes. After the assay is completed, remove the SPRs and strips from the instrument.
10. Dispose of the used SPRs and strips into an appropriate recipient.



## Calibration

***VIDAS® PTC Protocol Data Entry***

When using the assay for the first time and before reading the MLE data, scan the barcode (at the end of the package insert) using the instrument barcode reader. This reading will allow the VIDAS® PTC protocol data to be transferred to the instrument software for its update. These data should only be read the first time the assay is used.

***Master Lot Data Entry***

Note: When using the assay for the first time, enter the VIDAS® PTC protocol (barcode at the end of the package insert) before reading the MLE data. If the MLE data have been read before the VIDAS® PTC protocol, read the MLE data again.
Before each new lot of reagents is used, specifications (or factory master calibration data) must

be entered into the instrument using a master lot entry (MLE) card included in each kit. If this operation is not performed before initiating the tests, the instrument will not be able to print results. The master lot entry (MLE) need only be entered once for each lot.
It is possible to enter MLE data manually or automatically depending on the instrument. For complete instructions refer to the Operator's Manual.

***Calibration***

Calibration, using the two calibrators provided in the kit, must be performed each time a new lot of reagents is opened, after the master lot data has been entered, and then every 28 days. This operation provides instrument-specific calibration curves and compensates for possible minor variations in assay signal throughout the shelf life of the kit.
The calibrators, identified by S1 and S2, must be tested in duplicate in the same run (see Operator's Manual). The calibration values must be within the set RFV ("Relative Fluorescence Value"). If this is not the case, recalibrate using S1 and S2.

# Quality Control

- Two controls are included in each VIDAS® B.R.A.H.M.S PCT kit.
    - These internal controls must be performed immediately after opening a new kit to ensure that reagent performance has not been altered. Each calibration must also be checked using these controls. The instrument will only be able to check the control values if they are identified as C1 and C2. Results cannot be validated if the control deviate from the expected values. Samples tested in the same run must be re-assayed.
- External controls from Biorad Lyphochek specialty immunoassay control level 1 and 3 should be performed every 24 hours.
- Note: It is the responsibility of the user to perform Quality Control in accordance with any local applicable regulations.



**Expected Values for Calibrators and Controls**
The expected values for the controls and calibrators are printed on the MLE card. If the result from testing the controls and calibrators do not meet these specifications, do not report patient results.

# Results

- Once the assay is completed, results are analyzed automatically by the computer using two calibration curves which are stored by the instrument; the concentrations are expressed in ng/mL.
- With VIDAS PC, if a result which is < 0.05 ng/mL is obtained, the printed report will include the alarm "J2 > J4 & J2 – J0 < RFV threshold" and *** will be indicated for the RFV. This alarm, which is linked with the reading mode of the VIDAS® B·R·A·H·M·S PCT (PCT) technique (dual reading), does not call into question the concentration measured.
- As no international standard is available, VIDAS® B·R·A·H·M·S PCT is calibrated against an internal panel of human sera with known procalcitonin concentrations. In case of patient

follow-up, it is recommended to use the same PCT assay technique.

- Samples with procalcitonin concentrations greater than 200 ng/mL should be retested after dilution by 1/10 (1 volume of sample + 9 volumes of PCT negative sample).

# Range of Expected Values

In agreement with the literature, the results obtained with VIDAS® B.R.A.H.M.S PCT during a study performed on patients admitted to intensive care units are as follows:

- A concentration <0.5 ng/mL represents a low risk of severe sepsis and/or septic shock.
- A concentration < 2 ng/ml represents a high risk of severe sepsis and/or septic shock.

Nevertheless, concentration <0.5 ng/mL do not exclude an infection, or account of localized infection (without systemic signs) which can be associated with such low concentrations, or a systemic infection in its initial stages (<6 hours). Furthermore, increased procalcitonin can occur without infection. PCT concentration between 0.5 and 2.0 ng/mL should be interpreted taking into account the patient's history. It is recommended to retest PCT within 6-24 hours if any concentrations <2 ng/mL are obtained.

**Performance**
Studies performed using VIDAS® B.R.A.H.M.S PCT gave the following results:



# Measurement range

- The VIDAS® B.R.A.H.M.S PCT measurement range is 0.05-200 ng/mL.

**Detection limits**
The analytical detection limit, defined as the smallest concentration of procalcitonin which is significantly different from the zero concentration with the probability of 95%, is less than 0.05 ng/mL.
**Hook effect**
No hook effect was found up to procalcitonin concentrations of 2,600 ng/mL.

# Limitation of Assay

Interference may be encountered with certain samples containing antibodies directed against reagent components. For this reason, assay results should be interpreted taking into consideration the patient's history, and the results of any other tests performed.

# Interferences

None of the following factors have been found to significantly influence this assay:

- Hemolysis - after spiking samples with hemoglobin, up to 347 µmol/L (monomer).
- Lipemia - after spiking samples with lipids, up to 30 g/L equivalent in triglycerides.
- Bilirubinemia - after spiking samples with bilirubin, up to 547 µmol/L.

*** **However, it is recommended not to use samples which appear to be hemolyzed, lipemic or icteric and, if possible, to collect a new sample.**

# References


1. DANDONA P. et al., Procalcitonin increase after endotoxin injection in normal subjects, JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM 1994 79(6) 1605-1608.
2. CHRIST-CRAIN M. et al., Effect of procalcitonin-guided treatment on antibiotic use and outcome in lower respiratory tract infections: cluster-randomised single-blinded intervention trial. LANCET 2004 363(9409) 600-607.
3. MULLER B. et al., Crit. Care Med. 2000; 28(4): 977-983. Calcitonin precursors are reliable markers of sepsis in medical intensive care unit.
4. HARBARTH S. et al., Am J. Resp. Crit Care Med. 2001; 164: 396-402. Diagnostic value of procalcitonin, interleukin-6 and interleukin-8 in critically ill patients admitted with suspected sepsis.
5. American College of Chest Physicians/Society of Critical Care Medicine (1992), Crit Care Med 20: 28(4): 864-874. Definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis.
6. LUYT C.E. et al., Procalcitonin kinetics as a prognostic marker of ventilator-associated pneumonia, AMERICAN JOURNAL OF RESPIRATORY AND CRITICAL CARE MEDICINE 2005 171(1) 48-53.
7. BRUNKHORST FM, et al. Kinetics of procalcitonin in iatrogenic sepsis. Intens care med. 1998; 24-888-892.
8. MEISNER M., Thieme Stuttgart, New York 2000, ISBN: 3-13-105503-0: Procalcitonin (PCT) - A new, innovative infection parameter. Biochemical and clinical aspects.
9. CHRIST-CRAIN M, MULLER B. Procalcitonin in bacterial infections-hype, hope, more or less? SWISS MED WKLY. 2005, 135(31-32): 451-60.




## All Revision Dates

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## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |

| | | |
|---|---|---|
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 8/2/2025 |

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# L.CHEM 3.18 Water Quality



# Policy

**Water Quality**

# Principle

The laboratory defines the reagent grade of water necessary for each of its procedures. Each grade is defined by CLSI for the following constituents: Maximum bacterial content (CFU/mL), minimum resistivity (mOHM/cm), and maximum silicate content (mg/L). Bacteria may inactivate reagents, contribute to total organic contamination or alter optical properties of test solutions. Resistivity provides a non-specific measure of the ion content. Silica adversely affects most enzyme determinations as well as electrolyte analyses.

**USES:**

Reagent Grade I water is used for reagent preparation, rehydration of lyophilized quality control materials and survey materials, and preparation of histology stains and dyes. Purchased water is used only in the analytic system that provided the water.

**PREPARATION**

Reagent Grade I water used by the laboratory is obtained by a Puretec reverse osmosis and deionization system. This system is maintained by the VCMC Maintenance Personnel. Dimension Vista® System feed water enters the Progard® 2 Pack, which pretreats the water to prevent mineral scaling, organic fouling and chlorine oxidation of the module's reverse osmosis (RO) membranes. The RO pump increases water pressure for more permeate flow from the RO membranes, which remove ions from the tap water, as well as much bacteria and organic matter. These ions, bacteria and organic matter are directed to the reject stream. After passing through the RO membranes, the water flows through a 185 nm ultraviolet (UV) lamp, which oxidizes remaining organic material. The water enters the Q-Gard® Pack

which removes trace ions and trace organic molecules, then flows through a degasser. Finally, the water passes through a filter that removes bacteria, nucleases and endotoxins. The product water is stored in a 10 L tank from which the instrument draws water. To maintain water purity, the tank has a 254 nm ultraviolet lamp. Additionally, the water is continuously recirculated through the 185 nm UV lamp, the Q-Gard® Pack, the degasser and filter. It is used solely for these analyzers and feeds directly into each analyzer. The Millipore system is maintained by the laboratory and by Millipore.

**STORAGE**
Bench water is changed daily.

**QUALITY CONTROL**
Reagent Grade I water from the Millipore system is monitored continuously for resistivity. A resistivity reading is obtained from the Ohm meter Resistivity must be maintained at > 10 mOHM/cm.
The Millipore Reagent Grade I water system is monitored continuously for resistivity: An alarm (located next to the Millipore System) sounds if the reading drops below 12 mOHM/cm.
The Millipore Reagent Grade I water system is monitored for resistivity continuously and displayed on the front panel LCD. If the resistivity falls below 10 mOHM/cm, a red alarm LED flashed.

1. Follow instructions in the Millipore User Manual located next to the Millipore System.
2. Check and make sure the Dimension water bottle is at least half full to allow remaining

Water from the Millipore system is checked monthly for bacterial growth by using Millipore Sampler Test kits. The bacterial count should be less than 10 CFU/mL (Colony forming units/mL):



# Procedure

## Collecting water sample from the DI water faucets

1. Clean faucet opening with alcohol wipes.
2. Turn on the faucet and let the water flow for more than 2 minutes
3. Remove the sampler assembly form the bag.
4. Write the date, type and sampling site on the outside of the collection case.
5. Separate the collection case from the sampler paddle.
6. Collect the water sample.
7. Carefully lay the sampler assembly, with paddle down, on a flat surface. Wait 30 seconds while the liquid filters through the sampler paddle.
8. Remove the sampler paddle from the collection case. Shake off excess liquid from the sampler paddle with a firm snap of your wrist. Empty the collection case and reinsert the sampler paddle.

# Collecting water sample from Siemens Dimension Vista Analyzer

1. Clean the Biopak Vent Valve port with alcohol or bleach.
2. Ensure that the WPM is not in Filling Tank mode.
3. Navigate to Advanced> Diagnostics> Prime Pumps
4. Change all pumps to 20 then click Prime All.
5. Remove the sampler assembly form the bag.
6. Write the date, type and sampling site on the outside of the collection case.
7. Separate the collection case from the sampler paddle.
8. Ensure that the WPM is in filling tank mode.
9. While holding the collection case to side of the Vent Valve port, open the Vent Valve port and allow approximately 500 mL of water drain (into a flash or beaker) before the starting the water sample collection
10. Collect the appropriate volume to fill the collection case, then close the valve.
11. Insert the sampler paddle firmly into the collection case.
    Note: Allow the water to uniformly wet the filter surface, but not shake the collection case.
12. Carefully lay the sampler assembly, with paddle down, on a flat surface. Wait 30 seconds while the liquid filters through the sampler paddle.
13. Remove the sampler paddle from the collection case. Shake off excess liquid from the sampler paddle with a firm snap of your wrist. Empty the collection case and reinsert the sampler paddle.
    **Caution:** Make sure the sampler assembly has an airtight seal to prevent drying during incubation. Drying may cause erroneous results.
14. Incubate the sampler assembly at 25-35C for 48 hours to 72 hours.
15. Remove the sampler assembly from the incubator and the sampler paddle form the collection case. Examine the filter surface and count the number of colonies directly from the filter surface.



Millipore Samplers provide a means for simple, fast microbiological analyses of environmental waters, cooling tower waters, process waters, laboratory grade and electronics waters, dialysis water, and food and beverage products. Each sampler is constructed to combine both an intimate contact of a 0.45 µm Millipore membrane filter to a nutrient-pad, and the incorporation of an air-vent on the upper back portion of the paddle. This configuration allows for the draw-through of 1 mL of sample to affix microorganisms to the filter surface for subsequent culturing within its transparent plastic case. The filter is gridmarked to aid in counting the microbial colonies grown on its surface. Each sampler assembly is sterilized and packaged in a sealed plastic envelope.

**NOTES FOR SAMPLE USE**

(a) Samples containing residual chlorine must be neutralized with sodium thiosulfate (0.1 mL of 10% solution/120 mL of sample) prior to testing with the Millipore Samplers.

(b) Where *exact* counts are not required, samples containing an estimated microorganism level of up to 400/mL may be tested with samplers without dilution. For *exact* counts, any sample containing more than 200/mL should be diluted. If a dilution level of 1:10 is required, simply fill Sampler-case with the liquid up to the lower graduated line (1.8 mL) add sterile water (or buffer) to the upper line (18 mL), insert Sampler paddle and proceed with test. For dilutions of 1:100, pipette 0.18 mL into case and add sterile diluent to 18 mL mark.
(c) For most water samples, the Sampler paddle should be immersed in the sample for 30 seconds. If, however, the sample is viscous, the paddle may require immersion for up to 2 minutes toallow the 1 mL aliquot to wet thoroughly, and pass through the membrane. If the entire membrane is properly wetted, the filter will appear dark gray, (a very light gray for Coli count sampler)
(d) Do not immerse paddle longer than is required, otherwise a loss of medium through the membrane and into the sample may occur.
(e) Sample dilutions should be made with a sterile phosphate buffer (pH 7.2). If this is unavailable, sterile, chlorine-free tap water may be used. Nonsterile dilution waters may be sterilized by means of the Millipore Sterivex-GS unit fitted with a 50mL syringe.

# Testing Liquid Samples

1. Remove the Sampler from its plastic bag and write on the case with indelible marker the date, type and location of sampling.
2. Pour sample liquid (or dilution) into the Sampler case, filling to the upper (18mL) graduation.
3. Insert the Sampler firmly into case containing sample, and carefully lay the unit with membrane facing down onto a flat surface. Make certain the membrane is uniformly wetted, and while in this position, the unit should not be agitated. Allow 30 seconds for sample to be drawn through filter. If the sample is viscous, the paddle should remain in the case for additional time (up to 2 minutes).
4. Remove the paddle and, with a firm snap of the wrist, shake off the excess liquid. Empty the case and reinsert the paddle. To prevent the paddle from drying out during incubation, it should be seated firmly in the case to form an air-tight seal.
5. Incubate the Sampler, gridded side down, using the time and temperature specified in the table shown in the "Culture-Incubation Guide".
6. Remove Sampler from incubator. For examination and counting please refer to the "Filter Examination" section.

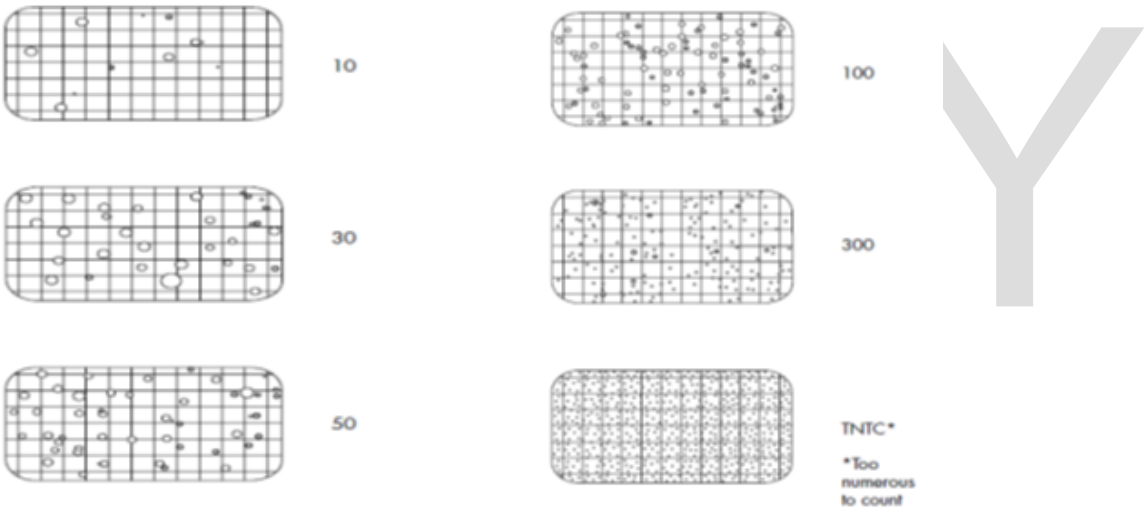
**Filter Examination**
After incubation is complete, remove paddle from case, and examine filter surface with either a stereoscopic microscope with illuminator (at 10X-20X) or an illuminated magnifier (preferably ≥ 5X). The appearance of the microbial colonies will vary, depending upon the Sampler used, and the organisms recovered. Generally they will appear as follows:
Coli-Count Sampler Coliforms are blue in color. Non-coliforms are green, gray, or cream color.

# Counting Colonies

Colonies growing on the filter surface of Samplers are counted as individual organisms. In recording

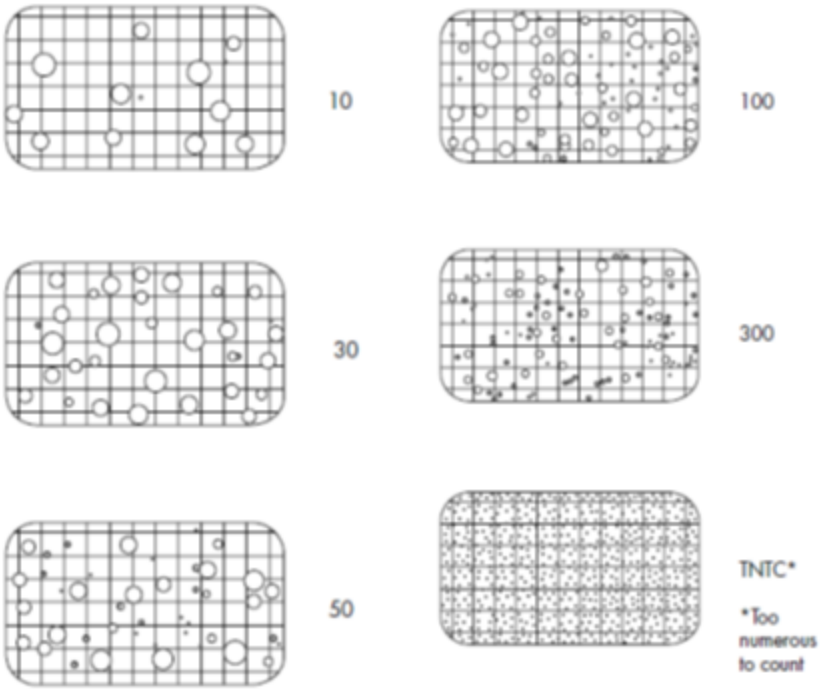
your count when using the Coli-Count Sampler for
coliform (or fecal coliform) analyses, count only the blue colonies. Coliform and fecal coliforms are Always reported as the number per 100 mL sample. Therefore in diluted samples, count the number of blue colonies obtained and multiply this result by 100. If the sample is diluted, multiply the 100 m L count by the appropriate dilution factor. For all other samples, the count per mL is the generally accepted system for recording your results. Therefore, for non-diluted samples, the number of colonies observed on the filter will be the number recorded (as sample count/mL). For diluted samples, the count obtained must be multiplied by the dilution factor.
For example: number of colonies on filter = 60
Sample dilution = 1:1000 (∴dilution factor is 1000)
Sample count/mL = 60 X 1000 = 60,000/mL
A rapid, approximate count can be made by comparing the filter to the examples shown in the "Colony Count Comparison Chart" section.

**Colony Count Comparison Chart**
**Small Colonies**
To obtain approximate count, align sampler with drawing showing same density of colonies.




**Colony Count Comparison Chart**

**Large Colonies**
To Obtain approximate count, align sampler with photo showing same density of colonies.




**Frequency**

Water from the Puretec system is checked at least quarterly for bacterial growth by using Millipore Sampler Test kits on all deionized water faucets, Chemistry, Hematology, Urinalysis, Send-outs, Blood bank, Microbiology, Vista A and Vista B Chemistry Analyzers.



# Results

## Results Interpretation

A. Samples should be read after 48 to 72 hours and results should be reported. If bacteria is evident (10 cfu/mL or greater), a request should be made to identify the type of bacteria

B. If positive results are reported, and it is determined that the WPM is the source, a service call will be dispatched at no charge in accordance with the service agreement or warranty. The appropriate WPM decontamination procedure will be completed.

C. The analyzer will be serviced in accordance with e appropriate decontamination procedures designated by Siemens Service.

**Technical Assistance**

For more information, contact the Millipore office nearest you. In the U.S., call 1-800-MILLIPORE (1-800-645-5476). Outside the U.S., see your Millipore laboratory catalogue for the phone number of the Millipore office nearest you. Or, look us up on the http//www.millipore.com

## All Revision Dates

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## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 8/3/2025 |

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# L.CHEM 3.19 Therapeutic Drugs- Collection Times



## Policy

Therapeutic Drugs - Collection Times

**THERAPEUTIC DRUGS – COLLECTION TIMES**

When monitoring therapeutic drug levels, it is important to provide clinical personnel with information about optimal specimen collection times in relation to drug dosing. This is necessary so that test results obtained will reflect true peak and trough values. Optimal collection times in relation to dosing are determined by VCMC Pharmacy Department and are listed below. All therapeutic drug levels are reported along with information about patient dosing and collection timing.

| | |
|---|---|
| Acetaminophen | Collect 1hour after dose (4 hours after suspected overdose). |
| Carbamazepine (Tegretol) | Collect just before the next dose. |
| Digoxin | Initial loading dose: collect 4 hrs after IV or 6 hrs after oral dose.<br>Patient at steady state: collect just before the next dose. |
| Gentamicin (Trough) | Collect just before the next dose. |
| Gentamicin (Peak) | Collect 30 minutes after the completion of a 60 minute infusion. |
| Gentamicin (Single Dose) | Collect after the first dose between 6 and 14 hours after the start of a 60 minute IVPB infusion. |
| Phenobarbital | Collect just before the next dose. |
| Phenytoin (Dilantin) | Collect just before the next dose. |
| Salicylate (Aspirin) | Collect 1 to 3 hours after an oral dose. |
| Theophylline | Collect just before the next dose. |
| Tobramycin (Trough) | Collect just before the next dose. |

| | |
|---|---|
| Tobramycin (Peak) | Collect 30 minutes after the completion of a 60 minute infusion. |
| Tobramycin (Single Dose) | Collect after the first dose between 6 and 14 hours after the start of a 60 minute IVPB infusion. |
| Valproic Acid | Collect just before next dose. |
| Vancomycin (Trough) | Collect just before next dose. |
| Vancomycin (Peak) | Collect 60 minutes after the completion of a 60 minute infusion. |
| Vancomycin (Single Dose) | Collect after the first dose between 6 and 14 hours after the start of a 60 minute IVPB infusion. |

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| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
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# L.CHEM 3.2 OSMOLALITY



## Policy

**OSMOLALITY**

**Intended Use:**
The osmolality method, performed on the Advanced Osmometer Model Osmo1 single-sample, is an *in vitro* diagnostic test intended for the quantitative determination of osmolality in serum, plasma and urine.

**Clinical Significance**

The term osmolality refers to the osmotic concentration of a fluid. The osmolality of serum, urine, or any other body fluid depends on the number of active ions or molecules in a solution. Tests of both serum and urine osmolality can yield important information about the patient's ability to maintain a normal fluid balance status.

Kidneys that are healthy will excrete water in relation to the amount the person consumes. Patients with impaired renal function may not be able to concentrate urine. As a result, the urine osmolality will resemble that of plasma, approximately 290 mOsm/kG. A urine osmolality test may be done on an early morning urine sample as water depletion during the night should concentrate the urine. The test may also be done using multiple timed samples or on a cumulative sample collected over a 24 hour period.

Sodium, blood urea nitrogen and blood glucose levels are major factors in determining serum osmolality. In severe dehydration serum osmolality will be increased, as there is less water in proportion to solutes in the serum or blood. Urine osmolality, like specific gravity, is a measure of the concentration of urine. Urine osmolality reflects the total number of osmotic active particles in the urine, without regard to the size or weight of the particles. Substances such as glucose, proteins, or dyes increase the urinary specific gravity. Therefore, urine osmolality is a more accurate measurement of urine concentration than

specific gravity, and urine osmolality can be compared with the serum osmolality to obtain an accurate picture of a patient's fluid balance.

# Principle of Procedure

When a solute is dissolved in a pure solvent, the following changes in the solution's properties occur:

- The freezing point is depressed
- The Boiling point is raised
- Osmotic pressure is increased
- Vapor pressure is lowered

The freezing point of pure $H_2O$ is precisely +0.010°C. One mole of a non-dissociating solute such as glucose (where the solute does not dissociate into ionic species, but remains intact), when dissolved in 1 kilogram (kg) of water will depress the freezing point 1.858°C. This change is known as the freezing point depression for water. The freezing point depression also depends upon the degree of dissociation of the solute. If the solute is ionic, the freezing point is depressed by 1.858°C for each ionic species. In a complex solution (i.e. serum or urine), all ionized and non-dissociated species contribute to the freezing-point depression and the concentration of each solute cannot be easily determined.
Osmolality is a common unit of concentration measurement that can be used to relate all the colligative properties to each other, and to other concentration units. Because of its universality, most osmometry applications regularly use Osmolality, expressed as "mOsm/kG $H_2O$", as the common unit of concentration rather than applying further conversion factors.



# Specimen Collection and Handling

- Normal procedures for collecting and storing serum, plasma and urine may be used for samples to be analyzed by this method.

**KNOWN INTERFERING SUBSTANCES:**

- Hemolysis, Icterus and Lipemia have minimal interference at moderate levels.
- Urine specimens should be centrifuged prior to use.

# Procedure

## Materials

- 20 µL Sample Pipettor
- Disposable Chamber Cleaners and Tips
- 50 mOsm/kG calibrator solution
- 290 mOsm/kG Standard solution
- 850 mOsm/kG calibrator solution
- 2000 mOsm/kG calibrator solution

# Test Steps

- Tap the Sample ID button. A keyboard displays and the bar-code scanner. The keyboard closes. On the home screen, the sample ID field is now populated.
- Placed a new sampling tip on the sampler with the plunger wire inserted carefully into the middle of the tip.
- With your thumb on the plunger top and fingers grasping the barrel depress the plunger; then insert the tip into the liquid sample at least ¼" (6mm) below the surface. Gently release the plunger to load a 20 ul sample.
- Look at the sample you have just drawn. If there are voids or bubbles in the sample, discard it and load another sample that does not contain voids.
- Remove any sample on the outside of the tip using a clean, lint-free, non-ionic paper. Quickly swipe the end of the sampler tip to remove any excess sample protruding beyond the tip.
- Holding the sample by the barrel, carefully insert the tip into the sample port; then rest the sampler body in the operating cradle.
- Grasp the operating cradle and push it slowly forward until you fell a positive stop.
- The test starts when the cradle reaches the forward position. When the test begins, the progress bar at the top of the display is yellow and the status is **TESTING**.
- Wait while the Osmo1 performs the test. The Osmo1 first cools the sample. After a moment, you will hear the solenoid impact several times during the last stages of testing. This is normal operation. When the test completes, the resulting osmolality displays in the middle of the screen. The software provides the instruction to remove the sampler and the clean chamber. Test result are stored in the results database.
- **NOTE**: If you want to cancel the test, you can withdraw the sample operating cradle at any time. If an error occurs during a test, you will hear a beep, and a message displays on the screen.
- Grasp the sampler tip and depress the plunger to help remove it. Discard the sampler tip.
- Wide the plunger tip with a soft, non-lint, non-ionic paper, being careful not to dislodge the Teflon tip.
- Insert a clean, dry chamber cleaner into the sample port until you feel a positive stop. Rotate four or five times in one direction while applying forward pressure.
- Withdraw the cleaner and use the other end of clean the probe again in the same manner.
- Leave the cleaner in the sample port until the next tests. NOTE: If you want to confirm that you cleaned the instrument correctly, remove the cleaner and inspect it. Each end of the cleaner should have a small puncture hole, indicating proper cleaning. If you have finished testing samples for the time being, insert the cleaner back into the port after inspecting it.

**REPEATABILITY TIPS**

- Treat all samples, as well as standards and reference solution, uniformly before the test.
- Discard ampules after use. Do not store open ampules. Do not store open ampules with parafilm.

- Keep sample containers closed when not in use. Microsamples are more susceptible to contamination and evaporation than larger samples. Cold samples are susceptible to condensation; warmer samples are susceptible to evaporation.
- Only use the sampler that was supplied with your instrument.
- Cross-contamination from previous samples can affect the results obtained from a subsequent test. To minimize this effect when testing samples who expected range is appreciably different from that for previous tests, run two or more replicates of the new sample and disregard the first result. Also, be sure to clean the cooling chamber and sample properly after each test.
- If an occasional sample produces irregular results but the instrument has been producing accurate readings, discard the irregular readings and repeat the sample in question.
- For repeat runs, use additional samples from the same source.
- Proper cleaning of the cooling chamber between tests is very important.
- **NEVER INJECT ANYTHING INTO THE COOLING CHAMBER.**

**SAMPLE TEST ERRORS**

Occasionally a test will not run to completion and the instrument will display an error message. Refer to the Troubleshooting Table at the end of the Troubleshooting and Service Chapter in the User's Guide for that particular message.



# Calibration

**IMPORTANT**: Calibrate the Osmo1 only with Advanced Instruments Calibration standards. Using calibration standards that are not manufactured by Advanced Instruments may yield inaccurate results and is not recommended.

**WHEN TO CALIBRATE**

Advanced Instruments recommends that you recalibrate the Osmo1 in any of the following cases;

- If the test results for the reference solutions are out of specification.
- NOTE: Advanced Instruments recommends that you test appropriate reference solutions daily to verify calibration.
- If the instrument has been serviced (especially if any instrument hardware was replaced).
- If the ambient temperature has changed more than $5^{o}C$ since the last calibration.
- In any other circumstanced where calibration is recommended or required based on the regulations that govern your laboratory.

**CALIBRATION PROCEDURE:**

The Osmo1 has a built-in calibration function that guides you through testing five samples each of either two or three known standards;

- 2-point calibration uses the 50 and 850 mOsm/kg H20 calibration standards
- 3-point calibration uses the 50, 850 and 2000 mOsmo/kg H2O calibration standards.
- By default , the system is configured to perform a 3-point calibration

**To perform a calibration**;

1. From the home careen, tap the menu icon
2. From the main menu, tap calibration
3. Select yourself from the list of available users
   NOTE: Supervisors can choose to allow all operators to perform calibrators, or they can restrict access to supervisor-only
4. Enter the password and tap Enter.
5. Follow the on-screen instructions to test samples from each specific standard five times.

**NOTE:** You will test samples of known standards; either 50 and 850 mOsm/kng H2O for a 2-point calibration; or 50, 850 and 2000 mOsm/kg H2O for 3-point calibration

- After each successful calibration test, a green check mark appears in the calibration matrix and units prints "DONE" for the calibration tests.
- If a single calibration test fails or is canceled, the system prompts for a retest using a new sample.
- If two failures occur within the same standard group, that calibration fails and the screen displays the message "Two replicate failures" .
- Upon completion of the last calibration test, the system displays a "Calibration successful" message or the reason of failure.
- Click OK to close the success (or failure) message.
- When you close a success message, the system returns you to Home screen.
- When you close a failure message, the system clears all check marks and returns you to Calibration screen. From there, you can restart the calibration or exit to the Home screen.
- When calibration is successful, the instrument calculates a new calibration slope and intercept and saves those values to memory. If a calibration test fails or canceled for any reason, the instrument does not save that calibration data; instead, it maintains the last successful calibration. The date if the last successful calibration is displayed on the calibration screen.



**CANCELING CALIBRATION**

You can cancel the calibration test in progress or the entire calibration procedure at any time.

**Canceling the test in progress**

To cancel the particular test in progress, retract the sample handler cradle. The system prompts you to retest with a new sample.

NOTE: You can cancel individual test as often as necessary. Cancellation of an individual test does not count towards the limits of two failures within a calibration set.

**Canceling the entire calibration**

If you cancel the entire calibration, the instrument maintains the last successful calibration.

**To cancel the entire calibration**:

1. Tap the Cancel button and a confirmation prompt appears ().
2. At the confirmation prompt, tap Yes to confirm cancellation, or No to continue calibration. If you tap Yes to confirm cancellation, the system discards any data from this calibration and

returns you to the Home screen.

**Calibration Error** - See Table 6- Calibration errors on Chapter 4.5 on the Osmo1 single-sample micro osmometer user guide.

# Quality Control

Two levels of controls for plasma and urine and Clinitrol 290 Reference Solution are run on each day of use. Currently used controls with means and standard deviations are posted in LIS, and print out on the Manual Worksheet.

# Results

Test results can be printed to the printer, and are also stored in the database. You can view, sort, filter and export the list of results recorded by the Osmo1. Up to 1000 records can be stored in the results database before the oldest results are overwritten with new ones.

# Reportable Range

- **50-2000 mOsm/kG**

# Reference Range

- **Plasma or Serum: 280 – 300 mOsm/kG**
- **Urine:300 – 900 mOsm/kG**



# References

1. Advanced Micro-Osmometer Model Osmo1 User's Guide, Advanced Instruments Inc. Norwood MA.
2. Todd-Sanford-Davidsohn, Clinical Diagnosis and Management by Laboratory Methods, 17th edition, WB Saunders Co, 1984, pp 122-124.
3. Advanced Instrument Osmolality Linearity Set Package Insert.

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## Approval Signatures

| Step Description | Approver | Date |
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| | | |
|---|---|---|
| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 7/31/2025 |

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# L.CHEM 3.20 Specimen Carryover



## Policy

**Specimen Carryover**

The pipetting system utilized by the Siemens Dimension Vista is evaluated annually for specimen carryover effects. The CAP Serum Carryover Survey (SCO) and Urine Toxicology Carryover Survey (UTCO) are used for this purpose.

The SCO and UTCO surveys use known high samples and know very low or zero level samples to determine if "clinically significant carryover" is present. If clinically significant carryover is present, the level past which low level samples can be affected is determined. This level is defined as the "upper limit". If no carryover is present, the highest concentration of analyte used in the carryover test becomes the upper limit for checking analytical runs for carryover effect.

- The SCO survey uses Creatinine, hCG and Lactate Dehydrogenase to test for carryover effect.
- The UTCO survey uses Benzoylecgonine, THC and Opiates to test for carryover effect. All results are documented on the forms provided with each survey.

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| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 8/3/2025 |

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# L.CHEM 3.21 Parallel Testing on Siemens Vista



# Policy

**Parallel Testing on Siemens Vista**

**PURPOSE**

A correlation is required to verify the comparability of quantitative laboratory results for analytes tested on Siemens Dimension Vista Analyzers.

**PREPARATION**

Analyzers should be up-to-date maintenance, calibration and validation (to include precision, accuracy, linearity and reference range of each analyte to be tested have been completed. Quality controls results of each analyte are within acceptable range and that there is no biases observed.

The use of fresh human samples (whole blood, serum, plasma urine, etc.) are recommended. However, the use of CAP samples, linearity samples and/or commercial controls maybe necessary to ensure that low, normal, and high specimens are tested.

The samples can be run on both instruments at the same time or within 2 hours (recommended).

If stored sample are used ensure that the samples are stored appropriately and that the storage conditions are the same for samples run on both instruments.

**FREQUENCY**

Correlation study is done every six months using twenty (20) samples of varying assay levels (low, normal, high) each time.

# Procedure

1. Select appropriate samples (numbers as defined by the laboratory). Ensure that this include the one sample with a low abnormal assay value, one with a normal value and one with a high abnormal value.

2. Run the samples on the first instrument then on the second instrument as soon as possible, ideally within two hours.
3. Enter the test results on the correlation/parallel testing Vista A & B worksheet.
4. The worksheet calculates the difference, % difference,s tandard deviation, and correlation ratio.
5. Evaluate the % difference with the target/performance values set and the correlation ratio of each analyte should be ≤1.
6. If % difference and correlation ratio is above ranges, investigate any type of issue that would cause a malfunction in the instrument and reflect in bias, shifts or trend in the quality control that could cause a discrepancy in the correlation study. It is also important to consider the differences between the instruments which might cause discrepant results. Such differences might be differences in methodologies, calibration, imprecision, reagent lot or shipment, lot of calibrators or assignment of values, age of calibrators (date opened) and reagent life in the instruments and instrument parameters (dilution ratios, incubation times, etc.) Once the differences are reconciled, re-run the correlation study to see if the difference is resolved.

| ANALYTE | Diff | % Diff. |
|---|---|---|
| Sodium | ±4 | ±3% |
| Potassium | ±0.5 | ±3% |
| Chloride | ±5 | ±5% |
| BUN | ±2 | ±10% |
| Creatinine | ±0.3 | ±15% |
| Glucose | ±6 | ±10% |
| Calcium | ±0.3 | ±5% |
| CO2 | ±5 | ±10% |
| ALB | ±0.2 | ±6% |
| ALP | ±5 | ±10% |
| ALT | ±5 | ±10% |
| AMY | ±5 | ±10% |
| AST | ±5 | ±10% |
| CHOL | ±5 | ±10% |
| TRIG | ±5 | ±10% |
| TP | ±5 | ±5% |

| ANALYTE | Diff | % Diff. |
|---|---|---|
| TBIL | ±0.2 | ±25% |
| DBIL | ±0.2 | ±25% |
| PHOS | ±0.2 | ±15% |
| MG | ±0.2 | ±20% |
| UA | ±0.2 | ±15% |
| Lipase | ±5 | ±15% |
| Lactic Acid | ±0.2 | ±30% |
| CRP | ±0.2 | ±15% |
| CNTI | ±0.1 | ±15% |
| CKI | ±5 | ±10% |
| CKMB | ±0.5 | ±10% |
| HDL | ±5 | ±10% |
| LDH | ±5 | ±10% |
| ETOH | ±5 | ±10% |
| HbA1C | ±0.5 | ±6% |
| LDLC | ±5 | ±12% |

Source: CLIA, CFR Part 439

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| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 8/3/2025 |

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# L.CHEM 3.22 Verification of Qualitative Cut-off Values



# Policy

**Verification of Qualitative Cut-off Values**

# Principle of Procedure

The cutoff for a qualitative test is the threshold established by the manufacturer above which the result is reported as positive and below which the result is reported as negative. Precision studies for qualitative tests should provide an estimate of the imprecision of the method at analyte concentrations near the cutoff. It is not appropriate to measure the imprecision of a qualitative assay with low-negative or high-positive samples, since these are usually too far away in analyte concentration from the medical decision point. In order to evaluate the precision near the cutoff, test material with analyte concentration near the cutoff is needed.
Manufacturers establish their test cutoff concentrations based upon the intended use of the test and the expected or desired clinical sensitivity and specificity. Once that cutoff has been established by the manufacturer, users often cannot change it. Results below the cutoff will be negative, and results above the cutoff will be positive.

**Verification of the qualitative cut-off values are performed every six months** and should also be performed under the following conditions: (unless the laboratory director has determined that such changes do not affect the cut-off)

1. Whenever major maintenance is performed or a critical component part of an analyzer has been replaced.
2. Whenever reagent lots are completely changed. (unless it has been stated and shown that these lot changes do not affect test results, as with manufacturer's instructions and guidelines in package inserts and analyzer specific manuals)

3. When control values are found to be continually unacceptable, as with shifts and trends in Levy-Jennings graphs over a period of time.

| LIST OF TESTS WITH QUALITATIVE CUT-OFF VALUES | |
|---|---|
| AMPH | AMPHETAMINES |
| OPI | OPIATES |
| COC | COCAINE |
| THC | URINE CANNABINOIDS |
| BARB | BARBITURATES |
| BENZ | BENZODIAZEPINES |
| PCP | PHENCYCLIDINE |

# Procedure

- Prepare two sample dilutions for each of the following tests;

| TEST | CUT OFF VALUE | 1ST DILUTION | 2ND DILUTION |
|---|---|---|---|
| AMPH | 1000 | 1:6 DIL | 1:5 DIL |
| BARB | 200 | 1:5 DIL | 1:4 DIL |
| BENZ | 200 | 1:6 DIL | 1:5 DIL |
| COC | 150 | 1:5 DIL | 1:6 DIL |
| OPI | 300 | 1:30 DIL | 1:20 DIL |
| PCP | 25 | 1:4 DIL | 1:3 DIL |
| THC | 50 | 1:3 DIL | 1:2 DIL |



Use Alere iscreen urine drug screen positive control and do the required dilution for each tests. The target values(ng/mL) for Alere iscreen urine drug screen positive control are as follows;

| ALERE ISCREEN POSITIVE CONTROL | |
|---|---|
| TEST | TARGET VALUES |
| AMPH | 3000 |
| BARB | 900 |
| BENZ | 900 |
| COC | 900 |
| OPI | 6000 |
| PCP | 75 |
| THC | 150 |

The dilution for each tests will ensure results from 20-25% below the cut-off value and 25% or more below the cut-off value and from 20-25% and 25% above the cut-off value or more above and below the

cut-off value. These samples should be prepared in sufficient volume to allow up to 20 or more replicates tests for each dilution on the same sample.

- Test the samples in replicates up to 20 and determine the percentage of positive and negative results for each sample.

| Method being Val | Diagnostic Sensitivity and Specificity (Results from Comparison Method) | | **Total** |
|---|---|---|---|
| | Positive | Negative | |
| Positive | ***# true positive TP*** | ***# false positive FP*** | ***TP+FP*** |
| Negative | ***# false negative FN*** | ***# true negative TN*** | ***FN+TN*** |
| **Total** | ***TP+FN*** | ***FP+TN*** | ***N*** |

- Results should be tabulated on the following table below;
- Diagnostic Sensitivity (True positive rate) = 100 x [TP/(TP+FN)]
  Diagnostic Specificity (True negative rate) = 100 x [TN/(FP+TN)]
  Percent Positive Agreement (Positive Predictive Value) =100 x TP/(TP+FP)
  Percent Negative Agreement (Negative Predictive Value) =100 x TN/(TN+FN)

| **Results** | **Lab Result (%)** | **Expected Result** | **Acceptability** |
|---|---|---|---|
| **Sensitivity=** 100 x [TP/(TP+FN)] | | 100%AMPH/PCP/ BENZCOC/OPI 93%BARB, 96% THC | |
| **Specificity=** 100 x [TN/(FP+TN)] | | 100%AMPH/PCP/BENZ/ COC/OPI 89%BARB, 96%THC | |
| **Positive Agreement (Positive Predictive Value) =**100 x TP/(TP+FP) | | 100%AMPH/PCP/BENZ/ COC/OPI 93%BARB, 96%THC | |
| **Negative Agreement (Negative Predictive Value)=** 100 x TN/(TN+FN) | | 100% BARB/BENZ/COC/ PCPOPI/THC 95%AMPH | |



- An acceptable result should yield 90% or more on positive results at 20-25% sample concentration above the cut-off value and 90% or more on negative results at 20-25% sample concentration below the cut-off value. Sample concentration more than ±25% away from the cut-off should yield consistent both positive and negative results.

# References

1. Department of Health and Human Services, Centers for Medicare AND Medicaid Services. Clinical Laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003 (Jan 24); (42CFR493.1255).

2. Department of Health and Human Services, Centers for Medicare AND Medicaid Services. Clinical Laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003 (Jan 24); (42CFR493.1253).
3. Siemen's Dimension Vista System Operator's guide 2012-01, 6-29-30
4. CLSI. *User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline—Second Edition.* CLSI document EP12-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2008.

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10/3/2025

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 8/3/2025 |

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| Owner | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services |
| Policy Area | Laboratory Services - Chemistry |

# L.CHEM 3.23 Control Range Verification



# Policy

**Control Range Verification**

In order to optimize controls, it is important for clinical laboratories to establish their own mean values and QC ranges for each new control lot number. For unassayed controls, the laboratory must establish a valid acceptable range by repetitive analysis in runs that include previously tested control material. For assayed controls, the laboratory must verify the acceptability ranges supplied by the manufacturer.

# Procedure

## Assayed Controls

For assayed Controls;

1. Collect at least 20 data points from the new QC lot.
2. Calculate the new mean and SD and CV for each chemistry analyte and each control level.
3. The calculated new lot CV must be comparable to the manufacturer's instrument-method CV.
4. Calculate the new control range by using the new mean with the SD determined by the equation (SD = CV /100 X Mean).
5. Compare your method CV (manufacturers) and peer group CV (Biorad QcNet). This data is very helpful in allowing you to judge your instrument's performance on a monthly basis. It is preferred to have your CV less than the peer's CV.

# Unassayed Controls

1. Run parallel testing with the current and new QC material together. Verify that the current QC material is within range. Then run the new QC lot 2 to 3 times throughout the day ideally for a minimum of seven to ten days before the old lot expires. Collect at least 20 data points.
2. Proceed with steps 2-5 on the procedure above (assayed controls).

# References

Chemistry Guideline for Establishing New Control Lot Means and Quality Control Ranges Through Parallel Testing and Historic Coefficient of Variation by Kurt Michael and Paul Richardson

## All Revision Dates

10/3/2025

## Approval Signatures



| Step Description | Approver | Date |
|---|---|---|
| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 8/3/2025 |

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| Last Revised | 10/3/2025 | Policy Area | Laboratory Services - Chemistry |
| Next Review | 10/3/2027 | | |

# L.CHEM 3.24 iPTH Outside Lab Testing



## Policy

**iPTH Outside Lab Testing**

Intraoperative PTH monitoring utilizes one of the rapid immunochemiluminescence assays, which allows for repeated measurements of PTH levels while the patient is in the operating room. The intraoperative PTH assay should be performed as the highest priority stat to avoid delay. Under special circumstances where the test is unavailable in-house due to analyzer breakdown, the lab should follow a special protocol not to delay iPTH result. As such, the test will be send out to CMH (Community Memorial Hospital) for testing.

1. The lab will be notified the day before by Surgery-Nursing supervisor or any designee if any surgery will take place.
2. If the analyzer is down on the day of the surgery, the operating room nurse or designee is notified that the specimen will be sent to CMH for testing.
3. The lab will call CMH Lab to inform them of an incoming iPTH specimen to be run as stat and a Courier should be paged to pick up the specimen. Results should be given verbally and faxed (805-652-6634) to VCMC lab.
4. Results are called to the operating room nurse stating result and time of collection.
5. Results are then entered into Cerner under the patient's accession number. On the PTH accession result entry, freetext "SEE COMMENT" and attached the following details; Performed at CMH Laboratory. Result, unit of measure and reference range
6. The faxed results are kept for data retention. (Chemistry Vista manual patient printout tray)

**CAP LAB GEN.41077 AND GEN.41096**

## All Revision Dates

10/3/2025

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| Step Description | Approver | Date |
|---|---|---|
| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 8/3/2025 |

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# L.CHEM 3.25 Critical Results - Chemistry Department



## Policy

**Critical Results - Chemistry Department**

## Principle

Critical results are test results that represent a life-threatening state to the patient and require rapid communication to the physician or responsible licensed caregiver (limited to Nurse Practitioner, Physicians Assistant, Registered Nurse, or Licensed Vocational Nurse). It is the policy of Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH) to safeguard patients by defining the process of reporting critical results. Critical results are established by the VCMC/ SPH Medical staff and are reviewed every two years and reported to the Performance Improvement Coordinating Council (PICC) quarterly.

All Chemistry critical results should be communicated immediately to the ordering physician or licensed responsible caregiver. Report must be verbally communicated no more than thirty (30) minutes from the availability of critical results.

This policy is derived from **Administrative Policy: 100.030 Critical Test Results** and is designed to fit the work flow of the chemistry department.

## Procedure

The following results have been established as critical results in VCMC chemistry Department by the VCMC Medical staff:

| Test | Low Critical Result | High Critical Result |
|---|---|---|

| | | |
|---|---|---|
| Bilirubin - Newborn | | > 18 mg/dL |
| Calcium | < 6.0 mg/dL | > 13.0 mg/dL |
| Glucose | < 60 mg/dL | > 500 mg/dL |
| Glucose – Newborn | < 40 mg/dL | > 300 mg/dL |
| Lactic Acid | | ≥ 4 |
| Phosphorus | < 1.0 mg/dL | |
| Potassium | < 2.9 mEq/L | > 5.7 mEq/L |
| Sodium | < 128 mEq/L | > 155 mEq/L |
| Magnesium | < 1 mEq/L | > 8 mEq/L |
| Troponin I, high-sensitivity | | Females: ≥120 ng/L<br>Males: ≥120 ng/L |
| Ethanol | | ≥ 400 mg/dL |
| Iron (less than 12 years) | | > 280 mcg/dL |
| Thyroid stimulating hormone (TSH) | | > 50 milli-International units/L |
| Vancomycin trough, if > 1 month age | | ≥ 20 mcg/mL |
| Vancomycin trough, 0-1 month age | | ≥ 15 mcg/mL |
| Lead | | ≥ 3.5 mcg/mL |



# Results

| | |
|---|---|
| 1 | Under Accession Result Entry in Cerner, go to the appropriate result entry mode (i.e. Instrument Queue, Accession, Worklist) for accepting patient test results. |
| 2 | The result would have transmitted from analyzer to patient's accession. If you manually enter result, do not convert result to free text or critical prompt will not appear. |
| 3 | Right click the result and select comment<br>**NOTE:** If there are multiple critical results on the same patient's test, uncheck all results from the test except the critical results. Right click one of the critical results and select Batch comments All selected. |
| 4 | Under result comments the following prompt should be present:<br>"Called to (name): _ Location: _ Time: _ Called results read back to Lab? (Y/N): _"<br>**Note:** If the above prompt is not present, press F2 and under Name, type mnemonic LCALL and select ok. **OR** Tiger text the physician who is in charge of the patient. |
| 5 | Call licensed care giver or physician and fill call prompt ensure there is a "read-back" of the critical results. Record FIRST and LAST name of personnel receiving critical results.<br>* For clinic's (outpatient) results analyzed during off hours (1700 – 0700) page the operator at x7-6075. The operator will contact the on-call clinic physician and report critical result to on-call physician.<br>**NOTE:** Due to CAP regulations, first name alone is NOT sufficient for documenting critical results. |
| 6 | Save and close comment box and verify results. |

# References

Administrative Policy: 100.030 – Critical test Results

CAP Accreditation Program – Chemistry and Toxicology Checklist

**CAP Checklist Requirements**

COM.30000 Critical Result Notification

COM. 30100 Critical Result Read-Back

## All Revision Dates

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## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 8/3/2025 |

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# L.CHEM 3.3 Corrected Calcium Calculation



## Policy

**Corrected Calcium Calculation**

## Principle

A Corrected Calcium is indicated when serum albumin is less than 3.4 gm/dl. This is a calculated value. It is not intended to replace the actual measured Total Calcium, but instead to indicate what the potential Total Calcium would be if the Albumin where greater than 3.4 gm/dl. Corrected Calcium is a calculation hook that is triggered by two tests; Calcium and Albumin.

## Specimen

- Serum or Plasma

## Procedure

Corrected Calcium will reflex to be performed if the Albumin result is less than 3.4 gm/dl for the following panels:

- Comprehensive Metabolic Panel (CMP)
- Renal Panel (RENP)
- Prenatal Nutrition Panel (PNP)
- Neonatal Trans parenteral Nutrition Panel (NTP)

To add a Corrected Calcium to an other

1. Enter CACOR and ALB (if not ordered).
2. Run the Albumin on the Chemistry Analyzer and verify the result. The Corrected Calcium will be automatically calculated.
3. A Corrected Calcium cannot be calculated on Total Calcium results that are less than 5.0 mg/dl. Report as "ND" (Test not performed) and comment that "Corrected Calcium cannot be calculated when Total Calcium is less than 5.0 mg/dl." (Use "LCORCA" in the LIS comment section).

# Calculation

- **((4.2 – Alb) x 0.8) + CA**
- **ALBUMIN RESULT MUST BE LESS THAN 3.4 GM/DL**

## All Revision Dates

10/3/2025

## Approval Signatures



| Step Description | Approver | Date |
|---|---|---|
| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 7/31/2025 |

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# L.CHEM 3.4 HCG (Urine) Qualitative



# Policy

**HCG (Urine) Qualitative**

**INTENDED USE**

The ICON® 25 hCG test (Urine) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

**SUMMARY AND EXPLANATION OF TEST**

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in both urine and serum as early as 7 to 10 days after conception.[1,2,3,4] hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period,[2,3,4] and peaking in the 100,000 – 200,000 mIU/mL range about 10-12 weeks into the pregnancy. The appearance of hCG in both urine and serum soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy.

The ICON® 25 hCG test is a rapid test that qualitatively detects the presence of hCG in urine samples at the sensitivity of 25 mIU/mL. The test utilized a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, the ICON® 25 hCG test shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

# Principle

The ICON® 25 hCG test is a rapid chromatographic immunoassay for the qualitative detection of human

chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The test utilized a combination of antibodies including the monoclonal hCG antibody to selectively detect elevated levels of hCG. The assay is conducted by adding urine sample to the sample well of the test device and observing the formation of colored lines. The sample migrates via capillary action along the membrane to react with the colored conjugate.
Positive samples react with the specific antibody-hCG-colored conjugate to form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

# Sample Collection and Handling

**URINE ASSAY**

- A urine sample must be collected in a clean and dry container. A first morning urine sample is preferred since it generally contains the highest concentration of hCG; however, urine samples collected at any time of the day may be used. Urine samples exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear sample for testing.

**SAMPLE STORAGE**

- Urine samples may be stored at 2 – 8˚ C for up to 48 hours prior to testing. For prolonged storage, samples may be frozen and stored below -20˚ C. Frozen samples should be thawed and mixed before testing.



# Procedure

## Materials

**MATERIALS PROVIDED**

- Test devices – containing anti-hCG particles and anti-hCG coated on the membrane
- Disposable sample droppers
- Zip lock with 2 extra sample droppers
- Product instructions

**MATERIALS REQUIRED BUT NOT PROVIDED**

- Sample collection container
- Timer

# Precautions

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- All samples should be considered potentially hazardous and handled in the same manner as

an infectious agent.

- The test device should be discarded in a proper biohazard container after testing.

# Test Steps

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approximately 100 µL) to the sample well [S] of the test device, and then start the timer. Avoid trapping air bubbles in the sample well [S].
3. Wait for the red line(s) to appear. Read the results at 3 minutes when testing a urine sample. It is important that the background is clear before the result is read.
4. **NOTE:** A low hCG concentration might result in a weak line appearing in the test region [T] after an extended period of time; therefore, do not interpret the result after 3 minutes when testing a urine sample.

Note: This is waived under CLIA-88. The laboratory follows the manufacturer's instruction.
**ALLOW THE TEST DEVICE, URINE SAMPLE, AND/OR CONTROLS TO EQUILIBRATE TO ROOM TEMPERATURE (15 – 30˚ C) PRIOR TO TESTING.**

**STORAGE AND STABILITY:**
Store as packaged in the sealed pouch at 2 – 30˚ C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.



# Quality Control

**Internal procedural controls** are included in the test device.

- A red line appearing in the control region [C] is the internal positive control. It confirms sufficient sample volume and correct procedural technique.
- A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

**An external positive and negative control** shall be run for each kit, new lot, new shipment of kits, and as deemed additionally necessary by the internal quality control procedure:

- Negative Control: BIO-RAD Urine Chemistry Control Level 1
- Positive Control: BIO-RAD Urine Chemistry Control Level 2
- Control results shall be entered in the Laboratory Information System® (LIS/ Cerner).

# Results

## Interpretation of Results

- POSITIVE:Two distinct red lines appear. One line should be in the control region [C] and another line should be in the test region [T].
- NEGATIVE:One red line appears in the control region [C]. No apparent red or pink line appears in the test region [T].
- INVALID:Control line fails to appear. Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact Technical Marketing: (800) 877-6242 or (650) 845-3526.
- NOTE:The intensity of the red color in the test line region [T] will vary depending on the concentration of hCG present in the sample. However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.

## Limitation of Procedure

1. Very diluted urine samples, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine sample should be collected 48 hours later, and retested.
2. False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine sample should be collected 48 hours later and retested.
3. Very low levels of hCG (less than 50 mIU/mL) are present in urine samples shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons[5], a test that is weakly positive should be confirmed by retesting with a first morning urine sample collected 48 hours later.
4. This test reliably detects intact hCG up to 500,000 mIU/mL
5. This test detects intact hCG only. This test does not reliably detect hCG degradation products, including free-beta subunits and beta-core fragment. Therefore, this test may show reduced reactivity in urine after 8 weeks of gestation. This test should not be used to monitor trophoblastic disease or post-partum patients.
6. Quantitative assays used to detect hCG may be detecting hCG degradation products, and therefore may disagree with the results of the ICON® 25 hCG test.
7. A number of conditions other than pregnancy, including trophoblastic neoplasm's including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG[6,7]. Therefore, the presence of hCG in urine samples should not be used to diagnose pregnancy unless these conditions have been ruled out.
8. As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the specimen. Specimens from patients who have received preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA.

Such specimens may cause false positive or false negative results.

9. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be a made by a physician after all clinical and laboratory findings have been evaluated.

# Expected Values

Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine samples. The amount of hCG will vary greatly with gestational age and between individuals.

The ICON® 25 hCG test has a sensitivity of 25 mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

**PERFORMANCE CHARACTERISTICS**

**ACCURACY**

A multi-center clinical evaluation was conducted comparing the results obtained using the ICON® 25 hCG test and another commercially available urine membrane hCG test. The urine study included 159 samples and both tests identified 88 negative and 71 positive results. The results demonstrated a 100% overall agreement (for an accuracy of > 99%) of the ICON® 25 hCG test when compared to the other urine membrane hCG test.

**SENSITIVITY AND SPECIFICITY**

The ICON® 25 hCG tests detects hCG at concentrations of 25 mIU/mL or greater. The test has been standardized to the W.H.O. Third International Standard. The addition of LH (300 mIU/mL, FSH (1,000 mIU/mL), and TSH (1,000 mIU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) samples showed no cross-reactivity.

**INTERFERING SUBSTANCES**

The following potentially interfering substances were added to hCG negative and positive samples:

| | | | |
|---|---|---|---|
| Acetaminophen | 20 mg/mL | Caffeine | 20 mg/mL |
| Acetylsalicylic Acid | 20 mg/mL | Gentisic Acid | 20 mg/mL |
| Ascorbic Acid | 20 mg/mL | Glucose | 2 gm/dL |
| Atropine | 20 mg/mL | Hemoglobin | 1 mg/dL |
| Bilirubin (serum) | 40 mg/dL | Bilirubin (urine) | 2 mg/dL |
| Triglycerides (serum) | 1200 mg/dL | | |

None of the substances at the concentration tested interfered in the test.

# References


1. Batzer FR "Hormonal evaluation of early pregnancy", *Fertil. Steril*. 1980; 34(1): 1-13.
2. Catt KJ, ML Dufau, JL Vaitukaitis "Appearance of hCG in pregnancy plasma following the

initiation of implantation of the blastocyte", *J. Clin Endocrinol. Metab*. 1975; 40(3): 537-540

3. Braunstein GD, J Rasor, H. Danzer, D Adler, ME Wate "Serum human chorionic gonadotropin levels throughout normal pregnancy:, *Am. J. Obstet. Gynecol*. 1976; 126(6): 678-681
4. Lenton EA, LM Neal, R Sulaiman "Plasma concentration of human chorionic gonadotropin from the time of implantation until the second week of pregnancy" *Fertil. Steril*. 1982; 37(6): 773-778
5. Steier JA, P Bergsjo, OL Myking "Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion and removed ectopic pregnancy:, *Obstet. Gynelcol*. 1984; 64(3): 391-394
6. Dawood MY, BB Saxena, R Landesman "Human chorionic gonadotropin and its subunits in hydatidiform mole and chorio-carcinoma", *Obstet. Gynecol*. 1977; 50(2): 172-181
7. Braunstein GD, JL Vaitukaitis, PP Carbone, GT Ross "Ectopic production of human chorionic gonadotropin by neoplasms", *Ann. Intern. Med*. 1973; 78(1): 39-45

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## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 7/31/2025 |

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| Origination | 10/3/2025 | Owner | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services |
| Last Approved | 10/3/2025 | | |
| Effective | 10/3/2025 | | |
| Last Revised | 10/3/2025 | Policy Area | Laboratory Services - Chemistry |
| Next Review | 10/3/2027 | | |

# L.CHEM 3.5 Plasma Ketones



## Policy

**Plasma Ketones**

**Intended Use**
AimTab Ketone tablets are for the semi-quantitative determination of ketones (acetoacetic acid and acetone) in plasma.

**Summary and Explanation**
The presence of ketone bodies is important in the evaluation of carbohydrate metabolism. The test is based on the nitroprusside reaction with ketone bodies to give a purple color.

## Principle

Acetoacetic acid or acetone in blood will form a colored complex with nitroprusside in the presence of glycine. A buffer provides the optimum pH for this reaction.

## Reagents

Each tablet contains sodium nitroprusside, aminoacetic acid, disodium phosphate, sodium borate, lactose and nonreactive binding ingredients.

## Storage and Handling

Store between 15°-30°C. Do not store the bottle in direct sunlight. Once opened, AimTab ketone tablets stability is decreased on exposure to moisture. The bottle must be recapped promptly after removing the tablet. Tablet should be used on a regular basis and not stored for an extended period after the bottle is

opened.

## Warning and Precautions

1. Do not swallow or eat the tablet.
2. Be sure to protect against exposure to light, heat and moisture as this may alter reagent reactivity.
3. Do not use when deterioration is noted by a tan-to-brown or darkening color of the tablet.

# Specimen Collection and Handling

Aimtab Ketone Tablets should be used with fresh specimens. Specimens should remain capped prior to use. If specimens are not run within 30 minutes, refrigerate at 2˚ to 8˚C. Hemolyzed specimens should not be used, as the released hemoglobin will interfere with color interpretation.

# Procedure

## Test Steps



1. Remove tablets needed from the bottle, and recap promptly. Place the tablets on a blood block high absorbance pad.
2. Put one drop of plasma directly on top of the tablet.
3. Compare the color of the tablet to the Color Chart at two (2) minutes after application of the specimen.
4. Interpret and record results in LIS (Cerner).

## Quality Control

- External positive and negative control shall be run on each lot and shipment of Aimtab Ketone Tablets received.
- When a new shipment of reagent tablets is received, check to make sure all boxes are of the same lot number.
- If there's more than 1 lot, controls must be run on each lot.
- The received date, lot number and expiration date and results of the external quality control shall be recorded in LIS.
- A "READY TO USE" sticker shall be placed on each bottle of reagents that have been QC'd.
- At least a positive and negative control must be run with each test run.

# Results

## Interpretation of Results

Results with Aimtab Ketone tablets are recorded as **NEGATIVE** if no purple color is apparent on the tablet

at two (2) minutes. Disregard any pink, tan or yellow color. **POSITIVE** results are recorded as small, moderate or large in comparison with the Color Chart. Results are entered into the Laboratory Information System® (LIS/ Cerner).

**INTERFERING SUBSTANCES**

Improper handling of the product to allow moisture absorption will adversely affect results. False positive results may occur with urine specimens containing bromsulfalein, large amounts phenylketones, levodopa metabolites or other sulfhydryl containing compounds.

# Reference Range

- Ketones are not found in plasma under normal conditions or carbohydrate metabolism.

**PERFORMANCE CHARACTERISTICS**

Aimtab ketone tablets are specific for the detection of acetoacetic acid and acetone. Aimtab ketone tablets are about 10 times more sensitive to acetoacetic acid than acetone and will not react with betahydroxybutyric acid. The lower limit of detection in plasma is approximately 10mg acetoacetic acid per dL.

# References




1. Free, H.M., Smeby, R.R., Cook, M.H and Free, A.H.; A comparative study of qualitative tests for ketones in urine and serum, *Clin. Chem*. 4:323, 1958
2. Riekers, H. and Miale, J.B.: Ketonuria; An evaluation of tests and some clinical implications, *Amer. J. Clin. Path*. 30:530, 1958
3. Levison, S.A. MacFate, J.H.: *Clinical Laboratory Diagnosis*, 7th ed., London, Lea & Febiger, 1969, p. 588
4. Free, A.H. and Free, H.M.: Nature of nitroprusside reactive material in urine in ketosis, *Amer. J. Clin. Path*. 30:7, 1958
5. Henry, JB. Et al.: *Clinical Diagnostic and Management by Laboratory Methods*, 19th Edition Philadelphia: WB Saunders; pp. 241-374, 454, 1996.
6. Csako, G.: False Positive Results for Ketone with the Drug Mesna and other Free Sulfhydryl Compounds. *Clinical Chemistry*: 33/2:289, 1987


## All Revision Dates

10/3/2025

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|

| | | |
|---|---|---|
| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 7/31/2025 |

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| Origination | 10/3/2025 | Owner | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services |
| Last Approved | 10/3/2025 | | |
| Effective | 10/3/2025 | | |
| Last Revised | 10/3/2025 | Policy Area | Laboratory Services - Chemistry |
| Next Review | 10/3/2027 | | |

# L.CHEM 3.6 Neonatal Urine Drug Screen



## Policy

**Neonatal Urine Drug Screen**

## Principle

Neonatal Urine Drug Screens are run on the Siemens Dimension VISTA. This system provides reagents for determining the qualitative presence of Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Opiates, PCP, and THC. These methods provide only a preliminary result. All positive results are sent to the NIDA Laboratory at Quest Laboratories for confirmation by GCMS.

## Specimen Collection and Handling

A minimum of 10 mL of urine is required, which allows for the screening of the above drugs and confirmation of one (1) positive. It is advised that as much urine as possible be collected on the first void, as subsequent voids may produce different results and more than one positive drug requires additional specimen for each confirmation.

## Reagents

Refer to individual assay procedure manuals for detailed information.

**CALIBRATION:**

The Urine Drugs of Abuse assays use a single level multi-analyte calibrator. The calibration results for each assay are normalized to provide a reference value of 1000. See the Dimension VISTA Operator's Manual for details.

**QUALITY CONTROL:**

Positive and Negative Urine Toxicology Controls are run, once each day of use.

# Procedure

## Specimen Collection (Nursing Personnel)

1. A urine drug screen is ordered in Laboratory Information System and the specimen is collected by nursing personnel. Place the specimen in a tamper-proof container labeled with the patient's name, chart number, and date and time of collection.
2. Obtain a security tape, peel off the tape backing and place over the top of the urine container.
3. Complete the Internal Chain of Custody form. Fill out all information in Section 1 & 2. The collector (nursing) must sign Section 3 Part A, on the "Released By" line when the specimen is turned over to transport or to the party delivering the specimen to the laboratory. The collector must also make sure that the person who received the specimen signs the "Received By" line at that time. The Internal Chain of Custody form must accompany the specimen.
4. Deliver the specimen and the Chain of Custody form to the Chemistry Laboratory immediately. Hand the specimen directly to a Clinical Laboratory Scientist. The CLS must then have the person delivering the specimen sign Section 3 Part B on the "Released" by line and the CLS must sign the "Received By" line on the Chain of Custody form.

## Laboratory Specimen Processing (Clinical Laboratory Scientist)

1. Verify that the Urine drug screen has been ordered into the Laboratory Information System. If the specimen has not yet been entered in the computer, contact the unit submitting the specimen, and have them enter it ASAP. Make sure that the specimen has a minimum volume of 10ml to be acceptable and must be in a tape sealed tamper proof container with patient's information, date and time of collection and collector's name. Complete section 4 of the Internal Chain of Custody form.
2. **If the specimen does not meet the criteria for acceptability.** List reasons on form (Sec.4) and call Nursery and notify them of unacceptability. Document name of the person, date and time notified on the form. ***The drug screen can be run as non-medicolegal specimen if ordered or requested by the Nurse or Clinician and report results with a comment not a chain of custody specimen***. Minimum volume for a non-medicolegal urine drug screen is 7ml. If a result is positive, then the specimen must be sent out for GCMS confirmation. ***Use a regular send out requisition instead of chain of custody requisition***.
3. **If the specimen is acceptable** remove the tape seal from the specimen container and removes a 0.5 mL aliquot, centrifuge in a labeled tube and run a drug screen on the Siemens Dimension Vista. See the Vista Operator's Manual for detail on processing specimens on Vista Analyzers.
4. Record patient and QC result. QC must be run once per 24 hours.
5. Complete the Certifying Review Document and if all conditions are met, results may be entered into the Laboratory Information System according to the following options.

**If the drug, screen is NEGATIVE:**

- Enter the results into the computer and verify.
- Attach the Vista result printout, QC result and the Internal Chain of Custody form to the Certifying Review Document.
- Place in the Supervisor's desk for review and documents should be filed in the Neonatal drug screen file.

**If the drug screen is POSITIVE:**

- Enter only the negative drug results into the computer and verify
- Enter: Result "**Preliminary Positive**" and Add comment "**Pending GCMS Confirmation**" for the drug or drugs that were positive.
- Fill out Section 5 on the Internal Chain of Custody form.
- Reseal the specimen with new pre-labeled security tape.
- Order Quest "**SO Misc-GL**"¯ (Sendout Miscellaneous General- lab) in the computer for each drug that tested positive.
- Fill out a Quest Chain of Custody Requisition
- Attach a photocopy of the Internal Chain of Custody form to the Quest Chain of Custody requisition to be sent with specimen to Quest.
- Request GCMS Confirmation for drugs that tested positive on screen and prepare specimen for send out.
- Attach *collector's copy of Quest requisition*, the Vista result printout, QC/Cal printout and the original copy of the Internal Chain of Custody form to the Certifying Review Document and place in the Chemistry Supervisor's desk for review. The documents will be stored and locked for safekeeping.
- When GCMS Confirmation results come back attach a copy to the previous paperwork in the Drug Screen file and complete the appropriate section on the Certifying Review Document for confirmation.
- Enter the final result in the computer: ¯PGC¯ Positive with GCMS CONFIRMATION or LPGC - Found to be Negative after GCMS Confirmation. Remove the Pending confirmation comment originally entered.

# References

Quest - Nichols Clinical Laboratories of Custody Collection-Submission Procedures. Publication

DADC Dimension RXE Operator's Guide. f997. Dade International- al. PN: 7731904.9117

## All Revision Dates

10/3/2025

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 7/31/2025 |

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|---|---|---|---|
| Origination | 10/3/2025 | Owner | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services |
| Last Approved | 10/3/2025 | | |
| Effective | 10/3/2025 | | |
| Last Revised | 10/3/2025 | Policy Area | Laboratory Services - Chemistry |
| Next Review | 10/3/2027 | | |

# L.CHEM 3.7 pH Body Fluids



## Policy

pH Body Fluids

## Principle

pH of body fluids is measured using pH test strips. By using pH 1 – 14 strips a target range can be determined and then selective range strips can be chosen. Pleural fluid pH measurements have been suggested as an aid in diagnosis of esophageal perforation. pH measurements of other fluids is of limited value. Synovial fluid pH measurement may provide a useful but nonspecific index of inflammation.

## Specimen

Body fluids (ie: pleural fluid for esophageal tear, pericardial fluid, ascities, peritoneal, and synovial fluids). There is no procedure for measurement of serum pH. Venous blood pH must be referred to Respiratory Therapy Department.

## Reagents

pH Indicator Strips — pH ranges: 0 — 14 ; 0 - 6: 5.1 — 7.2 ; 2 - 9; 6.0 — 7.7; 7 - 14

pH Buffer Solution: pH of 4.0; 7.0 and 10.0

# Procedure

## Test Steps

1. Using a pH strip (0 — 14 range), dip into fluid to be tested, covering whole area of p11 color square. Keep immersed until color change is stable (approx. 10 sec.). Match color to color chart on pH strip box.
2. Choose appropriate specific pH range strip based on results of step 1.
3. Dip strip into fluid and allow for color change to stabilize and match color to color chart. Record result to nearest $10^{th}$ pH unit.

## Quality Control

**Each pH range strip is tested with a pH buffer that is within the range being used. This is done each day of use. Current buffers and ranges are indicated in LIS (Cerner QC result entry).**

# Results

## Expected Values

Pleural Fluid pH < 6.0 is highly suggestive of esophageal perforation
Synovial Fluid: pH < 7.3 is suggestive evidence of septic or non-septic inflammation.



# References

Clinical Diagnosis and Management by Laboratory Methods, Todd-Sanford, Henry, $17^{th}$ Edition, 1984.

## All Revision Dates

10/3/2025

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |

| | | |
|---|---|---|
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 7/31/2025 |

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| Last Approved | 10/3/2025 | | |
| Effective | 10/3/2025 | | |
| Last Revised | 10/3/2025 | Policy Area | Laboratory Services - Chemistry |
| Next Review | 10/3/2027 | | |

# L.CHEM 3.8 Specimen Aliquoting Procedure



# Policy

**Specimen Aliquoting Procedure**

# Principle

To provide guidance on the proper procedure for preparing specimen aliquots to prevent cross-contamination and specimen mix-ups.

**SPECIMEN COLLECTION:**
Refer to the Phlebotomy Collection Manual for specimen collection procedures.

# Reagents

## Materials needed

1. Patient's specimen, QC material, or calibrators
2. Patient's Laboratory Information System Label
3. Permanent Ink Marker
4. Sample cup or specimen tube

# Procedure

When a patient specimen, QC sample, or calibrator requires aliquoting, the following guideline is set:

**Aliquoting Patient Specimens**

1. Verify that the Laboratory Information System label matches the patient's information on the tube.
2. Obtain the clean sample cup or the empty specimen tube (whichever the technician chooses to use)
    1. If using a sample cup, label the sample cup with any of the small Laboratory Information System labels.
    2. If using a sample tube, any of the Laboratory Information System labels can also be used.
    3. Verify that the information on the sample cups or tubes is the same as the information on the original collection tube. Carefully pour or pipette specimen into the labeled sample cup or tube. Use clean pipette for each specimen aliquoted.
    4. Refer to each analyzer procedure manual for instruction on processing patient specimens in sample cups.

**Aliquoting QC Samples and Calibrators**

1. Using a permanent ink marker, write the level of QC or calibrator on a clean sample cup. Use a clean sample cup for each level of QC or calibrator requiring analysis.
2. Ensure the correct level of QC or calibrator is added to each assigned cup.
3. Refer to each analyzer procedure manual for instruction on processing QC or calibrators.

# References

CAP REFERENCE:
**CHM.12133, CHM.12266**



## All Revision Dates

10/3/2025

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 7/31/2025 |

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| Effective | 10/3/2025 | | |
| Last Revised | 10/3/2025 | Policy Area | Laboratory Services - Chemistry |
| Next Review | 10/3/2027 | | |

# L.CHEM 3.9 Lipemic Specimens



## Policy

**Lipemic Specimens**

## Procedure

Whenever a lipemic specimen is received, run a "Triglyceride" on the sample to determine if ultra-centrifugation is necessary.

- Specimens with a triglyceride value of <600 mg/dL can be analyzed without ultra-centrifuging for all tests on the Siemens Dimension Vista.
- All specimens with a triglyceride ≥ 600 mg/dL must be ultra-centrifuged for all analytes except triglyceride, cholesterol, HDL and LDL.
- DO NOT RUN TRIGLYCERIDES, CHOLESTEROL, HDL OR LDL ON AN ULTRA-CENTRIFUGED SPECIMEN. Instead, run each of these test on an appropriate dilution for the linear range of that test.
- Document a chemistry specimen comment "**That specimen was ultra-centrifuged for testing**".
- If there is no adequate sample to ultra-centrifuge, then add the comment "Results questionable due to lipemia". For glucose, phosphorus or magnesium, use the appropriate comment as indicated on the "KNOWN INTERFERING SUBSTANCES" chart.
- If it is not possible to obtain an accurate or reliable result (i.e. result has an error code or is below the analytical measurement range on dilution) then do not report the result. Enter a "ND" (not done) and enter the comment "Unable to analyze due to marked lipemia".

## All Revision Dates

10/3/2025

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Hospital Administration | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 10/3/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |
| Laboratory Services Department | Yewubdar Argaw: Supervisor-Chemistry, Laboratory Services | 7/31/2025 |

# VENTURA COUNTY MEDICAL CENTER

*Property of the Medical Staff, Privileged and Sensitive Information*

**CONFIDENTIAL**

## Medical Executive Committee Document Approvals

December 2025

**a. Policies & Procedures / Clinical Practice Guidelines / Forms / Orders**



**b. Medical Staff Forms**

VENTURA COUNTY HEALTH CARE AGENCY

| | |
|---|---|
| **Origination:** | *10/1/1986* |
| **Effective:** | *Upon Approval* |
| **Last Approved:** | *N/A* |
| **Last Revised:** | *1/27/2020* |
| **Next Review:** | *3 years after approval* |
| **Owner:** | *Danielle Gabele: Chief Nursing Executive, VCMC & SPH* |
| **Policy Area:** | *Administrative - Patient Care* |
| **References:** | |

# 100.066 Ambulatory Care Clinic Referral Procedure

## POLICY:

To assist staff when helping patients who are being discharged from Ventura County Medical Center (VCMC)/Santa Paula Hospital (SPH) and are referred to an outpatient clinic, and to improve the management of patients through the clinic system.

## PROCEDURE:

1. Inpatients being discharged from VCMC/SPH with orders to return to an Ambulatory Care clinic will be given a specific appointment time with the clinic indicated on their discharge instructions. The inpatient medical office assistant (MOA) or designee shall call the clinic to schedule the appointment prior to giving the discharge instructions to patient. For appointments needed after clinic hours, the inpatient MOA or designee shall instruct the patient to call the appropriate number the following day. The inpatient staff then documents those instructions on the patient's discharge instruction sheet. Appointments with specific satellite clinics are made by calling that clinic.
2. When the discharging physician feels that laboratory procedures will be helpful to the outpatient clinic physician at the time of the patient's return to the clinic, these procedures will be ordered and recorded in the chart, and the necessary order entered in the electronic health record (EHR). The patient will be instructed to report to the Laboratory for testing prior to their clinic appointment as appropriate whenever possible. Results of the tests will be given to the patient by the physician at the time of his/her clinic appointment. If x-rays are requested, an x-ray order will be entered in the EHR. The patient will be given a Radiology appointment for the work ordered. Patients requiring special laboratory tests (chemistries, gastric contents, etc.) may need a specific appointment date and time. The Laboratory will be contacted to obtain this information.
3. The outpatient clinic will make every attempt to adhere to the appointment schedule as closely as possible. Patients will be informed that they are to call the clinic and cancel their appointment if they are unable to attend on the assigned day. This information will also be included on the appointment slip given to the patient.
4. Informational fact sheets are available in all areas of the hospital in both English and Spanish for distribution to patients utilizing outpatient clinics.
5. Patients seen in the Emergency Department and then referred to a clinic are instructed to call the

appropriate clinic number the following day.

All revision dates: 1/27/2020, 1/1/2017, 5/1/2006, 2/1/1995, 11/1/1989

## Attachments

No Attachments

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Medical Executive Committee | Stephanie Denson: Manager, Medical Staff Office | pending |
| Hospital Administration | Osahon Ekhaese: Chief Operating Officer, VCMC & SPH | 11/20/2025 |
| Hospital Administration | Minako Watabe: Chief Medical Officer, VCMC & SPH | 11/5/2025 |
| Nursing Administration | Sherri Block: Associate Chief Nursing Executive, VCMC & SPH | 10/28/2025 |
| Nursing Administration | Danielle Gabele: Chief Nursing Executive, VCMC & SPH | 10/28/2025 |
| Policy Owner | Danielle Gabele: Chief Nursing Executive, VCMC & SPH | 10/28/2025 |

VENTURA COUNTY
HEALTH CARE AGENCY

| | |
|---|---|
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| **Last Revised:** | *1/10/2023* |
| **Next Review:** | *3 years after approval* |
| **Owner:** | *Minako Watabe: Chief Medical Officer, VCMC & SPH* |
| **Policy Area:** | *Administrative - Patient Care* |
| **References:** | |

# 100.068 Medical Examination and Transfer from Ventura County Medical Center/Santa Paula Hospital

## POLICY:

The Emergency Medical Treatment and Labor Act (EMTALA) was enacted by Congress to regulate and restrict the transfer, for economic or other non-medical reasons, all patients presenting for emergency services. The primary focus of EMTALA is to ensure access for all patients to emergency services and prohibiting discrimination in the provision of emergency services. A Medical Screening Examination (MSE) conducted by a physician or Qualified Medical Person (QMP) will be provided to all patients presenting to the Emergency Department at Ventura County Medical Center (VCMC)/Santa Paula Hospital.

## PROCEDURE:

A. An MSE will be offered to any individual presenting for examination or treatment of a medical condition. The examination will be the same appropriate screening examination that would be performed on any individual with similar signs and symptoms, regardless of the individual's ability to pay for medical care.

B. The MSE or necessary stabilizing treatment shall not be delayed in order to inquire about an individual's method of payment or insurance status. Prior authorizations will not be requested for emergency services until the MSE has been conducted.

C. The hospital will not transfer any patient with an unstabilized emergency condition (includes a pregnant patient having contractions or a patient with severe pain) unless a physician certifies that the medical benefits reasonably expected from the provision of treatment at the receiving facility outweigh the risks of the transfer.

   1. Prior to the transfer, the receiving Hospital and physician have agreed to accept the patient and to provide appropriate medical treatment;

   2. The Hospital shall send to the receiving facility all medical records (or copies thereof) available at the time of transfer related to the emergency condition of the patient, including:

      a. Records related to the patient's emergency condition, observations of signs or symptoms, preliminary diagnosis, treatment provided, results of any tests and vital signs at the time of transfer. Other records (including pending test results or records not available at the time of transfer) must be forwarded as soon as practicable after the transfer.

b. The patient's informed written consent to transfer or the physician's certification (or copy thereof); and

c. The name and address of any on-call physician who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment.

3. The transfer is effected using proper personnel and equipment, as well as necessary and medically appropriate life support measures.

If a patient who has or may have an emergency medical condition is transferred to another facility for a test with the intention of the patient returning to the Hospital after the test, the Hospital will transfer in accordance with EMTALA standards.

## PATIENT REFUSAL OF EMERGENCY SERVICES OR TRANSFER

A. Under EMTALA, the patient retains the right to refuse necessary stabilizing treatment and further medical examination, as well as a transfer to another facility.

B. If a patient leaves the hospital before receiving a MSE, either with or without notice to staff, staff should document the circumstances and reasons (if known) for the patient's departure and the time of departure.

C. If a patient refuses stabilizing treatment after receiving a MSE, the physician or QMP at VCMC/SPH will offer examination and treatment, and inform the patient of the risks and benefits of the examination and treatment and request that the patient sign an *Against Medical Advice* form that he/she has refused further treatment. A summary of the risks of not receiving treatment as described to the patient shall be documented in the medical record.

## SIGNAGE

Signs will be posted in lobbies and other appropriate locations where patients may be waiting for treatment or where examination may occur. The signage specifies the rights of individuals to examination and treatment for emergency medical conditions and to indicate participation in the Medi-Cal program. The signs will also state the name, address and telephone for the State Department of Health Services. The signs will be posted in English and Spanish and posted in the Emergency Department and Labor and Delivery.

## DOCUMENTATION LOG

Each location that provides MSE's will maintain a central log recording the name of the person who presents for emergency services and whether the person refused treatment, was refused treatment or whether the patient was transferred, admitted and treated, stabilized and transferred or discharged.

## ON-CALL RESPONSE

There is a list of on-call physicians maintained in the Emergency Department. These physicians are to provide consultation or treatment necessary to stabilize a patient with an emergency medical condition (see Administrative policy 100.107, *On-Call Coverage*).

## MAINTENANCE OF RECORDS

Transfer logs, on-call lists and changes to the on-call list and central logs shall be maintained for five years.

## DISPUTES

In the event of any concern over emergency services to a patient, or a dispute with another hospital regarding a patient transfer or a concern about VCMC/SPH's compliance with EMTALA, the Hospital Administrator on duty and the Medical Director are to be notified immediately.

## REPORTING

VCMC/SPH will report to HCFA or State Licensing within 72 hours if it concludes that it has received an individual who has been transferred in an unstable emergency condition from another hospital. All hospital staff who believe an EMTALA violation has occurred shall report the violation to the Hospital Administrator on duty and Medical Director.

The hospital shall not retaliate, penalize or take adverse action against any Medical Staff member or employee for reporting violations of EMTALA or State laws to the proper authorities.

## DEFINITIONS

**Emergency Medical Condition**

- A medical condition manifesting itself by acute symptoms of sufficient severity such that the absence of immediate medical attention could reasonably be expected to result in either placing the health of the individual in serious jeopardy, serious impairment of bodily functions, or serious dysfunction of any bodily organ or part; or
- With respect to a pregnant woman who is having contractions, there is inadequate time to effect a safe transfer to another hospital before the delivery or the transfer may pose a threat to the health or safety of the woman or her unborn child.

**Medical Screening Exam (MSE)**
An MSE is the process required to reach, within reasonable clinical confidence, the point at which it can be determined whether the individual has an emergency medical condition (EMC) or not. An appropriate MSE is dependent on the presenting signs and symptoms and may involve a wide spectrum of actions ranging from a simple process involving only a brief history and examination of the presenting symptoms to a complex process that includes ancillary studies and procedures. Medical includes both physiological and psychological symptoms.

Qualified Medical Person (QMP)
A Qualified Medical Person is a physician, nurse practitioner, physician assistant, and a specialty trained nurse, such as an obstetrics nurse, who performs the examination and communicates the findings to an attending physician to determine if an EMC exists.

**Transfer** is defined as the movement of an individual outside of a hospital's facility at the direction of any person employed by the hospital, but does not include such movement of an individual who has been declared dead or leaves the facility without permission of any such person.

**Labor** is defined as the process of childbirth beginning with the latent or early phase of labor and continuing through delivery of the placenta. A woman is in true labor unless the physician certifies that after a reasonable time of observation the woman is in false labor.

**Stabilization** is defined as follows:

**Labor and delivery patients.** Stabilization is defined as delivery of the child and the placenta. A woman

having contractions "may not be transferred unless she, or a legally responsible person acting on her behalf, request a transfer or if a physician or other qualified medical personnel, in consultation with a physician, certifies that the benefits to the condition of the woman and/or unborn child out weigh the risks associated with the transfer."

**Medical patients.** Stabilization is defined as no material deterioration of the condition is likely, within reasonable medical probability, to result for or occur during transfer. A patient is deemed stabilized if the treating physician has determined, within reasonable clinical confidence, that the emergency medical condition has been resolved.

**Capacity** refers to the ability of the hospital to accommodate the individual requesting examination or treatment of a transfer patient. Capacity encompasses adequacy of staff, beds, equipment and past practices in accommodating additional patients beyond occupancy limits.

## Psychiatric Patients

**Stable for transfer.** A psychiatric patient is considered "stable for transfer" if the patient has been assessed by the treating physician and determined to have no underlying organic basis for the presenting psychiatric symptoms, initial treatment has been provided as indicated, the patient has been treated sufficiently so that he/she is stable for transfer.

**Stable for discharge.** A psychiatric patient is considered "stable for discharge" if the patient is no longer considered to be a threat to himself/herself or others.

All revision dates: 1/10/2023, 9/1/2015, 5/1/2006, 4/1/2000

## Attachments

No Attachments

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Medical Executive Committee | Stephanie Denson: Manager, Medical Staff Office | pending |
| Hospital Administration | Minako Watabe: Chief Medical Officer, VCMC & SPH | 11/24/2025 |
| Hospital Administration | Osahon Ekhaese: Chief Operating Officer, VCMC & SPH | 11/20/2025 |
| Nursing Administration | Sherri Block: Associate Chief Nursing Executive, VCMC & SPH | 11/6/2025 |
| Nursing Administration | Danielle Gabele: Chief Nursing Executive, VCMC & SPH | 11/5/2025 |
| Policy Owner | Minako Watabe: Chief Medical Officer, VCMC & SPH | 11/5/2025 |

**Current Status:** *Pending* **PolicyStat ID:** *15076548*

VENTURA COUNTY HEALTH CARE AGENCY

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| **Next Review:** | *3 years after approval* |
| **Owner:** | *Jason Arimura: Associate Hospital Administrator, VCMC & SPH* |
| **Policy Area:** | *Administrative - Patient Care* |
| **References:** | |

# 100.228 Chain of Command

# POLICY:

To ensure that patients are provided safe ~~and~~, high quality care in a timely manner. Ventura County Medical Center (VCMC), Santa Paula Hospital (SPH) and ~~Ambulatory Care clinics~~Inpatient Psychiatric Unit (IPU) are committed to providing safe, high quality patient care. Members of the health care team are obligated to work toward resolution of identified real and potential problems within the health care system, that may affect patient care. If the member is unable to resolve such issues independently, the team member is obligated to present the issue in a timely manner to successively higher levels of command, until a satisfactory resolution is achieved.

"Chain of Command" in health care, refers to an authoritative structure, established to resolve administrative, clinical, or other patient safety issues by allowing health care clinicians to present an issue of concern through the lines of authority, up to and including, the highest levels of decision making, until a resolution is reached.

# PROCEDURE:

## Immediate Patient Care Clinical Concern:

1. Any member of the health care team who observes potentially unsafe/sub-optimal care or a failure of a health care provider to respond, shall first report the situation to the Charge Nurse/~~Area~~Department Manager and/or House Supervisor.
    a. If there is a potential immediate threat to the wellbeing of a patient, contact shall be made to the physician primarily responsible for care of the patient.
    b. If contact cannot be made, or resolution of the concern cannot be achieved, contact shall be made to the Administrator on Duty (AOD).
    c. If unable to contact the AOD, contact the Chief Medical ~~Director~~ Officer.
2. The AOD, together with the Chief Medical ~~Director~~Officer or Chief of the Medical Staff, may call in another physician as they determine necessary, to evaluate and treat the patient.
    a. The AOD, Chief Medical ~~Director~~Officer, Chief of the Medical Staff, shall inform the practitioner if care is being transferred to another practitioner, or the other practitioner is being brought in to consult/advise.

## Non-Immediate Patient Care Concerns:

Concerns regarding treatment, communication, or responsiveness, which do not pose an immediate safety concern, are handled in a similar chain of command process, but with extended time frames for resolution (concerned staff member ==> Charge Nurse/Nursing Supervisor/Area Supervisor ==> Department Manager/Director ==> Associate Chief Nursing ~~Supervisor ==>~~Officer/Chief Nurse Executive and/or Associate ~~Chief Nursing Officer/Chief Nursing Officer and/or a Chief of~~ Hospital ~~Operations (CHO)~~Administrator ==> Chief Medical Officer (CMO) and/or Chief Operating Officer (COO) ==> Chief Executive Officer (CEO)).

Each immediate supervisor shall attempt to resolve the issue or report it to the next level of authority.

## Documentation:

Medical record documentation must be factual and objective, and must not express personal staff opinions or comments. Documentation shall include the care that was provided to the patient, as well as the interactions taken on the patient's behalf.

All revision dates: 11/5/2025, 3/9/2021, 3/21/2019

## Attachments

- Attachment A - Chain of Command
- Attachment B - Chain of Command for Upgraded Patient Needing Higher Level of Care Bed

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Medical Executive Committee | Stephanie Denson: Manager, Medical Staff Office | pending |
| Hospital Administration | Minako Watabe: Chief Medical Officer, VCMC & SPH | 11/24/2025 |
| Hospital Administration | Osahon Ekhaese: Chief Operating Officer, VCMC & SPH | 11/21/2025 |
| Nursing Administration | Danielle Gabele: Chief Nursing Executive, VCMC & SPH | 11/5/2025 |
| Nursing Administration | Sherri Block: Associate Chief Nursing Executive, VCMC & SPH | 11/5/2025 |
| Policy Owner | Jason Arimura: Associate Hospital Administrator, VCMC & SPH | 11/5/2025 |

VENTURA COUNTY HEALTH CARE AGENCY

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| **Owner:** | *Kristina Swaim: Nurse Director, Maternal Child Health* |
| **Policy Area:** | *Administrative - Patient Care* |
| **References:** | |

# 100.265 Epidural Analgesia

## POLICY:

Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH) provides safe and effective administration and management of epidural analgesia. The scope of this policy and procedure is to outline the patient care and management of inpatients who receive epidural analgesia for labor pain and surgical procedures.

## OVERVIEW:

A. The Department of Anesthesia is the primary service responsible for assessment and management of all epidural drug administration

B. An epidural catheter may be inserted/initiated in the Operating Room (OR), Post Anesthesia Care Unit (PACU), Interventional Radiology (IR), Intensive Care Unit (ICU), and Labor and Delivery.

C. For Obstetrics (OB) patients, epidural anesthesia should not be administered until a baseline maternal-fetal assessment, physical exam, and progress of labor are evaluated by the Licensed ~~Independent~~ Practitioner (~~LIP~~LP) on duty for OB.

D. For guidance on the timing between anticoagulant and epidural insertion/removal, see CPG.46 Anticoagulation Management Surrounding Epidural-Intrathecal-Lumbar Puncture

E. Nursing shall provide nursing care consistent with the guidelines and procedures outlined in this policy. See Lippincott's for detailed process.

1. Assessment, evaluation, and documentation of the patient's baseline vital signs which include patient's level of pain, level of consciousness, motor/sensory function, effectiveness of epidural analgesia, and any untoward effects related to epidural analgesia. See policy 100.076 Pain Assessment, Management, and Documentation.
2. Maintenance of the epidural catheter and tubing used for continuous infusion.
3. Assessment of the epidural catheter site and dressing every shift.
4. Contacting Anesthesia Service for assessment and evaluation of the patient as needed

F. Controlled substance waste must be documented as per policy PH.88 Controlled Substances

# PROCEDURE:

## Equipment

A. Epidural Pump Set-Up
   1. ICU Medical Sapphire Patient Controlled Epidural Analgesia (PCEA) Pump
   2. Dedicated lock box with yellow label "Epidural Only"
   3. Dedicated yellow, portless epidural tubing

B. Epidural kit

C. Monitoring equipment for continuous vital signs and oxygen saturation of peripheral capillaries (SpO2) monitoring

D. Emergency supplies
   1. Crash Cart
   2. Epidural Cart (OB only)
   3. Oxygen and suction set up

E. Epidural medication bag with yellow label "Epidural Only"
   1. Bupivacaine
   2. Remifentanil

## Roles and Responsibilities

### Licensed ~~Independent~~ Practitioner (~~LIP~~LP)

A. The ~~LIP~~LP shall consult with the patient, explain the procedure prior to initiation, and document the patient's approval.
   1. For OB patients the ~~LIP~~LP shall also determine the woman's knowledge, desires and concerns about methods of labor pain management. Education about analgesia and anesthesia techniques and effects, acknowledging and respecting individual and socio-cultural preferences
   2. For OB patients, the ~~LIP~~LP shall assess patients for appropriateness in using a PCEA. The patient must be able to comprehend instructions, be willing to self-dose, and be assessed according to patient specific monitoring and assessment criteria.

B. The ~~LIP~~LP shall make certain there are no contraindications to the procedure including platelet count, previous spinal surgery, etc.

C. The ~~LIP~~LP shall communicate with the nurse regarding the need for the epidural.

D. The ~~LIP~~LP shall initiate epidural orders using the appropriate, approved Epidural PowerPlan

E. The following orders may be entered by the ~~LIP~~LP, under Anesthesia supervision:
   1. Changes to the standard starting continuous infusion rate
   2. Changes to the PCEA dosing parameters
   3. Single re-bolus injection from a vial.

F. Upon cessation of therapy, the ~~LIP~~LP must discontinue all orders from the electronic health record (EHR).

## Anesthesiologist

A. Anesthesia will monitor and maintain a sterile, patent epidural catheter in a tamper-free environment, to administer continuous analgesia for the relief of labor or surgical pain, and to decrease the incidence of central nervous system depression and pulmonary complications.

B. Anesthesia will place the epidural catheter, administer the initial injection, connect the tubing to the epidural catheter connector, and initiate the continuous infusion.

   1. Additional re-boluses from the vial may be administered by the ~~LIP~~LP.
   2. **Exception:** Registered Nurses in Labor and Delivery (LD) and Intensive Care Unit (ICU) may connect the epidural tubing to the epidural catheter.

C. Anesthesia will evaluate the catheter placement including re-evaluation of potential catheter mis-positioning with bolus test doses of local anesthetic.

D. Anesthesia will assess the duration of time the catheter will remain in place and the duration of the epidural therapy.

## Nurse (RN)

A. Registered Nurses who have performed a one-time competency are able to set-up, ,connect tubing to catheter, administer medication, and monitor epidural pumps.

B. After informed consent is given by the ~~LIP~~LP, Nursing will obtain patient signature on the consent forms, assess and reinforce patient knowledge about procedure, and answer any questions or appropriately refer them to the Anesthesiologist.

C. Set Up

   1. The RN shall ensure the patient has IV access and administer IV fluid preload as ordered.
   2. The RN shall gather the necessary equipment and supplies prior to anesthesiologist's arrival.
   3. The RN shall place patient on continuous vital sign, SpO2 and if indicated, a fetal monitor.
      a. Continuous Fetal Heart Rate (FHR) monitoring should be maintained to the best of RN's ability during catheter placement. If there is concern regarding the status of the fetus, consideration should be given to placement of fetal scalp electrode for monitoring. If the FHR has not been assessed for >15 minutes, the provider should pause to allow the RN to assess the FHR and then proceed with catheter placement.
   4. The RN shall assist the Anesthesiologist to clear visitors including support person from room.
   5. The RN shall assist the patient and Anesthesiologist with positioning patient for catheter insertion.

D. Administration

   1. The initial double check is completed with anesthesia as Anesthesiologists are initiating the initial infusion or setting as ordered. **Exception: two RN double check is permitted for certain patient areas(Labor and Delivery and adult Intensive Care Unit)**
   2. Once the epidural infusion has been established by Anesthesia, the RN has the following pump privileges:
      a. Stop and/or continue the epidural infusion
      b. Prime the pump, hang a new bag, and continue the epidural infusion at the previous ordered setting.

c. Ordered rate change -- not to exceed 4 mL/hr per rate change.

3. Nursing shall perform an Independent Double Check with required witness cosign in the EHR for epidural medications following rate and bag changes. See policy PH.70 High Alert Medications.

E. PCEA Education (OB patients only)

1. The RN shall educate the patient on the proper use of the patient controlled bolus handle and the safety measures with the use of the PCEA including hourly limits and lockout time.
2. The RN shall instruct the patient and family members that "PCEA by proxy" is not allowed.
3. The RN should encourage the patient to use the bolus handle for breakthrough pain
4. The RN should inform the patient it usually takes 10-15 minutes before the full effect of the demand dose is reached.
5. The RN shall document the education to the patient and family in the EHR.
6. If the patient controlled boluses do not bring adequate pain relief, the anesthesia service should be notified for evaluation and troubleshooting.

F. Monitoring and Documentation

1. Nursing should follow the following monitoring guidelines:

| Prior to Epidural Placement | | |
|---|---|---|
| **Unit** | **Monitoring Parameter** | **Frequency** |
| OB | Vital signs, SP02 | Baseline or as ordered |
| | Fetal monitoring | Continuous or as ordered |
| ICU/DOU | Vital signs, pain, respiratory rate (RR) | Baseline |
| | Level of sensation (Dermatome) | Baseline |
| | Continuous ETCO2 if ordered | As ordered |

| Immediately BEFORE/AFTER Epidural Placement by Anesthesia | | |
|---|---|---|
| **Unit** | **Monitoring Parameter** | **Frequency** |
| OB | BP, HR, Sp02 | Test dose (before and after)<br>Insertion: every 15 minutes x 1 hour |
| ICU/DOU | BP, HR, Sp02 | Test dose (before and after)<br>Insertion: every 15 minutes x 1 hour |
| | Pain, sedation, RR, level of sensation (Dermatome) | Test dose (before and after)<br>Insertion: every 15 minutes x 1 hour |
| | Continuous ETCO2 if ordered | As ordered |

| Following Initiation and after each LIP bolus | | |
|---|---|---|
| **Unit** | **Monitoring Parameter** | **Frequency** |
| OB | BP | Every (Q) 5 minutes throughout the administration of anesthetic dose, then every 15 minutes x 2, then every 60 minutes until epidural discontinued unless otherwise indicated |
| | Fetal Monitoring | Continuous per policy OB.45 OB management of fetal heart rate tracing |
| | RR, SP02 | Q1h until epidural is discontinued. |
| | Level of sensation (Dermatome) | Q1-2 hours, as ordered |
| | Pain | Q1 hour |
| | PCEA – total amount received | Q shift |
| | Line status and dressing every shift | Q shift and PRN and when assuming care |
| ICU/DOU | BP | Q1 hour x 4 hours, then every 2 hours while on the epidural |
| | RR, ETCO2, SP02 | Q1 hour x 12 hours, then Q2 hours x 12 hours, then Q4h until epidural is discontinued. |
| | Level of sensation (Dermatome) | Q1-2 hours, as ordered |
| | Pain | Q1 hour |
| | PCEA – total amount received | Q shift |
| | Line status and dressing every shift | Q shift and PRN and when assuming care |

| After discontinuation of Epidural Catheter by Approved Clinician | | |
|---|---|---|
| OB and ICU/DOU | Level of sensation (Dermatome) | Every 4 hrs X 24 hours |
| | Post-removal site | Every 4 hours x 24 hours |
| Abbreviation key: Obstetrics (OB), oxygen saturation (SpO2), Intensive care unit (ICU), direct observation unit (DOU), Respiratory Rate (RR), End-tidal carbon dioxide (ETCO2), Blood Pressure (BP), Heart Rate (HR), Patient Controlled Epidural Analgesia (PCEA), As needed (PRN) | | |

| Prior to Epidural Placement | | |
|---|---|---|
| **Unit** | **Monitoring Parameter** | **Frequency** |
| OB | Vital signs, SP02 | Baseline or as ordered |
| | Fetal monitoring | Continuous or as ordered |
| ICU/DOU | Vital signs, pain, respiratory rate (RR) | Baseline |
| | Level of sensation (Dermatome) | Baseline |
| | Continuous ETCO2 if ordered | As ordered |

| Immediately BEFORE/AFTER Epidural Placement by Anesthesia | | |
|---|---|---|
| **Unit** | **Monitoring Parameter** | **Frequency** |
| OB | BP, HR, Sp02 | Test dose (before and after)<br>Insertion: every 15 minutes x 1 hour |
| ICU/DOU | BP, HR, Sp02 | Test dose (before and after)<br>Insertion: every 15 minutes x 1 hour |
| | Pain, sedation, RR, level of sensation (Dermatome) | Test dose (before and after)<br>Insertion: every 15 minutes x 1 hour |
| | Continuous ETCO2 if ordered | As ordered |

| Following Initiation and after each LIP bolus | | |
|---|---|---|
| **Unit** | **Monitoring Parameter** | **Frequency** |
| OB | BP | Every (Q) 5 minutes throughout the administration of anesthetic dose, then every 15 minutes x 2, then every 60 minutes until epidural discontinued unless otherwise indicated |
| | Fetal Monitoring | Continuous per policy OB.45 OB management of fetal heart rate tracing |
| | RR, SP02 | Q1h until epidural is discontinued. |
| | Level of sensation (Dermatome) | Q1-2 hours, as ordered |
| | Pain | Q1 hour |
| | PCEA – total amount received | Q shift |
| | Line status and dressing every shift | Q shift and PRN and when assuming care |
| ICU/DOU | BP | Q1 hour x 4 hours, then every 2 hours while on the epidural |
| | RR, ETCO2, SP02 | Q1 hour x 12 hours, then Q2 hours x 12 hours, then Q4h until epidural is discontinued. |
| | Level of sensation (Dermatome) | Q1-2 hours, as ordered |
| | Pain | Q1 hour |
| | PCEA – total amount received | Q shift |
| | Line status and dressing every shift | Q shift and PRN and when assuming care |

| After discontinuation of Epidural Catheter by Approved Clinician | | |
|---|---|---|
| OB and ICU/DOU | Level of sensation (Dermatome) | Every 4 hrs X 24 hours |
| | Post-removal site | Every 4 hours x 24 hours |
| Abbreviation key: Obstetrics (OB), oxygen saturation (SpO2), Intensive care unit (ICU), direct observation unit (DOU), Respiratory Rate (RR), End-tidal carbon dioxide (ETCO2), Blood Pressure (BP), Heart Rate (HR), Patient Controlled Epidural Analgesia (PCEA), As needed (PRN) | | |

2. Documentation in the Electronic health record
    a. Vital signs
    b. Level of sensation (every 1-2 hours as ordered)

c. Pain scale assessment (every hour and PRN)
d. Any interventions associated with assessments
e. Rate and Bag changes with independent double check
f. Total amount received from PCEA each shift
g. Condition of dressing
h. Notation of discontinuation of epidural catheter, date, time, by whom, condition of catheter
i. Wasted medication in Pyxis requires two nurse visual verification
j. Document epidural medication in EHR

3. For OB patients, see Maternal and Fetal Monitoring and Management for additional information.

G. Dressing Change

1. There is no need for regular dressing changes.
2. Secure catheter with tape or plastic dressing the entire length, to one side of the spine and secure connector to patient's gown and shoulder or neck.
3. If dressing is compromised (e.g., pad is gone or wet), call ~~LIP~~LP.

H. Discontinuing the Catheter

1. Epidural catheter may be removed or discontinued by a ~~LIP~~LP or OB RN who has met competency. The epidural catheter should be removed prior to transfer to another unit, unless there is a ~~LIP~~LP's order to state otherwise.
2. A patient who has been receiving anticoagulant therapy of any type while the epidural has been in place will require consultation with the anesthesiologist before removing (see CPG.46 Anticoagulation Management Surrounding Epidural-Intrathecal-Lumbar Puncture).
3. Removal of the epidural catheter will take place when the patient is stable, comfortable, and the infusion is no longer required. For OB patients, epidural catheters should be discontinued after delivery unless otherwise ordered.
4. Explain procedure to patient.
5. Position patient on their side, with their back rounded.
6. Remove tape, pulling in a downward motion.
7. If any resistance other than gentle pressure, stop and notify physician.
8. Assess skin site for redness, edema or discharge,
9. Cover site with a band-aid to the epidural site if needed.
10. Inspect catheter tip for intactness once removed, document in EHR that catheter tip is intact. If the catheter tip is not intact notify the anesthesia team ***immediately.***

# Maternal and Fetal Monitoring and Management

A. **Maternal and Fetal Maintenance**

1. Responses to initial catheter dosing or during the perianesthesia period may include hypotension, alterations in fetal heart rate (FHR), signs of Intravenous (IV) injection of local anesthetic and pruritus. Nursing assessment and interventions include but are not limited to:

2. Monitoring maternal vital signs, SpO2, and FHR patterns as directed by ~~LIP~~LP based on consideration of factors such as the type of anesthesia, route and dose of medication, the maternal-fetal response to medication, maternal-fetal condition and the stage of labor.
3. Facilitate lateral or upright maternal position with uterine displacement to minimize hypotension.
4. Patients will receive continuous fetal monitoring for at least one hour following initiation of epidural anesthesia and ongoing fetal monitoring should be performed in accordance to policy OB.45 Ob Management of Fetal Heart Rate Tracing
5. Managing hypotension or non-reassuring FHR patterns, which may include notifying the anesthesia or OB care provider or both, repositioning the patient, administering IV fluid bolus, oxygen or medications as needed and ordered.
6. Monitoring for signs of IV injection of local anesthetic, which may include FHR alterations, hypertension, dizziness, tinnitus, metallic taste in mouth, maternal dysrhythmia and loss of consciousness.
7. Notify anesthesiologist immediately if patient complains of numbness in upper extremities or shows difficulty in breathing. If this occurs, discontinue the infusion by turning off the pump.
8. Managing IV injection of local anesthetic, including initiation of emergency procedures if necessary and notifying the anesthesia or OB care provider or both.
9. Monitoring for pruritus that may occur initially or persist after medication administration; administering medication as ordered for severe or unresolved itching.

B. **Pain and Motor Blockade Assessment**

1. Evaluate maternal pain and comfort levels using pain assessment tools.
2. The dermatome level (level of sensation) should be monitored every hour by using ice or an alcohol swab to stroke the skin comparing areas of normal sensation with areas of block. Start on one thigh and work upward to determine upper boundary and repeat on the other side. (Refer to Attachment A for dermatome levels). If dermatome level is higher than T4, stop infusion and notify anesthesiologist. The goal is to maintain patients comfort with a dermatome level no more than T4.
3. NEVER administer narcotics, sedatives or anticoagulants without first discussing with and getting an order from the Anesthesiologist.
4. Urinary retention should be anticipated. Insert Foley Catheter

C. **Assessment and Management of Maternal Side Effects**

1. Monitor for nausea and vomiting; administer medication as ordered and intervene to prevent aspiration if vomiting occurs.
2. Monitor for elevations in maternal temperature and differentiate between benign fever related to anesthesia vs. infection by assessing for fetal tachycardia, uterine tenderness, foul-smelling amniotic fluid or vaginal discharge, and laboratory results.
3. Monitor of signs of postdural puncture headache; if present, avoid the upright position, provide support, administer medications as ordered and prepare for blood patch procedure if ordered.

D. **Assessment and Management of Neonatal Side Effects**

1. Communicate information about medications used for regional analgesia/anesthesia to neonatal care providers.

2. Monitor the neonate for neurobehavioral changes or decreased respiratory rate.
3. Administer narcotic antagonist as ordered if indicated.

# REFERENCES:


1. Association of Women's Health, Obstetrics& Neonatal Nurse (2020) Role of Registered Nurse in the Care of Pregnant Women Receiving Analgesia and Anesthesia by Catheter Techniques:AWONN Postion Statement. Nursing for Women's Health.
2. ACOG Bulletin #36, 7/2002, Reaffirmed 2013.
3. Guidelines for Neuraxial Analgesia or Anesthesia in Obstretics. American Society of Anesthesiologists. October 13, 2021. Accessed 8/2022.
4. Simpson, K.R.,&Creehan, P.A. (2014). AWHONN Perinatal Nursing 5th Edition. 2021
5. Statement on Regional Anesthesia. American Society of Anesthesiologists. October 25, 2017. Accessed 8/2022.


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## Attachments

Attachment A - Dermatomes Chart
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## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Medical Staff Committees: OB & Surgery | Stephanie Denson: Manager, Medical Staff Office | pending |
| Nursing Administration | Sherri Block: Associate Chief Nursing Executive, VCMC & SPH | 7/31/2025 |
| Nursing Administration | Danielle Gabele: Chief Nursing Executive, VCMC & SPH | 7/31/2025 |
| Policy Owner | Kristina Swaim: Nurse Director, Maternal Child Health | 7/31/2025 |

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VENTURA COUNTY HEALTH CARE AGENCY

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| **Owner:** | *Danielle Gabele: Chief Nursing Executive, VCMC & SPH* |
| **Policy Area:** | *Administrative - Operating Policies* |
| **References:** | |

# 100.278 Surge Plan

## PURPOSE:

To coordinate hospital-wide efforts to manage patient surges, reduce emergency department (ED) boarding, and maintain safe care.

## POLICY:

The surge plan establishes a hospital-wide approach for Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH) to manage fluctuations in patient demand. When demand exceeds normal capacity and inpatient beds are unavailable, patients board in the ED— a situation linked to increased mortality, morbidity, and length of stay. The Ventura County diversion protocol requires hospitals to have a surge plan. This plan proactively identifies resources and adjusts workflows to respond to surges, providing a daily operational framework with escalating actions to maintain safe patient care.

## DEFINITIONS:

**Shared Responsibility:** Surge management is a team effort—physicians, advanced practice providers (APP), nursing, ancillary staff, and leadership all play active roles.

**Physicians as Key Drivers:** ED physicians, hospitalists, and specialists lead patient flow by making timely discharge, transfer, and level-of-care decisions.

**Real-Time Communication:** ED and hospitalist directors coordinate directly with hospital leaders and managers to quickly identify barriers and improve throughput.

**Team Support:** Leadership, APPs, nursing, and ancillary staff redirect energy to assist physicians and streamline processes.

**Coordinated Communication:** Surge huddles and Tiger Text threads provide rapid updates and decision-making.

**Surge Levels:** Green (normal), Yellow (moderate overcrowding), Red (severe overcrowding) with escalating team interventions.

**Goal:** A unified, collaborative approach to safely improve patient flow and reduce capacity strain.

**ED Crowding:** a situation in which the identified need for emergency services exceeds available resources for patient care in the ED.

**Mass Casualty Incident (MCI):** an event that exceeds the healthcare capabilities of the response. An MCI exists when healthcare needs exceed resources.

**Surge**: a sizeable increase in demand for resources compared with a baseline demand. Components include Influx (volume, rate), Event (type, scale, duration), and Resource Demand (consumption, degradation).

**Against Medical Advice (AMA)**- The patient chooses to leave the hospital before the treating clinician has the opportunity to complete the assessment and diagnostic testing necessary to reach a clinical impression or diagnosis. As such, the treating clinician advises the patient of the risks of leaving before the determination of a clinical impression and the benefits of remaining until crucial differential diagnoses have been ruled out.

**Boarding**- The process of holding an admitted patient in the ED while waiting for an inpatient bed.

**Capacity**- The ability to accommodate the patient including the availability of qualified staff, beds, and equipment.

**Early Warning System**- A real-time process to assess for and anticipate a forthcoming and imminent overcrowding crisis in the ED and alert administrators so that strategies may be promptly implemented to avert a breach in the ED's capacity to evaluate and treat patients in a timely manner.

**Left without Being Seen (LWBS)**- The patient checks into the ED and may or may not have been triaged. Ultimately the patient decides to leave the ED before being evaluated by the treating medical clinician.

**Seen by Physician**- When the medical clinician (including APP) first makes contact with the patient to begin evaluation and treatment. Simply noting that the patient walked through the door does not constitute being "seen."

# PROCEDURE:

## Surge Level Assessment

Hospital capacity is calculated by evaluating current bed occupancy against incoming bed needs. As hospital capacity reaches or exceeds maximum utilization, clinical and administrative leaders are to follow a process of escalating communication/notification and initiate actions to alleviate high surge level and overcrowding. Actions that will be taken are appropriate to the situation and maybe modified according to specific challenges. See surge level thresholds below; there are three levels of resource consumption indicating when the demand increases, thereby meeting and/or exceeding capacity. The table below is associated with communication and action steps to be taken according to resources utilized. The thresholds assist in identifying the three surge levels for the hospital demand and capacity providing guidance on recommended actions from department leadership to alleviate congestion within the hospital.

The nursing supervisor assesses the surge level status every six hours and more frequently as needed to promote patient flow, increase capacity and avoid bottlenecks. When we meet the thresholds outlined below to move up or down a surge level the nursing supervisor will contact the Administrator on Duty (AOD). The AOD is responsible for considering the number of patients boarding in the ED, anticipated discharges, pending admissions and time of day to determine whether it is appropriate to change the surge level status. Given the time required to call in additional staff and to change workflows, the surge plan should be activated

during daytime hours (7 am to 9 pm) if it is anticipated that the current level of patient demand will be over 4 hours. Between the hours of 9 pm and 7 am, the surge plan will be activated at 7 am the following morning.

# Determining Surge Levels

Surge levels are determined using the National Emergency Department Overcrowding Scale (NEDOCS) score located on the ED Real Time Dashboard. Cutoffs are as follows:

- < 100 Surge level Green (i.e. normal operations)
- 101 - 180 Surge level Yellow (moderately overcrowded)
- >181 Surge level Red (severely overcrowded)

# Communications plan

1. The nursing supervisor will monitor the surge level criteria defined above and notify the AOD when we meet criteria to move to a different surge level. The AOD is responsible for directing a change to the surge level. When the AOD has determined that the hospital should move either up or down a surge level, the AOD will call paging to send out a Pagegate notification and they will contact the IT department leadership or trained designee to send a SnapComms message. The managers will communicate the surge level with floor staff via radio when the Pagegate communication is sent, for all departments that communicate with floor staff via radio including but not limited to, security, environmental services (EVS), and ED. Since the notice to change the surge level will be announced at the time the surge level is changed and will not be repeated at every change of shift, it is the responsibility of managers and charge nurses to notify the oncoming teams at change of shift about the current surge level.
2. The surge plan will be readily available in the departments so that staff can reference it and are familiar with their responsibilities at the different surge levels.

## SURGE LEVEL GREEN: NORMAL OPERATIONS

### System:

1. Administration:
    a. Patient flow discussion occurs in the daily safety huddle.
2. Admissions: Inpatient beds assigned per protocol
3. Diagnostic Services: follows standard operations

### Staff, Supplies, Space:

1. Standard operating procedures in effect.

### Medical Center Response:

1. Standard operating procedures in effect.
2. ED Status: Open
    a. ED Diversion Status: Open.
    b. ED Transfer Status: Open.
    c. Base Station mobile intensive care nurse (MICN) will update ReddiNet as needed.
3. Daily Operations Huddle:

a. All hospital department directors and managers/designees and executive team

# SURGE LEVEL YELLOW: Moderately Overcrowded

## System:

1. Daily Operations Huddle: normal operations
2. ED Status:
    a. Consider ambulance diversion criteria based on Emergency Medical Services (EMS) policies.
    b. MICN will update the ReddiNet as needed.
3. Level of Care Re-evaluation:
    a. Resident physician and attending physician will speak by phone and run the list of every admitted patient boarding in ED or pending admit. Attending physician will identify patients that require a lower level of care than currently ordered, and resident physician will immediately write orders to downgrade those patients. Results of that conversation will be communicated by medicine resident to ER charge nurse. ER charge nurse will document these downgrades on report sheet.
    b. Create Tiger Text Surge Thread with AOD, Chief Medical Officer (CMO), Chief Nurse Executive (CNE)/Associate Chief Nursing Officer (ACNO), SPH nursing supervisor and VCMC nursing supervisor.
        a. SPH nursing supervisor to reply with available staffed beds. Nursing supervisor to contact hospitalists for transfers if indicated.
    c. Charge nurses to identify patients for potential downgrade or discharge and report to nursing supervisor. Nursing supervisor will request re-evaluation of care level for patients and medicine team will respond within 30 minutes.
    d. CNE will assign a nurse manager to reassess if all patients on telemetry meet such level of care indications.
4. Psychiatric patients
    a. Nursing supervisor to create sign up sheet for nursing assistants willing to work overtime as safety attendants. Sheet will be posted on nursing supervisor office door. Nursing supervisor will deploy additional patient safety attendants or security to psychiatric patients boarding in the ER.
    b. If no nursing assistants are available, security may be utilized with AOD approval. Alternatives also include any registered nursing staff or ED Technicians.

## Space, Staff, Supplies

1. Med/Surg admission handoffs:
    a. If patients have beds assigned but primary registered nurse (RN) is not available, the charge nurse will take report if the charge RN does not have a full patient assignment.
    b. If there is greater than 30-minute delay from bed assignment to hand off for med/surg patients and the charge nurse does not have a full patient assignment, then the patient can be transported to the floor for face-to-face handoff with the charge nurse. The sending unit RN will call the receiving unit to notify of their impending arrival.
2. Monitored patient admission handoffs:

a. If handoff is complete, but no additional RN is available for transport, then nurse manger, charge nurse, nurse educator, resident or attending may accompany the nursing assistant or RN to transport the patient upstairs.

3. Off duty staff:
    a. Department leaders to review and ensure call back trees are updated.
    b. Managers to notify staff of potential to be called in to work.
    c. Refer to Policy 108.010 for nursing alternative staffing: Policy 108.010 Alternate Nurse Staffing Assignments
4. Education / Classes:
    a. AOD will contact the CNE or ACNO to determine which classes and meetings may be canceled to return staff to patient care.
5. Charge nurses:
    a. Will assume patient assignments.
6. Additional Staff:
    a. Exempt staff can be placed into work units to assist (example: educators, supervisors) within their scope of practice.
    b. CNE or ACNO to approve and utilize supplemental agency staff.
    c. Nursing supervisor or staffer to send out mass text offering extra shifts.
    d. Consider when staffing allows to utilize an RN as admit and discharge nurse (can consider modified duty staff if restrictions permit).
7. Central Supply:
    a. Will stock extra carts including but not limited to linen, crash carts ad supply carts so that they are available for staff to grab after hours as needed
8. Dietary:
    a. Nursing supervisor to call the dietary manager to arrange sack lunches to expedite discharges.

## Medical Center Response

1. Inpatient teams:
    a. Prioritize discharges.
2. Nursing directors:
    a. Open any closed beds if possible.
3. Patient Transportation Home:
    a. Patients needing to wait more than 4 hours at any time for a ride home will be sent by Uber Health if appropriate. If not appropriate for Uber Health, the nursing staff will contact case management for alternative options.

# SURGE LEVEL RED: SEVERELY OVERCROWDED

## System:

1. Daily Operations Huddle (930 am):
    a. All directors, managers, executive team, hospitalist member, chief of surgery and/or anesthesia to attend.
2. ER status:
    a. Consider closing to ED Saturation, criteria based on Emergency Medical Services (EMS) policies.
    b. MICN will update the ReddiNet as needed.
3. Level of Care Re-evaluation:
    a. Resident physician and attending physician will speak by phone and run the list of every admitted patient boarding in ED or pending admit. Attending physician will identify patients that require a lower level of care than currently ordered, and resident physician will immediately write orders to downgrade those patients. Results of that conversation will be communicated by medicine resident to ER charge nurse. ER charge nurse will document these downgrades on report sheet.
    b. Create Tiger Text Surge Thread with AOD, CMO, CNE/ACNO, SPH nursing supervisor and VCMC nursing supervisor.
        i. SPH nursing supervisor to reply with available staffed beds. Nursing supervisor to contact hospitalists for transfers if indicated.
    c. Charge nurses to identify patients for potential downgrade or discharge and report to nursing supervisor. Nursing supervisor will request re-evaluation of care level for patients and medicine team will respond within 30 minutes.
    d. CNE will assign a nurse manager to reassess if all patients on telemetry meet such level of care indications.
4. Psychiatric patients
    a. Nursing supervisor to create sign-up sheet for nursing assistants willing to work overtime as safety attendants. Sheet will be posted on nursing supervisor office door. Nursing supervisor will deploy additional patient safety attendants or security to psychiatric patients boarding in the ER.
    b. If no nursing assistants are available, security may be utilized with AOD approval. Alternatives also include any registered nursing staff or ED Technicians.
    c. AOD, CNE or ACNO will contact inpatient unit (IPU) manager to evaluate if other resources are available.
5. Post-Anesthesia Care Unit (PACU):
    a. Notify perioperative services director to arrange for after hours PACU staffing coverage.
    b. PACU may hold patients until an inpatient bed is obtained. Nursing supervisor to call perioperative services director if patients are holding in PACU. Appropriate level of care for PACU is med/surg and telemetry level of care. Intensive care unit 2 (ICU2) and direct observation unit (DOU) can be used as DOU and ICU overflow instead.

## Space, Staff, Supplies

1. Med/Surg admission handoffs:
    a. If patients have beds assigned but primary RN is not available, the charge nurse will take report if the charge RN does not have a full patient assignment.
    b. If there is greater than 30-minute delay from bed assignment to hand off for med/surg patients and the charge nurse does not have a full patient assignment, then the patient can be transported to the floor for face-to-face handoff with the charge nurse. The sending unit RN will call the receiving unit to notify of their impending arrival.
2. Monitored patient admission handoffs:
    a. If handoff is complete but no additional RN is available for transport, then nurse manger, charge nurse, nurse educator, resident or attending may accompany the nursing assistant or RN to transport the patient to the floor.
3. Off duty staff
    a. Department leaders to review and ensure call back trees are updated.
    b. Managers to notify staff of potential to be called in to work.
    c. Refer to Policy 108.010 for nursing alternative staffing: Policy 108.010 Alternate Nurse Staffing Assignments
4. Education / Classes:
    a. AOD will contact the CNE or ACNO to determine which classes and meetings may be canceled to return staff to patient care.
5. Charge nurses:
    a. Assume patient assignments.
6. Additional staff:
    a. Exempt staff will be placed into work units to assist (example: educators, supervisors) within their scope of practice.
    b. CNE or ACNO to approve and utilize supplemental agency staff.
    c. Nursing supervisor or staffer to send out mass text offering extra shifts.
    d. Consider when staffing allows to utilize an RN as admit and discharge nurse (can consider modified duty staff if restrictions permit).
    e. ED director may alert CNO/ACNO to request additional personnel from other areas of clinic or hospital.
    f. Nursing supervisor may activate available inpatient staff to report to ED charge nurse to assist with non-emergency care including sitter duties, care of admitted boarding patients and monitored patient transport.
    g. AOD to email hospital department directors to identify staff available for helping hands.
    h. Any staff members working on special projects will be pulled into direct care staffing as needed.
7. Case Management:
    a. Case management director to call in per diem staff if available. Their role will be to go to the ED to

reevaluate admissions, determine need for transfers to capitated hospitals and transfers for decompression and or lower level of care.

b. Discharge planning staff are expected to round prior to 10 am and again before 4 pm to evaluate barriers to discharge and patient needs.

c. Case management leadership to give overtime to discharge planning staff (authorize 12-16 hour shifts as needed to assist with late discharges).

d. Case management to arrange transportation for discharges prior to 4 pm.

8. Radiology:
    a. AOD will notify the in house radiologist of the surge level 3 (red) status so they can prioritize ER reads and pending discharges.
9. Central supply:
    a. Will stock extra carts including but not limited to linen, crash carts ad supply carts so that they are available for staff to grab after hours as needed
10. Dietary:
    a. Nursing supervisor to call the dietary manager to arrange sack lunches to expedite discharges.
11. Physician Huddle:
    a. 4pm huddle will occur with attending physicians, residents and their respective case managers to proactively identify potential discharges for the next day and address any remaining barriers to discharge.
12. Residents:
    a. CMO/Associate Chief Medical Officer (ACMO) to contact residency director to evaluate for any additional support options available
13. Biomed:
    a. Contact head of biomed as needed for daily rental of tele units, ventilators, and beds. Decision to rent will be made by AOD and CNE.
    b. Critical items out for repair will be reported out at huddle.
    c. If necessary there are two rooms of equipment that can be brought over from SPH.
14. Facilities:
    a. If surge is predicted to be prolonged, request can be sent to California Department of Public Health (CDPH) for permission to set up alternative patient care locations.
15. Staffing:
    a. Leadership will work to ensure adequate staffing by holding over and/or calling in staff as needs dictate.
    b. Relevant policies: #101.007: Mandatory Overtime: Policy 101.007 Overtime
    c. #108.010 Alternate Nursing Staffing Arrangements: Policy 108.010 Alternate Nurse Staffing Assignments
    d. #108.006 Nurse Staffing and Scheduling: Policy 108.006 Nurse Staffing and Scheduling

## Medical Center Response:

1. Inpatient teams:
    a. Prioritize discharges.
2. Nursing Directors:
    a. Open any closed beds if possible.
    b. NOTE: if surge of monitored patients, consider increasing telemetry capacity from 4 to 8 beds on MS3.
    c. Consider closing off 3S addiction medicine elective admissions until surge ends.
3. Leadership:
    a. Available leadership will assist medicine teams with contacting consultants to expedite consults.
4. Cohorting:
    a. Pair any appropriate non-suicidal, non-homicidal patients with sitters where possible to consolidate resources.
    b. Ensure all 4S rooms have double occupancy (ie move isolation patients to next available single rooms) to create capacity.
5. Bed Huddle activation:
    a. CNE/ANCO will activate 4pm bed huddle to included department directors who will report on pending discharges and their remaining barriers, as well as follow up on patients identified at the 9am huddle as discharging who did not discharge. Reasons for failure to discharge must be provided.
6. Administration:
    a. May consider implementing medical center emergency response plan if indicated.
7. Surgery:
    a. Chief of Surgery and Chief of Anesthesia will look ahead at the next 2 days to evaluate if rescheduling some cases may be beneficial.
    b. Surgery, anesthesia and hospital leadership may consider canceling non-emergent inpatient cases with CEO approval.
8. Anesthesia:
    a. Evaluate the surgical schedule especially for cases requiring postop admission to determine if needed or if able to postpone.
9. Consulting Physicians:
    a. Medicine attendings to identify which patients have pending consults as a barrier to discharge and relay list to CMO/ACMO who will assist with contacting consultants to prioritize those patients.
10. Utilization Management (UM):
    a. UM physician will review ED admits to ensure that hospitalization is medically necessary and patient needs can not be met as an outpatient.
    b. UM physician will also assist with identifying appropriate patient to transfer to SPH.
11. EVS:

a. Offer double shifts for EVS to increase coverage especially for afternoon (second) shift.

b. EVS dispatch to discuss prioritization of room cleaning with nursing supervisor.

12. Patient transportation home:

    a. Patients need to wait more than 4 hours at any time for a ride home will be sent by Uber Health if appropriate. If not appropriate for Uber Health the nursing will contact case management for alternative options.

13. Chain of Command:

    a. AOD to notify hospital CEO that we are in surge level red. AOD to notify ED to ensure status is logged into Reddinet.

# DOCUMENTATION:

A. Each time the surge plan is initiated, the nursing supervisor is responsible for ensuring proper documentation.

    1. Time surge level was initiated and concluded in RL Datix.
    2. Start and end times of any diversion. Note: Trauma diversion cannot be implemented without documented discussion between AOD and Trauma Medical Director/Deputy Trauma Medical Director with subsequent CEO approval.
    3. Time AOD was notified and CMO if applicable.
    4. Log of any surgeries or procedures cancelled secondary to surge. Log to be provided to Perioperative Service Director to ensure timely rescheduling.

# REFERENCES:

Policy #107.003 Emergency Department Saturation and Ambulance Diversion

All revision dates: 11/20/2025

## Attachments

image1.jpg

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Medical Executive Committee | Stephanie Denson: Manager, Medical Staff Office | pending |
| Medical Staff Committees: ED, Surgery & Medicine | Stephanie Denson: Manager, Medical Staff Office | 12/3/2025 |
| Nursing Administration | Sherri Block: Associate Chief Nursing Executive, VCMC & SPH | 12/2/2025 |
| Nursing Administration | Danielle Gabele: Chief Nursing Executive, VCMC & SPH | 12/2/2025 |

| Step Description | Approver | Date |
| --- | --- | --- |
| Policy Owner | Danielle Gabele: Chief Nursing Executive, VCMC & SPH | 12/2/2025 |

**Current Status:** *Pending* **PolicyStat ID:** *19198477*

VENTURA COUNTY HEALTH CARE AGENCY

| | |
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| **Next Review:** | *3 years after approval* |
| **Owner:** | *Magdy Asaad: Infection Prevention Manager* |
| **Policy Area:** | *Administrative - Environment of Care* |
| **References:** | |

# 106.005 Diseases and Conditions Reportable to the Ventura County Public Health Department

# POLICY:

To comply with the California Code of Regulations, Title 17 Section 2500 and The Joint Commission Hospital Accreditation Standards regarding reporting diseases and conditions to the Ventura County Public Health Department.

# PROCEDURE:

**RESPONSIBILITY** for reporting includes, but is not limited to:

Physicians
Infection Control Practitioners
Physician's Assistants
Nurse Practitioners
Nurses

Laboratory Staff

Anyone having knowledge of a reportable condition

There are two methods of reporting to the Ventura County Public Health Department. The first is the Confidential Morbidity Report (Attachment A), Communicable Diseases other than Tuberculosis and AIDS. The preferred method of reporting is by using the CalRedie electronic reporting program. A login can be obtained by contacting the Communicable Disease office of the Ventura County Public Health Department.

The list of diseases, conditions and the required form for reporting is attached to this policy. A diagnosis or a suspected case of any of the diseases or conditions listed on Attachment B must be reported to the Ventura County Public Health Department within the designated time frame.

~~Tuberculosis reporting requires a separate form (Attachment C). "The Legal Aspects of TB Reporting" information is included as Attachment D. These forms can also be found on the Ventura County Public Health Department website at: www.vchca.org/ph. Click on Communicable Disease Reporting and select the appropriate form.~~

Tuberculosis cases are reported to local Public Health according to Gotch Law (California Health and Safety Code §121361) when:

- A patient known to have active tuberculosis disease.
- A patient who the medical staff of the health facility or of the penal institution has reasonable grounds to believe has active tuberculosis disease.

Example summary of reasonable grounds:

- ◦ A persistent cough for 3 + weeks (especially with hemoptysis)
  - ◦ Constitutional symptoms (fever (especially low-grade and prolonged), night sweats, unexplained weight loss)
  - ◦ A chest X-ray showing cavitary upper-lobe lesions or other TB-typical patterns (specially miliary (diffuse) pattern)
  - ◦ Sputum smear positive for acid-fast bacilli (AFB)
  - ◦ Positive nucleic acid amplification test (NAAT) for Mycobacterium tuberculosis
  - ◦ Previous TB diagnosis with incomplete or uncertain treatment history.
  - ◦ Patient is placed on two or more individual anti-TB drugs
  - ◦ Consider TB risk factors such as Incarceration, congregate settings, significant exposure, Malnutrition, immunosuppression
- It is up to the hospital medical staff clinicians to determine if they believe based clinical judgment that a patient has active TB and document on patient chart accordingly.
- Once documented, a separate form (Attachment C) will be submitted to Public health. "The Legal Aspects of TB Reporting" information is included as Attachment D. These forms can also be found on the Ventura County Public Health Department website at: www.vchca.org/ph. Click on Communicable Disease Reporting and select the appropriate form.

Reported TB Discharge approval process

- During normal business hours, Infection Control and case management collaborate to obtain the required discharge information and Infection Control submits the discharge plan form.
- TB Control has up to 24 hours to review the discharge plan. Patient must not be discharged prior to securing the required approval.
- During Weekend and after hours, it is the responsibility of the treating physician to reach out to the TB doctor on call by phone (805-214-7057) to obtain verbal approval and document the approval in patient chart for proper processioning next business day.

Reportable Influenza Case History form must be completed for any patient with influenza who is in the Ventura County Medical Center/Santa Paula Hospital:

- Influenza-associate deaths in laboratory-confirmed cases less than 18 years of age, reported vis CalRedie.
- Influenza due to novel strains (humans) reported by phone as well.

Tuberculosis Report are faxed to the respective numbers at the Ventura County Public Health Department. The fax numbers are on the forms.

The regular CMR's should be entered into CalRedie. In lieu of this, the form may be faxed to Ventura County Public Health at the number on the form.

AIDS cases are telephoned to the AIDS office. The telephone number is located on the front of the CMR

**All reports faxed/sent to the Ventura County Public Health Department must also be faxed to the Infection Control Office at (805) 652-3273.**

# Reference:

California Code of Regulations Title 17 Section 2500
The Joint Commission Hospital Accreditation Standards

# Attachments:

A. Confidential Morbidity Report Fax form
B. Confidential Morbidity Report Instructions
C. TB Suspect/Case Report and Plan Form
D. Legal Aspects of TB Reporting information

All revision dates: 11/5/2025, 10/17/2025, 5/1/2016, 11/1/2013, 9/1/2006, 3/1/2004

## Attachments

- A: Confidential Morbidity Report Form
- B: Confidential Morbidity Report Instructions
- C: TB Suspect/Case Report and Plan Form
- D: Legal Aspects of TB Reporting Information

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Medical Executive Committee | Stephanie Denson: Manager, Medical Staff Office | pending |
| Infection Prevention Committee | Magdy Asaad: Infection Prevention Manager | 11/5/2025 |
| Policy Owner | Magdy Asaad: Infection Prevention Manager | 11/5/2025 |

VENTURA COUNTY HEALTH CARE AGENCY

| | |
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| **Owner:** | *Sharon Waechter: Clinical Nurse Manager, Nursing Education* |
| **Policy Area:** | *Administrative - Nursing* |
| **References:** | |

# 108.020 Lippincott Procedures

## POLICY:

Nursing standards drive consistency and high-quality outcomes in patient safety, patient care, service, and operations. At Ventura County Medical Center (VCMC)/Santa Paula Hospital (SPH), nursing standards are managed using the Lippincott Patient Care Standards management system accessible via the intranet. Lippincott Standards are evidence-based standards that are updated ~~every three (3) months~~annually. The frequency of standard reviews is determined by a need resulting from process or technology change or by regulatory requirements (e.g., The Joint Commission mandates review every three years and the State of California mandates annual review).

## PROCEDURE:

1. VCMC and SPH nursing staff will use the Lippincott Nursing Procedure online program as the reference for standard nursing procedures.
2. Lippincott's Nursing Procedures provides detailed descriptions of procedures that allow users to identify the procedure they need quickly and easily. Users can search by alphabetical list, browse by nursing or clinical category, or perform a search to identify a particular procedure. Each entry provides complete instructions, including the equipment needed, preparation guidelines, implementation steps, special considerations, documentation, and references. ~~Video clips are included to clarify complex procedures.~~ Each procedure is linked with at least one quick list. Quick lists provide a quick, less-detailed version of a procedure when only an overview is needed.
3. The Nursing Education Department will manage developments, new procedures, or revise existing procedures according to submission criteria. Submission requires the co-signature of at least one member of the ~~Patient Care Standards Group~~Interprofessional Practice Committee.
4. The Chief Nurse Executive will review and ~~approval~~approve changes to the all nursing policies and nursing standardized procedures.
5. The Chief Nurse Executive or designee will submit substantial nursing practice changes to the Medical Director for review and approval.
6. The Medical Director will determine if substantial nursing practice changes require submission to the Medical Executive Committee for review and approval.

All revision dates: 11/5/2025, 11/1/2016

## Attachments

No Attachments

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Medical Executive Committee | Stephanie Denson: Manager, Medical Staff Office | pending |
| Nursing Administration | Danielle Gabele: Chief Nursing Executive, VCMC & SPH | 11/5/2025 |
| Nursing Administration | Sherri Block: Associate Chief Nursing Executive, VCMC & SPH | 11/5/2025 |
| Policy Owner | Sharon Waechter: Clinical Nurse Manager, Nursing Education | 11/5/2025 |

VENTURA COUNTY HEALTH CARE AGENCY

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| **Owner:** | *Sherri Block: Associate Chief Nursing Executive, VCMC & SPH* |
| **Policy Area:** | *Administrative - Nursing* |
| **References:** | |

# 108.031 Treatment of Hemodialysis Patients

# POLICY:

To outline the process of care for patients receiving hemodialysis at Ventura County Medical Center (VCMC)/Santa Paula Hospital (SPH).

# PROCEDURE:

A. Patients admitted for hemodialysis can be assigned to the following rooms:
   1. At VCMC – all dialysis-equipped rooms
   2. At SPH – all rooms except "001"

B. Dialysis vendor staff will contact the assigned nurse once an order for dialysis is received to ensure the patient is ready for treatment. The RN will ensure the Dialysis Readiness checklist is complete. See Attachment A.
   1. Checklist ensures that the patient has a signed consent, is in the room and available and has a confirmed dialysis access. For patients in the outpatient setting, informed consent is valid for 30-days as long as the reason for the dialysis remains unchanged.
   2. Once checklist is complete, VCMC/SPH RN will call Fresenius to notify that patient is ready for treatment.

C. Staff shall do all pre-dialysis work/SBAR before the arrival of the dialysis nurse and should:
   1. Provide/receive warm hand-off to/from dialysis RN prior to/post procedure.
   2. Check pertinent Lab work and confer with dialysis nurse.
   3. Assist dialysis nurse with weighing the patient, if not already done.
   4. ~~Review consent for dialysis procedure comprehensiveness of completion. For patients in the outpatient setting, informed consent is valid for 30-days as long as the reason for the dialysis remains unchanged.~~Document handoff in the electronic health record (EHR).

D. Unit nursing staff is responsible for nursing care medications and any other treatments.

E. No BP's, IV's or NEEDLE STICKS ON SHUNT ARM. Protect arterial/venous access.

F. IN THE EVENT OF A CODE BLUE WHEN ON DIALYSIS:
   1. Dialysis nurse will terminate treatment as quickly as possible.

2. Dialysis nurse will leave the room with as much equipment as possible.
3. Code team will assume care.
4. Continuation of treatment after emergency will be at the discretion of the patient's physician and the nephrologist.

G. ** Prior to any AV shunt placement in an arm or leg, place a sign above the bed stating: DO NOT DRAW BLOOD OR PLACE IV'S (FROM EXTREMITY PLANNED FOR AV SHUNT).

NOTE: Remember to inform the patient not to allow blood draws or needle sticks to the extremity planned for AV shunt placement.

H. In the event of an internal/external disaster, treatment will be terminated as soon as possible and hand-pumped, if necessary, by the dialysis nurse.

All revision dates: 11/11/2025, 7/23/2018, 1/1/2017, 12/1/2013, 6/1/2013, 4/1/2011, 4/1/2008, 6/1/2006, 11/1/2004, 5/1/2004, 10/1/2001, 10/1/1998, 11/1/1995, 7/1/1994, 7/1/1992, 4/1/1991, 11/1/1990

## Attachments

 readiness checklist.png

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Medical Executive Committee | Stephanie Denson: Manager, Medical Staff Office | pending |
| Nursing Administration | Danielle Gabele: Chief Nursing Executive, VCMC & SPH | 11/11/2025 |
| Nursing Administration | Sherri Block: Associate Chief Nursing Executive, VCMC & SPH | 11/11/2025 |
| Policy Owner | Sherri Block: Associate Chief Nursing Executive, VCMC & SPH | 11/11/2025 |

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| **Owner:** | *Kelly Valenzona: Director, ICU/ DOU/Telemetry* |
| **Policy Area:** | *Administrative - Nursing* |
| **References:** | |

# 108.047 Centralized Telemetry Monitoring

## PURPOSE:

To identify the process for continuous monitoring of heart rate and rhythm of patients to ensure life-threatening rhythms can be detected and treated. Centralized telemetry monitoring ensures redundancy of monitoring both at the department level and in the centralized telemetry station. The centralized telemetry station is located in the direct observation unit (DOU) and is responsible for the remote monitoring of patients within the adult critical care and medical surgical patient populations at Ventura County Medical Center (VCMC) only.

## POLICY:

The nursing personnel covered in this policy include telemetry technicians, licensed vocational nurses (LVN), registered nurses (RN) and anyone competent to cover these roles. Under the direction of Nursing Directors, these individuals are accountable for the quality of care of the patients and are accountable through nursing administration. The telemetry technicians assigned to the central telemetry station are responsible for maintaining accurate patient information on the system and notifying the RN staff of any changes.

Qualified personnel to perform the telemetry monitoring function are those individuals who have received training for telemetry monitoring. Nursing staff must demonstrate competency in ~~evaluating~~the evaluation of life-threatening arrhythmias.

## PROCEDURE:

I. Utilization

A. ~~A~~Verify licensed provider's (LP) order ~~must be obtained for all patients receiving~~for continuous cardiac monitoring (CCM) ~~when it is not the standard of care~~. An LP's order must also be obtained for all patients ~~on the unit. A provider's order must be obtained for all patients~~ receiving continuous pulse oximetry monitoring.

B. ~~Orders for continuous cardiac monitoring~~CCM orders must be re-evaluated at least every 24 hours.

C. Intravenous (IV) access is required on all CCM patients ~~who are receiving CCM~~.

II. Management of the Patient

A. ~~When an order is~~Units with telemetry box: the Registered Nurse (RN) or surrogate will obtain a

telemetry box or inform the telemetry technician (monitor tech) that a patient has been placed ~~for cardiac monitoring for a patient, the RN or surrogate obtain a~~on telemetry ~~box or inform the telemetry technician that a patient has been placed on telemetry~~ via hard-wires. At this time both parties will validate two patient identifiers (name and date of birth), as well as that the monitor is on. They will identify the telemetry box number and identify the patient's baseline rhythm.

~~The telemetry technician and RN will set the gain to achieve a QRS amplitude large enough to be detected by the monitor and assure that a clear tracing is visible on the monitor for at least two leads.~~

~~The telemetry technician and RN will select the appropriate lead based on the goals of monitoring and the patient's clinical situation.~~

1. ~~For Arrhythmia diagnosis or Wide QRS tachycardia, V1 (RSB, 4th intercostal space) is the best lead with V6 as second choice.~~
2. ~~If a true V1 or V6 is not a lead option, MCL 1 and MCL6 can substitute.~~
3. ~~Dual lead monitoring is superior to single lead monitoring- lead II and V1.~~
4. ~~Note: if other leads in use, justification required and documented.~~

B. The monitor tech and RN will set the ECG size, so the components may be easily detected and ensure a clear tracing from both leads.

C. The monitor tech and RN will attach the electrodes to the patient, utilizing the default monitor leads placement, II and V1. If there is artifact from V1, then MCL may be utilized by the RN, with an LP order.

D. The assigned RN will notify the monitor tech when the telemetry ~~technician~~monitoring is ***briefly*** removed for bathing, or discontinued (e.g., patient discharged). The RN must also notify the monitor tech when ~~the telemetry box~~transporting the patient to a procedure, patient is ~~being taken off for bathing or discharge~~receiving physical therapy (PT)/Occupational Therapy (OT), chest physiology therapy, requires pacemaker mode, and patient has an Automatic Implantable Cardiac-Defibrillator (AICD). ~~They must also call when transporting the patient to a procedure or while the patient is having physical therapy.~~

E. All monitored patients are accompanied by an RN for intrahospital transport and ensures HR volume is on. If telemetry monitoring is not required for a procedure, an LP order is required.

F. Physicians shall be notified in the event of any changes in cardiac rhythm or vital signs.

III. Equipment/Parameter alarms

~~All telemetry equipment including pulse oximetry (SPO2) probes and cables will be kept in the telemetry monitoring room. (VCMC only)~~

~~All requests for equipment will be through the monitor tech and returned to the telemetry monitoring room when the patient's monitoring is discontinued. (VCMC only)~~

A. All nursing units are required to clean equipment with germicidal agent before returning equipment.

B. Cleaned equipment will be placed in a designated basket at the nursing station and delivered to and/or picked up by staff to the telemetry monitoring room. (VCMC only)

~~Initial set up for alarms is established by using patient's baseline settings. A specific physician order~~

~~for parameters would supersede using baseline settings.~~

~~The parameters can be individualized for any patient by a RN or monitor tech. When the monitor tech adjusts parameters it will be in collaboration with the nursing and/ or medical staff.~~

~~Parameters should be based upon the patient baseline average if there are no specific orders from the provider. Default alarm parameters are standardized for a range between 50-130 bpm.~~

C. Default heart rate alarm parameters are standardized: upper limit: 130 bpm; lower limit: 50 bpm

D. Volume alarms should never be set below 50%.

E. ~~Certain dysrhythmia alarms (e.g.: irregular rhythms) may be changed by the registered nurse on the basis of the patient's clinical situation, current heart rate, rhythm, and treatment plan. Changing the heart rate standard alarm limits requires an order from the provider. The RN shall document the clinical justification for altering the alarm limits and dysrhythmia alarms in the patient's medical record. The physician/care team is to be notified of changes from the default settings made by the RN. Heart rate alarm limits, different from the default settings, may also be ordered by the physician. Alarm limits can only be adjusted with provider order.~~

   Changing a heart rate alarm parameter requires an LP order

F. The other parameter that is monitored via the central monitoring station O2 saturation.

   - *O2 Saturation: Between 90-100% unless otherwise directed by medical provider*

G. Frequency of Cardiac Rhythm Interpretation

   A. The ~~telemetry technician~~monitor tech will do the q shift ECG strip interpretation and will be sent to the primary patient's nurse for validation.

   B. ~~Strip documentation is to be done at the following times.~~

      Frequency of ECG rhythm documentation:

      1. Upon admission ~~or~~, transfer into unit, every 12 hours and prn (e.g., acute rhythm change).
      2. Every shift or with changes for DOU and telemetry patients (ICU patients will be monitored by primary nurses)

         ~~For any changes in rhythm or rate, change in vital signs, or in mental status; the patient experiences chest pain; change in lead placement; and when evaluating effects of anti-dysrhythmic agents.~~

      3. For Rapid Response event or Code Blue (continuous)~~.~~
      4. Document on each recorded rhythm strip the two patient identifiers, interval measurements and interpretation (Telemetry: monitor tech or primary RN**).**
      5. ~~Telemetry~~Monitor tech will send all saved telemetry rhythm strips to the patient's primary nurse at intervals mentioned above.

         ~~During any rapid response event.~~

   C. Communication: RN and ~~Telemetry Technician~~Monitor Tech

      ~~The RN and Telemetry Technician should communicate the following information to each~~

~~other:~~

- ~~Request for equipment to include two patient identifiers one of which cannot be room number~~
- ~~Initiation of monitoring~~
- ~~Discontinuation of monitoring~~
- ~~Interruption of monitoring~~
- ~~Chest physiotherapy~~
- ~~Transfer to another room~~
- ~~Pacemaker or automatic implantable cardiac defibrillator (AICD)~~
- ~~Transporting for diagnostic testing and/or procedure~~

A. ~~The RN should call the Telemetry Technician to inform of any specific orders received.~~

The RN should call the Monitor Tech to inform of any specific orders received.

B. Nursing assignments will be sent to the Central Telemetry Room within 30 minutes of the start of the shift. Additional changes to assignments must be communicated to include change in mid-shift assignments, patient admissions, and/or transfers and discharges.

IV. Dysrhythmia Notification

A. Follow the Alarm Intervention Flowchart (attached) for any changes in patient condition, rhythm changes and/or lethal dysrhythmias

1. Lethal Dysrhythmias
    a. Asystole
    b. Ventricular tachycardia
    c. Ventricular fibrillation
2. Warning Alarms
    a. Bradycardia (patient's low heart rate (HR) parameter)
    b. Non-sustained ventricular tachycardia > 2 beats
    c. Accelerated ventricular rate
    d. Heart rate greater than patient's high parameter, such as supraventricular tachycardia (SVT) or paroxysmal atrial tachycardia (PAT)
    e. ~~pause~~Pause or any dysrhythmia not addressed as a lethal alarm
    f. ~~new~~New onset of atrial fibrillation
3. Message Alarms
    a. Bigeminy
    b. Couplets
    c. Trigeminy
    d. Premature ventricular contraction (PVC)
    e. Sinus tachycardia (ST) alarms

B. Escalation pathway: all telemetry alarms are to be called to the unit immediately. If no response, the charge nurse will be notified via walkie talkie. If no response from the charge nurse, the central telemetry staff will active a telemetry alert to trigger an overhead page. All notifications will be logged on the telemetry monitoring log.

C. Telemetry alerts are also to be called immediately for any lethal dysrhythmia.

V. Telemetry Tech Responsibilities

A. Communicates battery change alarm

B. Creates copies of the telemetry ECG strips and ~~does the~~performs initial interpretation for ~~each nurse to review~~***each RN to review***.

C. Notifies Bio-Medical Engineering of faulty equipment and takes equipment our of service

D. Admits patient to the Central Telemetry Monitor in coordination with the RN, including patient data and initial ECG rhythm strip

E. ~~Sets~~Utilizes default parameters and re-checks ~~parameter~~parameters every 12 hours

F. Monitors patients continuously via central station

G. Reviews prior alarm history and clears out artifact related alarms

H. The monitor tech will follow the "Alarm Intervention Flowsheet" to escalate any lethal dysrhythmias, warning alarms and/or messages

I. The monitor tech will document all notifications to ~~nurse on~~RN in the telemetry monitoring log

J. The monitor tech will label each telemetry strip with the following information:

1. Patient's name and MRN
2. Patient's room number
3. Time and Date
4. Measured parameters

VI. Specific Nursing Responsibilities

~~Patients on telemetry monitoring who require transport for testing will be transported without a RN to the department, unless otherwise ordered by the provider. The patient will be continuously monitored by telemetry by the monitor tech. In those areas where telemetry is not monitored or telemetry is not transmitted, the RN will accompany the patient. When transporting a patient, the RN must ensure the heart rate alarm is turned on and is audible.~~

A. Electrodes are ~~changes~~changed prn and at least every 24 hours.

B. Telemetry ECG strips are to be placed in the chart and the RN signature confirms the monitor ~~technician~~tech's interpretation.

C. Broken or faulty equipment should be returned to the Central Telemetry Monitor. The monitor ~~technician's~~tech will be responsible for notifying bio-medical engineering and ensuring the equipment is repaired and returned.

D. The RN will promptly notify the monitor tech ~~when~~of any monitoring changes (listed above). Telemetry monitoring remains on the patient~~'s telemetry is discontinued, the patient leaves the floor, and/or the unit is taken off for any reason. Telemetry monitoring remains on the patient~~ at all times including ambulation and while toileting.

E. The assigned ~~telemetry technician~~monitor tech will distribute the ECG strips to each unit. The RN will validate the interpretation of the strip and place in the medical record.

F. ~~In the event of an arrhythmia, the RN will:~~

~~a. Verify the patient by name and MRN~~

~~b. Immediately check on the patient~~

~~c. Nursing assessment will include:~~

~~1. Airway, Breathing, Circulation~~

~~2. Heart rate and rhythm regularity to include a full set of vital signs (VS)~~

~~3. Assess for presence of chest pain~~

~~4. Skin color~~

In the event of an arrhythmia, the RN will: immediately verify the patient by name and MRN and assess the patient

G. Communicate patient status to monitor tech

H. Call rapid response and notify provider for all symptomatic rhythms.

I. Review of need for continuous telemetry monitoring daily. The telemetry technicians will send a list of patients who have been on telemetry monitoring > 48 hours each morning to the unit charge nurse. The Charge RN and/or primary RN will use the protocol to discontinue telemetry. (Telemetry Discontinuation Worksheet). If telemetry is no longer indicated, the RN will notify the physician to discontinue.

VII. Handoff

A. Any changes to cardiac monitoring orders require handoff between providers using SBAR format.

B. Handoffs must also occur between ~~telemetry technicians~~monitor tech and must include alarm volumes, alarm limits (if not standard), basic rhythms and arrhythmias of any patients being monitored.

C. Telemetry box log book will be maintained and updated by telemetry technicians.

VIII. Telemetry Discontinuation

A. Every morning (dayshift only), the charge RN in any unit where telemetry is in use at either campus will review all patients on telemetry monitoring.

B. Charge RN will identify any patients on monitoring >48 hours that meet criteria for discontinuation. RN will document in here: Telemetry Discontinuation Worksheet

C. Charge RN will notify primary ~~nurse of their patients where it~~RN when telemetry is no longer ~~indicated~~needed.

D. In rounds, primary RN will notify physician that telemetry will be discontinued for those patients identified. Physician can then choose to re-enter order or discontinue it. (Attachment: Nurse-Driven Telemetry Discontinuation Protocol).

E. If patient is continued on telemetry, the process will repeat at Step A above daily until telemetry is discontinued or patient is discharged, whichever is first.

IX. Downtime

A. If downtime occurs, the ~~telemetry technician~~monitor tech will immediately notify the house supervisor

to contact BioMed and department charge nurses. House supervisor will call AOD if downtime extends > 10 minutes.

B. When department monitoring stations are down, the department charge nurse will notify the centralized telemetry room.

C. If any monitoring is down in the centralized telemetry room, the house supervisor will place patients on alternative monitoring, call BioMed and call the AOD.

D. Once downtime resolves, conduct a debrief to understood root causes and mitigate future risk.

# REFERENCE(S):


AACN Procedure Manual for High Acuity, Progressive and Critical Care. (2017). 7th ed.

Alarm Management- American Association of Critical Care Nurses.

procedures.lww.com/lnp/view.do?pId=3378804&hits=telemetry&a=false&ad=false&q=telemetry

Standards for Inpatient Electrocardiographic Monitoring - American College of Cardiology (acc.org)


All revision dates: 8/11/2025, 3/4/2024, 11/15/2023, 6/14/2023, 4/12/2023

## Attachments

- Alarm Intervention Flowchart (1).docx
- Tele Removal Workflow.xlsx

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Medical Executive Committee | Stephanie Denson: Manager, Medical Staff Office | pending |
| Hospital Administration | Osahon Ekhaese: Chief Operating Officer, VCMC & SPH | 11/20/2025 |
| Hospital Administration | Minako Watabe: Chief Medical Officer, VCMC & SPH | 11/5/2025 |
| Nursing Administration | Sherri Block: Associate Chief Nursing Executive, VCMC & SPH | 10/28/2025 |
| Nursing Administration | Danielle Gabele: Chief Nursing Executive, VCMC & SPH | 10/28/2025 |
| Policy Owner | Kelly Johnson: Director, ICU/DOU/Telemetry | 10/28/2025 |

VENTURA COUNTY
HEALTH CARE AGENCY

| | |
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| **Next Review:** | *2 years after approval* |
| **Owner:** | *Erlinda Roxas: Director, Laboratory Services* |
| **Policy Area:** | *Laboratory Services* |
| **References:** | |

# L.68 AmniSure Rupture of Membranes

# POLICY

The AmniSure® ROM (Rupture of Membranes) Test is a non-invasive, qualitative immunoassay used to detect PAMG-1 protein in vaginal fluid. This test helps identify if fetal membranes have ruptured. The test must be performed according to the manufacturer's instructions by trained healthcare personnel.

# PURPOSE

The AmniSure® ROM Test detects placental alpha microglobulin-1 (PAMG-1), a protein found in amniotic fluid. Its presence in vaginal discharge indicates membrane rupture.

# EQUIPMENT & SUPPLIES

- AmniSure® ROM Test kit (includes sterile swab, solvent vial, test strip in foil pouch)
- Timer
- Gloves
- Pen and test log
- Personal Protective Equipment (PPE)
- Optional: Positive and Negative Control vials

## PRECAUTIONS

- Do not use tests within 6 hours of vaginal medications or disinfectants.
- Avoid digital vaginal exams prior to specimen collection.
- Do not use expired or damaged kits.
- Used test components are biohazards – dispose properly.
- Do not interpret results after 15 minutes.

# PROCEDURE

## SPECIMEN COLLECTION & ANALYSIS

1. Have the patient lie on their back.
2. Insert the provided sterile swab 2–3 inches into the vagina.
3. Keep the swab in place for 1 minute.

4. Remove swab and place tip into solvent vial; swirl for 1 minute.
5. Discard swab.
6. Open test strip pouch and insert white end (arrows down) into solvent.
7. Wait exactly 10 minutes or until two lines appear.
8. Remove the test strip, place it on flat surface, and read the result within 5 minutes.

# INTERPRETING RESULTS:

- **Two lines = Positive**
- **One line (Control only) = Negative**
- **No lines or Test line only = Invalid** (repeat test)

# QUALITY CONTROL

Each AmniSure® ROM Test contains built-in procedural and reagent controls to verify the integrity of each test. The appearance of one or two lines within the result window confirms the test has functioned properly.

External quality control using **positive** and **negative controls** is **optional** but recommended. To perform external QC:

- Reconstitute the control vial with the provided solvent.
- Insert the test strip into the solution.
- After exactly 10 minutes, interpret results:
  - **Positive control** should show **two lines**.
  - **Negative control** should show **one control line**.

**The laboratory will perform external quality control on all new kit lot numbers upon receipt and at a minimum of once per month thereafter.** All QC activities must be **documented in the QC logbook** and performed in accordance with applicable local, state, and federal regulatory requirements, as well as Ventura County Medical Center policy.

## CLEANING & DISINFECTION

- Dispose of swab, test strip, and vial as biohazard waste.
- Clean the workspace with approved disinfectants after testing.

## STORAGE & STABILITY

- Store kits between **4–25°C (40–77°F)**.
- Do not freeze.
- Use test strip within **6 hours** of opening the pouch.
- Store collected sample in fridge (4–8°C) if not tested within 4 hours; discard after 6 hours.

## PROBLEM SOLVING & TECHNICAL SUPPORT

- **Invalid result?** → Repeat the test with a new kit.
- **Control line missing?** → Test is invalid, repeat test.
- **Reagent or test malfunction?** → Contact QIAGEN:
  - Phone: 1-800-DNA-PREP

- Web: www.qiagen.com

## REFERENCES


1. *AmniSure ROM Test Instructions for Use, QIAGEN, 2019.*
2. *AmniSure ROM Test Controls Instructions for Use.*
3. *AmniSure ROM Test Quick Reference Guide, QIAGEN.*


All revision dates:

## Attachments

No Attachments

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Medical Executive Committee | Stephanie Denson: Manager, Medical Staff Office | pending |
| Medical Staff Committees: OB & Familly Medicine | Stephanie Denson: Manager, Medical Staff Office | 11/26/2025 |
| Laboratory Services Department | M. Anwar Molani: Medical Director, Laboratory Services | 10/2/2025 |
| Laboratory Services Department | Erlinda Roxas: Director, Laboratory Services | 9/6/2025 |

VENTURA COUNTY
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| **Owner:** | *Kristina Swaim: Nurse Director, Maternal Child Health* |
| **Policy Area:** | *OB Nursing* |
| **References:** | |

# OB.47 Use of Magnesium Sulfate in the Obstetrics Department

# POLICY:

To identify magnesium sulfate as a high-risk medication and to provide specific recommendations that apply.

**Indications:**

1. **Preeclampsia:** Magnesium sulfate is indicated for seizure prophylaxis and management in women with severe preeclampsia.
2. **Eclampsia**: Magnesium sulfate is the first-line treatment for preventing and managing eclamptic seizures
3. **Neuroprotection:**Magnesium sulfate may be considered for neuroprotection in preterm labor, particularly for fetal neuroprotection to reduce the risk of cerebral palsy.
4. **Preterm Labor:**Magnesium sulfate may be used as a tocolytic agent to delay preterm delivery in specific circumstances.

# PROCEDURE:

Upon receiving the physician's order, a Registered Nurse (RN) may administer Magnesium Sulfate intravenously.

## GUIDELINES:

A. Identify patient who is a candidate for magnesium sulfate.

B. Position patient in lateral position to increase uterine blood flow.

C. For initiation of magnesium sulfate, obtain physician order, specifying the loading dose to be given (4-6 gm) and maintenance dose (1-2 gm/hr)

D. Independent double check with another licensed personnel to verify initial physician orders, drug, concentration, infusion rate, pump settings, line attachment and patient before administering the drug and upon transfer of the patient to another unit.

E. Have a second nurse check when every magnesium bag is added including loading dose and maintenance dose and each time a rate is changed.

F. Once magnesium therapy is discontinued remove the line from IV port to prevent accidental infusion or

overdose.

G. IV Magnesium Sulfate is administered only by infusion pump by inserting tubing at the lowest possible portal site of the primary IV tubing. Label tubing with red medication label near the IV pump. When starting infusions or changing bags, trace the tubing by hand from the IV bag to the pump and then to the patient for verification. The usual loading dose is a piggyback premixed from Pharmacy magnesium of 4 grams in 100 ml sterile water. For patients weighing ≥ 113kg or 250 lbs a 6 gram bolus. The Magnesium Sulfate bolus will be administered over 20 minutes. If using Magnesium Sulfate for Neuroprotection, only a loading dose is required. The maintenance infusion is administered as a premixed 4% solution (20 grams in 500 ml sterile water) through an infusion pump.
**Maintenance Dose** 2 – 4 gram/hr as ordered
(40 mg/ml in 500 ml)
1 gm/hr = 25 ml
2 gm/hr = 50 ml
3 gm/hr = 75 ml
4 gm/hr = 100 ml

H. Insert foley catheter ~~as~~when ordered by physician.

I. Magnesium Sulfate is a high risk medication that requires vigilance for safe care of mothers and babies

1. Laboratory Data:
    a. Serum magnesium level will be drawn every 6 hours after bolus dose is infused. Baseline magnesium level can be drawn with admission CMP.
    b. Therapeutic levels range from 4 – 7 mEq/L
    c. Only 0.3% of the body's total magnesium content is located in the serum, therefore, clinical manifestations are important indicators of physiological response.
    d. Electrolytes initially per ~~PHYSICIAN~~ order, repeat if indicated
    e. Calcium levels should be kept above 7mg/100ml
2. Monitoring, assess patient for signs of toxicity every 2 hours or as ordered by physician:
    a. Visual changes
    b. Somnolence
    c. Flushing
    d. Muscle paralysis (respiratory depression: O2 sat less than 95%)
    e. Loss of Deep Tendon Reflexes (DTRs) or pulmonary edema
    f. Lab values of magnesium levels
    g. ~~Urine output~~Urine output using foley catheter or strict urine output measurements.If output < 30 ml/hour, reassess Magnesium Sulfate dosage and notify physician.
3. Maternal effects:
    a. Sense of heat (facial flushing due to vasodilatation)
    b. Complaining of nasal congestion
    c. Nausea and vomiting, headache
    d. Dizziness

e. Lethargy
f. Inability to sense full bladder
g. Pulmonary edema can occur, causing shortness of breath
h. Respiratory depression

4. Notify physician:
    a. Levels below 5mEq/L or greater than 6mEq/dl
    b. DTRs decreased or absent
    c. Urine output less than 120 ml/4hours
    d. Respirations less than 14 breaths/min or greater than 24
    e. Changes in breath sounds suggestive of pulmonary edema
    f. Changes in LOC
    g. Tachycardia, bradycardia or significant changes in blood pressure from baseline values
5. Fetal/Neonatal effects:
    a. Decreased muscle tone
    b. Respiratory depression
    c. Drowsiness
    d. Low apgar scores when prolonged maternal treatment is used
6. Toxic effects:
    a. DTR depression, followed absence.
    b. Respiratory depression followed by arrest.
    c. Cardiac arrest, arrhythmia, bradycardia, heart block
    d. Death
7. Antidote: Calcium gluconate 1 gram IVP over 3 minutes per physician order
8. For seizures due to eclampsia:
    a. Use prepared 4-6* gm IV loading dose of Magnesium Sulfate. Run in over 20-30 minutes. If using 6 gm bolus run in over 30 minutes. Follow by a 1-2 gm/hour maintenance dose if renal function is normal.
    b. *If patient weighs ≥113 kg or 250 lbs a 6 gram loading dose is required, followed by 2 gm/hour mainteance dose.
    c. One or two minutes after patient should maintain respiratory function and show evidence of muscle relaxation. Should seizure activity continue, give additional 2-4 grams of magnesium sulfate over 5 minutes.
    d. If patient has recurrent seizure after 2nd loading dose of magnesium sulfate, notify physician.
9. Maternal assessment:
    a. When initiating therapy, take temperature, blood pressure, pulse rate, respiratory rate, DTRs and chest assessment prior to initiation of drug.
    b. When giving a bolus, take vital signs every 5 minutes X 15 minutes; remain at the beside to

continuously monitor and record vital signs q 15 minutes for the remainder of the first hour. For the second hour, record every 30 minutes and then hourly monitoring

c. DTRs should be checked every 2 hours or per physician order and as needed, based on maternal signs and symptoms.

d. Monitor uterine activity continuously.

e. Measure intake and output every hours by Foley catheter with urometer, or by strict urine output measurements. If output < 30 ml/hour, reassess Magnesium Sulfate dosage and notify physician.

f. Auscultate chest every 2 hours to R/O lung fluid.

g. Oxygen saturation should be assessed once per hour.

10. Fetal assessment:

a. Continuous fetal monitoring and UC activity if drug is being used for preterm labor.

b. If continuous FHR recording is not done, check FHT with each set of vital signs.

## DOCUMENTATION

Record vital signs in Electronic Health Record (EHR) (including mother's temperature, blood pressure, pulse rate, Sp O2, lung sounds, respiration rate, DTRs and fetal heart rate). Indicate type and dosage of medication on EHR. Chart I&O hourly. Document lung sounds every 2 hours. Document uterine activity.

# REFERENCES:

AWHONN: Perinatal Nursing, 5TH edition, 2021
Gestational Hypertension and Preeclampsia, ACOG Practice Bulletin #222,2020 Hypertensive Disorders of Pregnancy, California Maternal Quality Care Collaborative, 2021

All revision dates: 7/31/2025, 8/14/2024, 1/1/2015, 11/1/2013, 7/1/2010, 3/1/2009, 1/1/2005, 12/1/2001, 12/1/1991

## Attachments

No Attachments

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Medical Staff Committees: Family Medicine & OB | Stephanie Denson: Manager, Medical Staff Office | pending |
| Pharmacy & Therapeutics Committee | Sul Jung: Associate Director of Pharmacy Services | 9/9/2025 |
| Nursing Administration | Sherri Block: Associate Chief Nursing Executive, VCMC & SPH | 7/31/2025 |
| Nursing Administration | Danielle Gabele: Chief Nursing Executive, VCMC & SPH | 7/31/2025 |

| Step Description | Approver | Date |
| --- | --- | --- |
| Policy Owner | Kristina Swaim: Nurse Director, Maternal Child Health | 7/31/2025 |

VENTURA COUNTY HEALTH CARE AGENCY

| | |
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| **Owner:** | *Gwendolyn Vontoure: Director Perioperative Services* |
| **Policy Area:** | *Surgical Services* |
| **References:** | |

# S.30 Fire Safety in the Operating Room

## PURPOSE:

To provide guidance to perioperative personnel for preventing fires during operative and other invasive procedures and responding appropriately if a fire should occur. The expected outcome is that the patient is free from signs and symptoms of injury related to thermal sources.

## POLICY:

~~To provide guidance to perioperative staff for preventing fires during operative and other invasive procedures and responding appropriately if a fire should occur. The expected outcome is that the patient is free from signs and symptoms of injury related to thermal sources.~~

It is the policy of Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH) that:

- A fire risk assessment will be performed before each operative or other invasive procedure using the current Association of periOperative Registered Nurses (AORN) Fire Risk Assessment and Prevention Algorithm (2024).
- Interventions must be implemented for each section of the algorithm with an affirmative response of ("YES") prior to beginning the surgical procedure.
- All perioperative team members are responsible for preventing fires.
- All perioperative team members are responsible for participating in perioperative fire safety education and skills validation.
- Perioperative fire drills will occur quarterly during each shift that the perioperative areas are operational.
- A mock evacuation scenario will occur as one of the fire drills on an annual basis.
- Annually, all members of the perioperative team will be tested on their ability to
  - demonstrate fire extinguishing techniques, including the use of fire extinguishers: Pull, Aim, Squeeze, Sweep (PASS).
  - identify perioperative evacuation routes.
  - identify fire extinguisher locations.
  - locate the medical gas panel and describe its operation and facility-specific staff that will be notified to turn off medical gases in case of an emergency situation; and
  - identify electrical panel locations and describe the facility-specific staff that will be notified to turn off the system.
- When the fire alarm sounds, personnel not directly involved in patient care will report to the team leader.
- The perioperative Registered Nurse (RN) in charge at the time of a fire or fire alarm will make the

decision as to whether to evacuate the perioperative areas. The RN will make this decision in collaboration with the surgeon, anesthesia professional, and, if available, fire department personnel.

# PROCEDURE: INTERVENTIONS

~~It is the policy of Ventura County Medical Center (VCMC)/Santa Paula Hospital (SPH) that:~~

- ~~All perioperative team members are responsible for preventing fires.~~
- ~~All perioperative team members are responsible for participating in perioperative fire safety education and skills validation.~~
- ~~All members of the perioperative team will be tested on their ability to~~
  - ~~demonstrate fire extinguishing techniques, including the use of fire extinguishers;~~
  - ~~identify perioperative evacuation routes;~~
  - ~~identify fire extinguisher locations;~~
  - ~~locate the medical gas panel and describe its operation and the facility-specific procedure for turning off medical gases in case of an emergency situation; and~~
  - ~~identify electrical panel locations and describe the facility-specific procedure for turning off the system.~~
- ~~A fire risk assessment will be performed before each operative or other invasive procedure.~~
- ~~When the fire alarm sounds, staff not directly involved in patient care will report to the team leader.~~
- ~~The perioperative Registered Nurse (RN) in charge at the time of a fire or fire alarm will make the decision as to whether to evacuate the perioperative areas. The RN will make this decision in collaboration with the surgeon, anesthesia professional, and, if available, fire department staff.~~

The following procedures, assessment tools, and interventions will be followed to prevent fire on or in a patient.

# PROCEDURES

- Surgical team members will
  - Survey the flammable materials that may be on or around the patient, including:
    - liquids (~~e.g.~~eg, alcohol-based skin antiseptic),
    - petroleum- or oil-based lubricants or ointments,
    - gases (~~e.g.~~eg, oxygen, methane, anesthetic agents, alcohol vapor),
    - plastics,
    - paper or gauze,
    - surgical drapes,
    - foam positioning devices,
    - adhesive or plastic tapes, and
    - endotracheal tubes.
- ~~The RN circulator will~~
  - ~~Perform a fire risk assessment before the operative or other invasive procedure begins, using the Fire Risk Assessment tool (see below).~~
  - ~~Initiate the actions associated with each of the critical questions that have an affirmative response.~~

  The RN circulator will
  - Perform the Fire Risk Assessment before the surgical procedure
  - Communicate the fire risk score to the team and confirm mitigation measures are in place.
  - Verify completion of fire preventions before incision.
  - Document the fire risk assessment in the electronic health record (EHR).

*Fire Risk Assessment Tool*

- **A: Is an alcohol-based skin antiseptic or other flammable solution being used preoperatively?**
  - Actions:
    - Use reusable or disposable sterile towels to absorb drips and excess solution during application.
    - Remove materials that are saturated with the skin antiseptic agent before draping the patient.
    - Wick excess solution with a sterile towel to help dry the surgical prep area completely.
    - Allow flammable skin antiseptics to dry completely and fumes to dissipate before surgical drapes are applied or using a potential ignition source (e.g., electrosurgical unit [ESU], laser).
    - Conduct a skin prep time out to validate that the skin antiseptic is dry before draping the patient.
    - Allow flammable solutions (e.g., alcohol, collodion, tinctures) to dry completely and fumes to dissipate before using a potential ignition source.
- **B: Is the operative or other invasive procedure being performed above the xiphoid process or in the oropharynx?**
  - Actions:
    - Cover the head and facial hair near the surgical site with water-soluble gel.
    - Use an adhesive incise drape between the surgical site and the oxygen source.
    - Use a laryngeal mask airway or an endotracheal tube when the patient requires supplementary oxygen greater than 30% unless using the tube is contraindicated by the procedure.
    - Inflate the endotracheal tube cuff with tinted solutions (e.g., methylene blue).
    - Pack wet sponges around the back of the throat during surgical procedures involving the airway.
    - Evacuate accumulated anesthetic gas using a metal suction cannula before an ignition source is used in or near an oxygen-enriched environment.
    - Evacuate surgical smoke in small or enclosed spaces (e.g., back of throat) when using electrosurgery or a laser near the endotracheal tube.
    - Suction the oropharynx deeply before using an ignition source if oxygen is used.
    - Check the anesthesia circuits for possible leaks.
- **C: Is open oxygen or nitrous oxide being administered?**
  - Actions:
    - Place drapes, including warming blankets with attached head drapes, over the patient's head in a manner that allows the oxygen to flow freely and not accumulate under the drapes.
    - Deliver 5 to 10 L/min of medical air under the drapes to flush out excess oxygen via a second delivery system.
    - Use the lowest possible concentration of oxygen that provides adequate patient oxygen saturation.
    - Stop supplemental oxygen or nitrous oxide for one minute before using electrosurgery, battery-powered, hand-held cautery units, or lasers for head, neck, or upper chest procedures.
    - Turn off the flow of oxygen at the end of each procedure.
- **D: Is an electrosurgical unit (ESU), laser, or fiber-optic light being used?**
  - Actions—ESU use:
    - Place the ESU in a location that does not put stress on the electrical cord.
    - Keep the electrical cord dry, and free of kinks, knots, and bends.
    - Inspect the ESU cord before use and do not use it if there is any evidence of breaks, nicks, or cracks in the outer insulation coating.

- ~~Keep the active electrode cord free of kinks and coils during use.~~
- ~~Only the person controlling the active electrode activates the ESU.~~
- ~~Use the lowest possible power setting for the ESU.~~
- ~~Store the active electrode in a clean, dry, non-conductive safety holster when it is not in use.~~
- ~~Keep surgical drapes or linens away from the activated ESU.~~
- ~~Moisten drapes (if absorbent), towels, and sponges used near the active electrode tip.~~
- ~~Do not use an ignition source to enter the bowel or the trachea.~~
- ~~Keep the ESU active electrode away from oxygen, nitrous oxide, or combustible anesthetic gas sources if possible.~~
- ~~Do not activate the active electrode in the presence of flammable agents until the agents are dry and vapors have dissipated (e.g., alcohol-based skin antiseptics, tinctures, de-fatting agents, collodion, petroleum-based lubricants, phenol, aerosol adhesives, uncured methyl methacrylate).~~
- ~~Keep the active electrode tip clean.~~
- ~~Use active electrode tips according to the manufacturer's instructions.~~
- ~~Use only active electrodes or return electrodes that are compatible with the ESU.~~
- ~~Seat the active electrode tip securely into the electrosurgical hand piece.~~
- ~~Do not alter the active electrode tip (e.g., bending, using insulation sheaths made from flammable materials such as rubber catheters).~~
- ~~Activate the active electrode only when it is in close proximity to the target tissue and away from other metal objects that could conduct heat or cause arcing.~~
- ~~Inspect minimally invasive electrosurgical instruments for impaired insulation and remove them from service if the insulation is not intact.~~
- ~~Use cut or blend settings instead of coagulation when possible.~~
- ~~Remove the active electrode tip from the electrosurgical hand piece before discarding it.~~
- ~~Remove the batteries or disable the cautery tip before disposing of battery-powered, hand-held cautery units.~~

- ~~Actions – laser use:~~
  - ~~Place the laser in a location that does not put stress on the electrical cord.~~
  - ~~Keep the electrical cord dry and free of kinks, knots, and bends.~~
  - ~~Inspect the laser cord before use and do not use it if there is any evidence of breaks, nicks, or cracks in the outer insulation coating.~~
  - ~~Only the person controlling the laser beam activates the laser.~~
  - ~~Do not activate the laser in the presence of flammable agents until the solutions are dry and vapors have dissipated (e.g., alcohol-based skin prep antiseptics, tinctures, de-fatting agents, collodian, petroleum-based lubricants, phenol, aerosol adhesives, uncured methyl methacrylate).~~
  - ~~Place the laser in standby mode when not in active use.~~
  - ~~Use a laser-resistant endotracheal tube during upper airway procedures.~~
  - ~~Place wet sponges around the endotracheal tube cuff if the laser is being operated in close proximity to the endotracheal tube.~~
  - ~~Fill endotracheal tube cuff with tinted solutions (e.g., methylene blue) during laser procedures involving the patient's airway or aerodigestive tract.~~
  - ~~Keep moist sponges, towels, and drapes around the surgical site for all laser procedures.~~
  - ~~Keep wet towels and saline on the sterile field during all laser procedures.~~
  - ~~Verify that water or saline and the appropriate type of fire extinguisher are immediately available before using the laser.~~

- ~~During perineal surgery, use moistened radiopaque sponges to cover or pack the anus.~~
  - ~~Actions—fiber-optic light use:~~
    - ~~Place the light source in standby mode or turn it off when the cable is not in use.~~
    - ~~Inspect light cables before use and remove them from service if broken light bundles are visible.~~
    - ~~Connect all fiber-optic light cables before activating the light source.~~
    - ~~Place the light source on standby when disconnecting fiber-optic light cables.~~
    - ~~Secure the working end (ie, the end that is inserted into the body) of the endoscope or cord on a moist towel or away from any drapes, sponges, or other flammable materials.~~
- ~~**E: Are there other possible contributors?**~~
  - ~~Actions:~~
    - ~~Select defibrillator paddles that are the appropriate size for the patient.~~
    - ~~Use only manufacturer-recommended lubricants for defibrillator paddles and pads.~~
    - ~~Use appropriate defibrillator paddle placement to allow optimal skin contact.~~
    - ~~Slowly drip saline on a moving drill, burr, or saw blade.~~
    - ~~Place drills or saws on the Mayo stand or back table when they are not in use.~~

~~*Interventions*~~

## Fire Risk Assessment and Prevention Algorithm (AORN, 2024)

- **A: Is an alcohol-based skin antiseptic or other flammable solution being used preoperatively?**
  - If YES, Implement the following interventions:
    - Allow adequate drying time before draping.
    - Avoid pooling or excess fluid under the patient or drapes.
    - Remove saturated materials from the field.
    - Do not drape until the prep is completely dry.
    - Confirm dryness of surgical prep during the "time out.
- **B: Is open oxygen or nitrous oxide being administered and/or is the site above the xiphoid process (head, neck, chest, or oropharynx) ?**
  - If YES, Implement the following interventions:
    - Cover nearby hair with water-soluble gel.
    - Allow oxygen to flow freely under the drapes.
    - Use the lowest oxygen concentration possible.
    - Stop supplemental oxygen/nitrous oxide for one minute before activating ignition sources.
    - Notify the surgeon before activating any ignition source.
- **C: Is an electrosurgical unit (ESU), laser, or fiber optic light being used?**
  - If YES, implement the following interventions:
    - Inspect all cords/cables before use.
    - Use the lowest power setting.
    - Keep ignition sources in standby when not in use.
    - Place instruments on a moist towel or holster.
    - Verify saline or water and a fire extinguisher are available.
    - Only the operator activates the ignition source.
- **D: Are there other possible contributors?**
  - If YES, implement the following interventions:
    - Select defibrillator paddles that are the appropriate size for the patient.
    - Use only manufacturer-recommended lubricants for defibrillator paddles and pads.
    - Use appropriate defibrillator paddle placement to allow optimal skin contact.

        - Slowly drip saline on a moving drill, burr, or saw blade.
        - Place drills or saws on the Mayo stand or back table when they are not in use.
- **E: Are there any other ignition sources (e.g., drills, burrs, saws, defibrillators) being used?**
    - If YES, implement the following interventions:
        - Follow manufacturer's instructions for use.
        - Slowly drip saline on moving drill, burr, or saw blades.
        - Place powered instruments on the Mayo stand or back table when not in use.
        - Verify saline/water and fire extinguishers are readily available.

# Roles and Responsibilities

## Perioperative Team

Participates in the fire-risk assessment, implement preventative measures, and communicate immediately when conditions change (e.g., oxygen concentration, ignition source use).

## Anesthesia Professional

Maintain the lowest feasible fraction of inspired oxygen ($FiO_2$) and nitrous oxide ($N_2O$) concentrations; coordinate gas flow with surgical team; suction or vent oxygen-enriched atmosphere before ignition sources are used; confirm communication during the time-out.

## Surgeon

Use ignition sources only when needed; ensure activation occurs only by the operator; avoid activating ignition sources in oxygen-enriched environments without verbal confirmation from anesthesia; verify extinguishing materials are available on the field.

### *Interventions*

- ~~Prevention of fire on or in equipment~~ **Prevention of fire on or in equipment**
    - Inspect all electrical cords ~~and~~, plugs, and devices for integrity ~~and~~before use; remove ~~them~~ from service if ~~they are broken~~damaged.
    - ~~Check~~Verify biomedical inspection stickers ~~on equipment for currency and remove the equipment from service if they~~ are ~~not~~ current.
    - Keep fluids ~~off~~away from electrical equipment (e.g., ESU, laser).
    - Do not bypass or disable equipment safety features ~~(e~~or audible alarms.~~g., turning audible alarms down).~~
    - ~~Use~~All medical devices must be operated according to the manufacturers~~'~~ instructions for use (IFU).
- ~~Handling a fire on a patient~~ **Handling a Fire on a Patient**
    - Small flames or a small area
        - Alert team members to the presence of the fire on patient.
        - Staff will activate "Code Red"
            - VCMC dial "7-6666"
            - SPH dial "7-8666"
                - House Supervisor will respond to all Code Red Activations
                    - Traffic Control: allowing only essential personnel, [Cover-Jumpsuits]
                    - Coordination of additional resources
        - Pour water or normal saline on the fire slowly to prevent spreading and to extinguish the fire, if it can be accomplished safely.

        - Lay a wet towel or sponge over the flame, place one arm over the end of the towel nearest the patient's head, and sweep the other arm over the towel and toward the patient's feet.
        - Lift the material used to smother the flame to vent heat.
        - Remove burning material from the patient.
        - Assess the surgical field for a secondary fire on the underlying drapes or towels.
        - Assess the patient for injuries and report to the physician.
        - Activate alarms if necessary.
        - Notify perioperative managers and administrative ~~staff.~~personnel per VCMC and SPH policy
    - Large ~~flames or a large area~~Flames or a Large Area
        - Alert team members to the presence of the fire.
        - Staff will activate "Code Red"
            - VCMC dial "7-6666"
            - SPH dial "7-8666"
                - House Supervisor will respond to all Code Red Activations
                    - Traffic Control: allowing only essential personnel, [Cover-Jumpsuits]
                    - Coordination of additional resources
        - Communicate with the anesthesia professional to stop the flow of anesthetic gases to the patient, and disconnect the breathing circuit from the anesthesia machine.
        - If a drape is involved, remove it to the ground and roll it on itself to smother the fire.
        - Avoid moving the drape into what may be an evacuation route for the people in the ~~OR~~operating room (OR) or other procedure room.
        - Assess the surgical field for a secondary fire on the underlying drapes or towels.
        - Assess the patient for injury and report injuries to the physician.
        - Verify the flames are extinguished and use a fire extinguisher if necessary.
            - Employ the PASS technique when using a fire extinguisher:
                - Pull the pin
                - Aim at the base of the fire
                - Squeeze the handle
                - Sweep from side to side
        - Activate alarms if necessary.
        - Notify perioperative managers and administrative ~~staff~~personnel per VCMC & SPH policy
- ~~Handling a fire in a patient~~ **Handling a Fire in a Patient**
    - Alert team members to the presence of the fire on or in the patient.
    - Staff will activate "Code Red"
        - VCMC dial "7-6666"
        - SPH dial "7-8666"
            - House Supervisor will respond to all Code Red Activations
                - Traffic Control: allowing only essential personnel, [Cover-Jumpsuits]
                - Coordination of additional resources
    - Consult with the anesthesia professional to determine the necessary actions to take to extinguish an airway fire.
    - Assist the anesthesia professional with ~~disconnecting and removing the anesthesia circuit,~~;
        - disconnecting and removing the anesthesia circuit,
        - turning off the flow of oxygen,
        - removing the endotracheal tube and any segments of the burned tube that remain in the airway,
        - pouring saline or water into the airway if instructed,
        - re-establishing the airway, and

        - examining the airway.

    ~~turning off the flow of oxygen,~~

    ~~removing the endotracheal tube and any segments of the burned tube that remain in the airway,~~

    ~~pouring saline or water into the airway if instructed,~~

        - ~~re-establishing the airway, and~~
        - ~~examining the airway.~~
    - Assess the surgical field for a secondary fire on the underlying drapes or towels.
    - Assess the patient for injury and report injuries to the physician.
    - Activate alarms if necessary.
    - Notify perioperative management and administrative ~~staff~~personnel per VCMC & SPH policy.
- ~~Handling a fire on a piece of equipment~~ **Handling a Fire on a Piece of Equipment**
    - Alert team members to the presence of the fire.
    - Staff will activate "Code Red"
        - VCMC dial "7-6666"
        - SPH dial "7-8666"
            - House Supervisor will respond to all Code Red Activations
                - Traffic Control: allowing only essential personnel, [Cover-Jumpsuits]
                - Coordination of additional resources
    - Disconnect equipment from its electrical source.
    - Shut off the electricity to the piece of equipment at the electrical panel if it is not possible to remove the plug from the outlet.
    - Shut off gases to equipment, if applicable.
    - Assess the size of the fire and determine whether equipment can be removed from the OR or other procedure room safely or if the room needs to be evacuated.
    - Extinguish the fire using a fire extinguisher if appropriate.
    - Activate alarms if necessary.
    - Notify perioperative managers and administrative ~~staff~~personnel per VCMC & SPH policy.
- ~~Handling a fire in another area of the building~~ **Handling a Fire in Another Area of the Building**
    - The RN in charge at the time of the fire or fire alarm will notify all operating and procedure room ~~staff~~personnel of the presence of the fire in another area of the building.
    - No elective cases will be started.
    - Perioperative ~~staff~~personnel will prepare to evacuate.
- ~~Evacuation~~ **Evacuation**
    - Follow the RACE protocol:
        - **R** escue
            - Determine the best method to remove the patient (~~e.g.~~eg, procedure bed, gurney, carry) from the area.
            - Determine the safest location to receive the patient (~~e.g.~~eg, behind smoke barriers).
            - Call for assistance.
            - Remove the patient and ~~staff~~personnel from the room containing the fire or smoke.
        - **A** larm
            - Communicate to all ~~staff~~personnel in the perioperative areas, especially staff in the adjoining rooms.
            - Follow ~~Administrative policy **106.003**~~ Administrative policy 106.003 for activating the alarm system.
            - Call the local fire department if necessary.
        - **C** ontain

        - Close the doors to the involved room.
        - Shut off medical gases to the involved room, per VCMC & SPH policy.
        - Turn off electricity to the involved room, per VCMC & SPH policy.
    - **E** vacuate
        - *When:* When a danger is posed to patients in adjoining areas because of fire or smoke.
        - *Where* : Transfer the patients to a designated area that is beyond the first set of smoke barriers, and then to an area where the operative or other invasive procedure may be completed safely.
        - *How:* Transfer patients by moving procedure beds with the patients remaining on the bed, by using gurneys, or by carrying them.

~~*Other Interventions*~~ **Other Interventions**

- Save all items that are involved in the fire to facilitate the investigation.
- Provide all items that are involved in the fire to quality/risk management ~~staff~~personnel.

## ~~Documentation~~

# Documentation

Documentation will be completed to demonstrate compliance with local, state, and federal regulations.

- Document the fire risk assessment score and the time the assessment was performed.
- Document the fire according to ~~**Administrative policy 107.023 (Adverse events)**~~ **Administrative policy 107.023 (Adverse events)** and local authority regulations.

## ~~Competency~~

# Competency

Perioperative ~~staff~~personnel will receive education and complete verification activities on the principles and processes of fire prevention and management in the perioperative areas.

## ~~Quality~~

# Quality

Perioperative ~~staff~~personnel will participate in quality assurance and performance improvement activities related to fire prevention and management in the perioperative areas.

## ~~References~~

~~*NFPA 101: Life Safety Code* . Quincy, MA: National Fire Protection Association; 2012.~~

## FIRE RESPONSE PLAN

- Staff Activates Code Red
  - VCMC "7-6666"
  - SPH "7-8666"
- House Supervisor Responds to All Code Red Activations
  - Traffic Control: Only essential personnel [covered jumpsuits]
  - Coordination of additional resources

### Fire On a Patient

**Small Flames or a Small Area:**
Team members announce, "Fire on patient".

**Surgical Team**

- Pour water or normal saline on the fire slowly to prevent spreading and to extinguish the fire, if this can be accomplished safely
- Perform Sheet Sweet method: Lay a wet towel or sponge over the flame, place one arm over the end of the towel nearest the patient's head and sweep the other arm over the towel and toward the patient's feet.
- Lift the material used to smother the flame to vent heat.
- Remove burning material from the patient.
- Assess the surgical field for a secondary fire on the underlying drapes or towels
- Assess the patient for injuries.

**Large Flames or a Large Area:**

- Announce "Fire"

**Anesthesia Professional**

- Anesthesia professional to stop the flow of anesthetic gases to the patient and disconnect the breathing circuit from the anesthesia machine.

**Surgical Team**

- If a drape is involved, remove it to the ground and roll it on itself to smother the fire.
- Avoid moving the drape into what may be an evacuation route for the people in the OR or other procedure room.
- Assess the surgical field for a secondary fire on the underlying drapes or towels.
- Assess the patient for injury.
- Verify the flames are extinguished and use a fire extinguisher if necessary.
- Employ the **PASS** technique when using a fire extinguisher:
- Pull the pin. ♣ Aim at the base of the fire. ♣ Squeeze the handle. ♣ Sweep from side to side
- Activate 911

### Fire on or in an Endotracheal Tube (ET)

- Team members announce, "Fire ET Tube".
- **Anesthesia professional** to determine the necessary actions to take to extinguish an airway fire:
  - Disconnecting and removing the anesthesia circuit
  - Turning off the flow of oxygen
  - Removing the endotracheal tube and any segments of the burned tube that remain in the airway
  - Pouring saline or water into the airway
  - Re-establishing the airway
  - Examination of the airway
- Assess the surgical field for a secondary fire on the underlying drapes or towels. • Assess the patient for injury.

### Fire on or In Equipment

- Team members announce, "Fire on patient".
- Disconnect equipment from its electrical source
- Shut off electricity to the piece of equipment at the electrical panel if it is not possible to remove the plug from the outlet
- Shut off gases to equipment, if applicable
- Assess the size if the fire and determine whether equipment can be removed from the OR or Procedure Room safely or if the room needs to be evacuated
- Extinguish the fire using a fire extinguisher if appropriate
- Isolate the room and call 911 if the fire is not quickly extinguished

**Evacuation of a Patient: RACE Protocol**

Rescue:

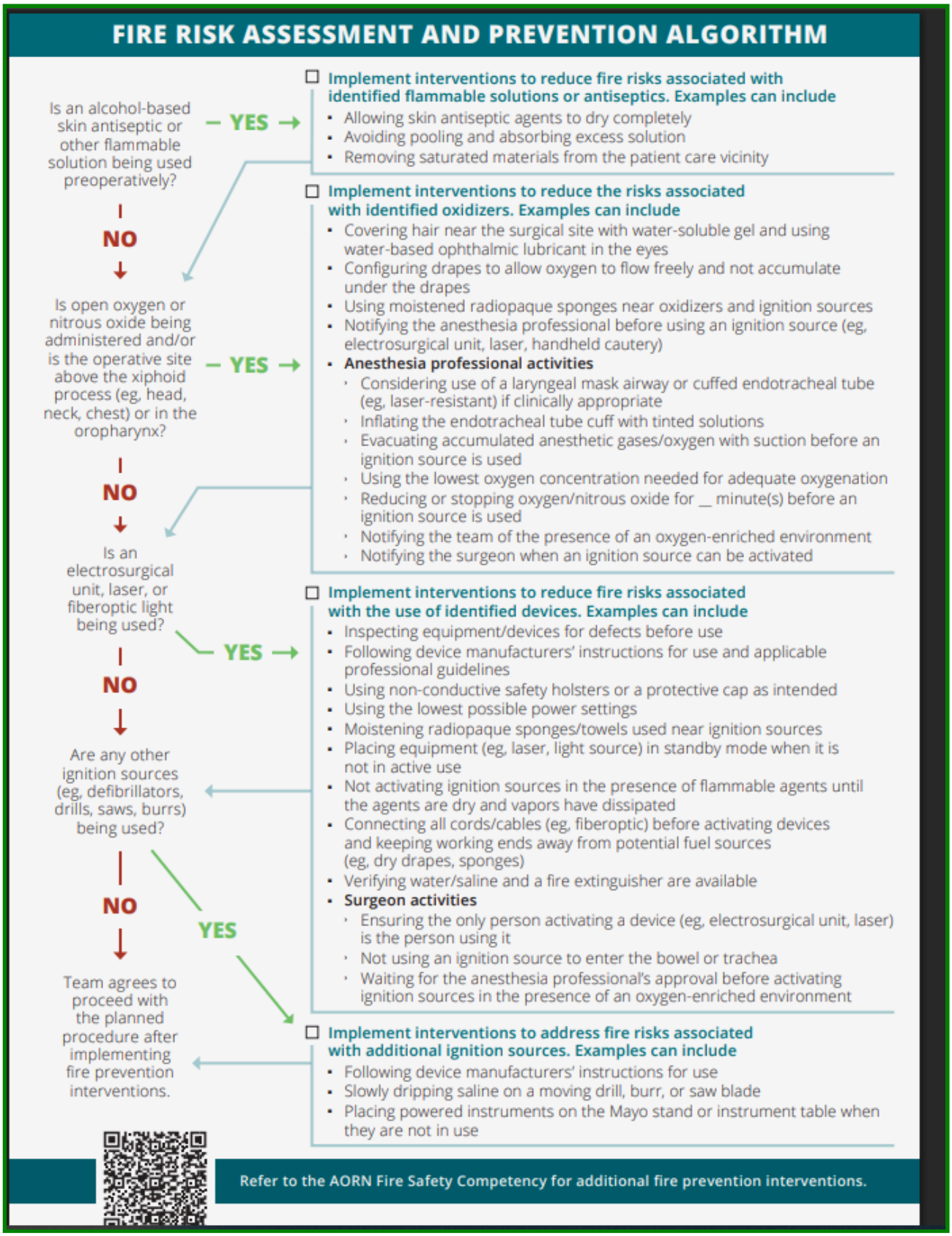
- Detetrmine the best method to remove the patient (procedure bed, gurney, cary from the aeaa
- Determine the safest location to receive the patient (behind smoke barriers
- Call for assistance
- Remove the patient and personnel from the room containing the fire or smoke

Alarm

- Communicate to all personnel in the perioperative areas
- Call 911
- Contain
- Close doors to the involved room
- Shut off Medical Gases to the involved room
- Turn off electricity to the involved room

Evacuate:
When: Danger is posed to patients in adjoining areas because of fire or smoke
Where
Transfer the patients to a designated area that is beyond the first se of smoke barriers, to an area where operative or other invasive procedure may be completed safeely
How
Transfer patients by moving procedure beds with the patients remaining on the bed, gurneys or by carrying them.

# Fire Risk Assessment And Prevention Algorithm



# Note

- Anesthesia and Respiratory Therapy to direct Emergency Gas Shut Off.
- Save all fire-involved materials and devices.
- Last person out of the room, closes the door, marks with "X" to alert fire personnel that the room is clear; do not reopen door.

# References


Association of periOperative Registered Nurses. (2024, January). *Fire-Prevention algorithm* [PDF]. https://www.aorn.org/docs/default-source/tool-kit-documents/fire-safety/cognitive-aids/fire-prevention-algorithm-011624.pdf?sfvrsn=8e8fcd63_3

National Fire Protection Association. (2012). *NFPA 101: Life safety code*. Quincy, MA: Author.

Petersen, C~~,~~. (Ed.). (2011). Thermal injury. In *Perioperative nursing data set* (3rd ed. ~~Thermal injury~~, pp. ~~In: *Perioperative Nursing Data Set*~~ 139–145). ~~3rd ed.~~ Denver, CO: AORN, Inc.~~; 2011:139-145.~~

~~Guideline for a safe environment of care, part I~~Association of periOperative Registered Nurses. ~~In: *Guidelines for Perioperative Practice*~~ (n.d.). *Guideline for a safe environment of care, part I.* In *Guidelines for perioperative practice.* Denver, CO: ~~AORN, Inc.~~Author


All revision dates: 12/2/2025, 10/4/2022, 8/10/2022, 10/1/2016

## Attachments

No Attachments

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Surgery Committee | Stephanie Denson: Manager, Medical Staff Office | pending |
| Nursing Administration | Danielle Gabele: Chief Nursing Executive, VCMC & SPH | 11/6/2025 |
| Nursing Administration | Sherri Block: Associate Chief Nursing Executive, VCMC & SPH | 11/6/2025 |
| Surgical Services | Gwendolyn Vontoure: Director Perioperative Services | 11/6/2025 |

VENTURA COUNTY HEALTH CARE AGENCY

| | |
|---|---|
| **Origination:** | *7/1/1997* |
| **Effective:** | *Upon Approval* |
| **Last Approved:** | *N/A* |
| **Last Revised:** | *7/25/2023* |
| **Next Review:** | *3 years after approval* |
| **Owner:** | *Gwendolyn Vontoure: Director Perioperative Services* |
| **Policy Area:** | *Surgical Services* |
| **References:** | |

# S.46 Patient Boarding Criteria in the Post-Anesthetic Care Unit (PACU)

## POLICY:

Ventura County Medical Center/Santa Paula Hospital will hold patients in the PACU at the discretion of the nursing supervisor when warranted by census or patient acuity.

## PROCEDURE:

A. Patients who require a bed when none is available may be housed in the PACU.

B. Staffing shall be in accordance with established acuity ratios and all efforts will be made by the receiving department to provide the necessary staff.

C. Additional registered nurse (RN) staff will be provided so "boarded" patients and PACU patients have ~~separate, appropriate staff present~~adequate staffing within mandated staffing ratios. Assigned RNs will have competency demonstrated in the care of the assigned patients.

~~There shall be two staff members present at all times when patients are being boarded. One staff member shall be a RN, and the other may be a RN, respiratory therapist (RT), or certified nurse assistant (CNA).~~

D. The Operating Room staff shall be aware of the number of boarders in the PACU.

E. The Evening and Night nursing supervisors shall make rounds a minimum of every four (4) hours.

F. The boarded patients shall have priority in obtaining an open bed, based upon overall acuity of patients waiting for an inpatient/cardiac care unit (CCU) bed.

G. Nursing hours spent boarding patients will be charged to the appropriate nursing unit (i.e., Med/Surg, CCU, etc.).

All revision dates: 7/25/2023, 2/18/2020, 7/1/2006, 1/1/2005

## Attachments

No Attachments

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Surgery Committee | Stephanie Denson: Manager, Medical Staff Office | pending |
| Nursing Administration | Danielle Gabele: Chief Nursing Executive, VCMC & SPH | 11/6/2025 |
| Nursing Administration | Sherri Block: Associate Chief Nursing Executive, VCMC & SPH | 11/6/2025 |
| Surgical Services | Gwendolyn Vontoure: Director Perioperative Services | 11/6/2025 |

VENTURA COUNTY HEALTH CARE AGENCY

| | |
|---|---|
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| **Last Revised:** | *12/2/2025* |
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| **Owner:** | *Gwendolyn Vontoure: Director Perioperative Services* |
| **Policy Area:** | *Surgical Services* |
| **References:** | |

# S.79 Surgical Site Hair Removal

# POLICY:

~~When hair removal is part of the preoperative preparation, staff will use clippers to remove hair at the intended operative site.~~

Hair at the surgical site should be left in place unless indicated based upon individualized patient assessment in which it is determined the hair will interfere with the procedure, wound closure, dressing adhesion, or creates a fire risk. When hair removal is necessary, it must be performed using clippers or depilatory methods that minimize skin injury, in accordance with Association of periOperative Registered Nurses (AORN) guidelines; Razors are prohibited.

# Purpose:

The purpose of this policy ist to minimize the risk of surgical site infections (SSI) and skin trauma, using evidence based practices for surgical site hair removal.

# PROCEDURE:

It is the policy of **Ventura County Medical Center and Santa Paula Hospital** that the perioperative registered nurse (RN) will, whenever possible, leave hair at the surgical site. Hair should only be removed per a physician's order.

## General Guidelines:

1. Leave hair in place unless its presence interferes with the procedure, wound closure,dressing adhesion, or creates a fire risk with the use of alcohol-based antiseptics.
2. An individualized patient assessment should be performed to determine the need for hair removal
3. When hair removal is indicated, remove only the minimum amount of hair necessary, using clippers or depilatory methods to minimize the risk of skin injury.
4. As close to the time of surgery as possible, use clippers to remove hair from the surgical site in Pre-op department (preoperative bay) before entering the operating room or procedure room.
5. Never shave the patient's face or eye brows or cut eye lashes unless per physician order.
6. When removing hair outside the operating or procedure room is contraindicated due to necessary intraoperative image guided surgical site planning, or sensitivity of the area, remove the patient’s hair in a

manner that prevents hair dispersal into the air.

7. Clip hair in the direction of hair growth.
8. Hold the skin taut while clipping to avoid pulling or nicking the skin.
9. Use electric clippers with disposable blades only. Do not use wet or dry shave single-blade razors.
10. Never use razors for surgical hair removal.
11. Avoid hair removal near flammable antiseptic agents until fully dry.

## Procedure Interventions:

Clip Prep:

1. Confirm hair removal is indicated and ordered, and that assessment findings support hair removal.
2. Assemble necessary supplies and equipment, i.e., clippers, single-use clipper blades and towels.
3. Identify yourself to the patient and explain the procedure to the patient.
4. Verify identification of the patient using two (2) patient identifiers and the correct surgical site.
5. Don gloves.
6. Properly drape the patient, exposing only the area to be clipped. If the entire body is to be clipped, only expose one area at a time (e.g., arm, leg, chest, abdomen), respecting the dignity of the patient by providing as much privacy as possible.
7. Remove the clipper blade from the package and place on the clippers.
8. Perform clip prep, keeping the skin taut and clipping the hair in the direction of hair growth, taking care to avoid skin trauma.
9. Rinse skin using a wet cloth to remove any loose hair.
10. Carefully remove the drape, catching and removing as much loose hair as possible.
11. Remove the clipper blade and dispose in the sharps container.
12. Between patients, disinfect all non-disposable items used in hair removal per manufacturer's instructions.

## Documentation:

The perioperative RN will document the clipper prep site in the electronic health record.

## Performance Improvement:

Perioperative RNs performing hair removal will participate in quality assurance and performance improvement activities related to infection control and prevention of surgical site infections.

**Resource:** Guideline for preoperative skin antisepsis. . (2019). In R. Conner (Ed.). *Guidelines for perioperative practice, 2019 edition*. Denver, CO: AORN, Inc. (Level VII)

All revision dates: 12/2/2025, 12/12/2019, 8/13/2019, 6/1/2016, 12/1/2013, 11/1/2010, 11/1/1996, 2/1/1996, 4/1/1992, 11/1/1990

## Attachments

No Attachments

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Surgery Committee | Stephanie Denson: Manager, Medical Staff Office | pending |
| Nursing Administration | Danielle Gabele: Chief Nursing Executive, VCMC & SPH | 11/6/2025 |
| Nursing Administration | Sherri Block: Associate Chief Nursing Executive, VCMC & SPH | 11/6/2025 |
| Surgical Services | Gwendolyn Vontoure: Director Perioperative Services | 11/6/2025 |

# Delineation Of Privileges

Medicine Privilege List

Name:

| Privilege | Requested | Granted |
|---|---|---|
| CATEGORY 1: This category includes those physicians who have successfully completed not less than three (3) years of approved residency training in Internal Medicine, Family Practice or equivalent sub-specialty training appropriate to clinical practice. These physicians should be either board certified or board admissible in their specialty area.<br><br>Such physicians should seek consultations when:<br>a. diagnosis and/or management remain in doubt over an unduly long period of time, especially in the presence of a life-threatening illness;<br>b. unexpected complications arise which are outside their level of competence;<br>c. specialized treatment or procedures are contemplated with which they are not familiar<br><br>Specific area in which privileges are requested: | ___ | ___ |
| Dermatology | ___ | ___ |
| Internal Medicine | ___ | ___ |
| Neurology | ___ | ___ |
| CATEGORY 2: This category includes those physicians who have successfully completed not less than three (3) years of graduate medical education in an approved internal medicine residency, and in addition, are considered sub-specialists in that they have additional education and a high level of competence in a given field or equivalency. They are qualified to act as consultants and should, in turn, request consultation whenever needed. These physicians must be either board certified or board admissible in their sub-specialty area.<br><br>Sub-specific area in which privileges are requested: | ___ | ___ |
| Allergy/Immunology | ___ | ___ |
| Cardiology | ___ | ___ |
| Endocrinology & Metabolic Diseases | ___ | ___ |
| Gastroenterology | ___ | ___ |
| Geriatric Medicine | ___ | ___ |
| Hematology | ___ | ___ |
| Infectious Diseases | ___ | ___ |
| Nephrology | ___ | ___ |
| Oncology | ___ | ___ |
| Pulmonary Diseases | ___ | ___ |
| Rheumatology | ___ | ___ |
| Other: _____ | ___ | ___ |
| CATEGORY 1 PRIVILEGES: | | |
| Admit patients to the hospital; includes history and physical examination | ___ | ___ |
| Treat patients in the hospital, Emergency Department & outside clinics | ___ | ___ |
| Osteopathic Manipulative Treatment (OMT) | ___ | ___ |
| Laser Tattoo Removal<br>INITIAL CRITERIA: Documentation of 1 hour training with dermatologist | ___ | ___ |
| Consultations only | ___ | ___ |

# Delineation Of Privileges

Medicine Privilege List

Name:

| Privilege | Requested | Granted |
|---|---|---|
| **Adult Moderate or Deep Sedation and Analgesia**<br>Initial Criteria:<br>a. Current ACLS<br>b. Completion of Sedation Module (minimum score of 80%)<br><br>Evaluation Criteria:<br>A minimum of 3 cases evaluated<br><br>Renewal Criteria:<br>a. Current ACLS<br>b. Completion of Sedation Module (minimum score of 80%)<br>c. A minimum of 6 cases within the previous 24 months<br>- If the volume is not met, the next case evaluated | ___ | ___ |
| Adult deep sedation in the ICU/CCU/Interventional Radiology **(Request on Critical Care/Radiology Privileges)**<br>INITIAL & RENEWAL CRITERIA:documentation of current ACLS, module completion w/minimum score of 80% | ___ | ___ |
| Bone marrow aspiration | ___ | ___ |
| Bone marrow biopsy | ___ | ___ |
| Abdominal paracentesis | ___ | ___ |
| Lumbar puncture | ___ | ___ |
| Arthrocentesis | ___ | ___ |
| Fine needle aspiration biopsy of thyroid | ___ | ___ |
| Insert central venous catheter | ___ | ___ |
| Insert arterial catheter | ___ | ___ |
| Insert thoracostomy tubes | ___ | ___ |
| Post gastric feeding tube placement | ___ | ___ |
| Percutaneous aspiration of organ, mass lesion, arterial venous cannulization, including PICC placement with fluoroscopy/CT or ultrasound | ___ | ___ |
| Suprapubic bladder taps | ___ | ___ |
| Thoracentesis | ___ | ___ |
| Venous cutdowns | ___ | ___ |
| I & D – abscesses, cysts and hematomas | ___ | ___ |
| Culdocentesis | ___ | ___ |
| Direct laryngoscopy | ___ | ___ |
| Flexible sigmoidoscopy | ___ | ___ |
| Rigid sigmoidoscopy | ___ | ___ |
| Endotracheal intubation | ___ | ___ |
| Monopolar hemorrhoid management | ___ | ___ |
| Parenteral hyperalimentation | ___ | ___ |

# Delineation Of Privileges

Medicine Privilege List

Name:

| Privilege | Requested | Granted |
|---|---|---|
| ~~Admit and treat patients in the ICU/CCU~~ **~~(Request on new Critical Care Privileges)~~**<br>~~EVALUATION CRITERIA: Refer to ICU Focused Professional Practice Evaluation criteria~~ | ___ | ___ |
| Consult and treat patients in the ICU | ___ | ___ |
| Resuscitation and stabilization of SPH critical patients pending transfer to a higher level of care to include but not limitedto ventilator management, management of vasopressors and sedative drips, management of arrhythmias, shock andother emergent case | ___ | ___ |
| Bedside ultrasound in urgent or emergent conditions<br>(Refer to *Screening ultrasound by ICU Physicians*) | ___ | ___ |
| Management of patients in respiratory failure requiring ventilator assistance for less than 48 hours | ___ | ___ |
| Admit patients for observation of suspected cardiac disease | ___ | ___ |
| Management of uncomplicated myocardial infarctions | ___ | ___ |
| Management of chemotherapy | ___ | ___ |
| WAIVED TESTING | | |
| Rapid STREP A Test | ___ | ___ |
| Amnio Test | ___ | ___ |
| Dipstick for Urine | ___ | ___ |
| Urine Pregnancy Test | ___ | ___ |
| Fecal Occult Blood by Hemoccult | ___ | ___ |
| PROVIDER-PERFORMED MICROSCOPY (PPM)<br>CRITERIA: Annual competence assessment required | | |
| Wet mount for presence/absence of bacteria, fungi, parasites and human cellular elements; KOH preparations, urine sediment examinations | ___ | ___ |
| PERFORM AND INTERPRET THE FOLLOWING CARDIAC NON-INVASIVE STUDIES: | | |
| ECG | ___ | ___ |
| Treadmill Stress Test | ___ | ___ |
| Holter ECG | ___ | ___ |
| DERMATOLOGY PROCEDURES | | |
| Cryosurgery | ___ | ___ |
| Skin biopsies | ___ | ___ |
| FLUOROSCOPY PROCEDURES FOR:<br>CRITERIA: Fluoroscopy certificate required, | | |
| Gastrointestinal Procedures | ___ | ___ |
| Cardiac Procedures | ___ | ___ |
| Pulmonary Procedures | ___ | ___ |
| **CATEGORY 2 PRIVILEGES:** | | |

# Delineation Of Privileges

Medicine Privilege List

Name:

| Privilege | Requested | Granted |
|---|---|---|
| PERFORM AND INTERPRET THE FOLLOWING CARDIAC NON-INVASIVE STUDIES: | | |
| Echocardiogram with/without intravenous saline contrast | ___ | ___ |
| Perform and interpret neurologic non-invasive graphic studies<br>CRITERIA: must be proficient in EEG, EMG and nerve conduction velocity studies | ___ | ___ |
| Angiography | ___ | ___ |
| Insert Swan-Ganz flotation catheter | ___ | ___ |
| Pericardiocentesis | ___ | ___ |
| Elective Cardioversion | ___ | ___ |
| Placement of transvenous temporary pacemakers | ___ | ___ |
| Placement of transcutaneous temporary pacemakers | ___ | ___ |
| Pleural biopsy | ___ | ___ |
| Lung biopsy | ___ | ___ |
| Kidney biopsy | ___ | ___ |
| Liver biopsy | ___ | ___ |
| Bronchoscopy with/without biopsy | ___ | ___ |
| Esophagogastroduodenoscopy with/without biopsy<br>CRITERIA: must request Adult Procedural Sedation, complete module & submit documentation of current ACLS | ___ | ___ |
| Colonoscopy with/without biopsy<br>CRITERIA: must request Adult Procedural Sedation, complete module & have current ACLS | ___ | ___ |
| Polypectomy | ___ | ___ |
| ERCP with/without biopsy<br>CRITERIA: Current Fluoroscopy certificate required | ___ | ___ |
| ERCP with/without spincterotomy<br>CRITERIA: Current Fluoroscopy certificate required | ___ | ___ |
| Esophageal dilation | ___ | ___ |
| Endoscopic Ultrasound | ___ | ___ |
| pH Probe placement and interpretation | ___ | ___ |
| Peritoneoscopy | ___ | ___ |
| Percutaneous endoscopic gastrostomy (PEG) | ___ | ___ |
| Esophageal manometry with interpretation | ___ | ___ |
| Management of patients in respiratory failure requiring assisted ventilation greater than 48 hours<br>CRITERIA: must be able to perform endotracheal intubations and insert chest tubes | ___ | ___ |
| Management of peritoneal dialysis in patients with renal failure | ___ | ___ |
| Management of hemodialysis inpatients with renal failure | ___ | ___ |

# Delineation Of Privileges

Medicine Privilege List

Name:

| Privilege | Requested | Granted |
|---|---|---|
| Management of plasmapheresis in patients requiring plasmapheresis | ___ | ___ |
| Manage complicated cardiac arrhythmias<br>CRITERIA: Elective cardioversion & temporary pacemaker placement privileges required | ___ | ___ |
| Manage cardiogenic shock and/or severe heart failure | ___ | ___ |
| **ACKNOWLEDGEMENT OF PRACTITIONER:**<br>*I have requested only those privileges for which, by education, training, current experience and demonstrated performance, I am qualified to perform, and that I wish to exercise at the Ventura County Medical Center, Santa Paula Campus Hospital and/or with the VCMC Ambulatory Care System. I understand that exercising any clinical privileges granted, I am constrained by hospital and medical staff policies and rules applicable generally and any applicable to the particular situation. I am willing to provide documentation of my current competence for the requested privileges.*<br>Applicant's electronic signature on file<br><br>**TEMPORARY PRIVILEGE APPROVAL**<br><br>Department Chief's Signature: _____ Date: _____<br><br>Evaluator Assignment: _____<br><br>**[ ] PROVISIONAL [ ] RENEWAL APPROVAL**<br><br>_____<br>Chief, Department of Medicine Date | | |

Ventura County Medical Center

# Delineation Of Privileges

Pediatrics Privilege Checklist

Name:

| Privilege | Requested | Granted |
|---|---|---|
| **PEDIATRIC CATEGORIES:**<br>Please check the category which best describes your level of expertise and training | | |
| CATEGORY C:<br>Privileges usually granted to non-pediatrician specialty consultants who, in the opinion of the attending physician and Chief of Pediatrics, are capable of performing diagnostic consultations and/or specialty services urgently needed in the care of a critically ill patient or one with a diagnostic problem. | ___ | ___ |
| CATEGORY S:<br>For those individuals who perform temporary services as contract physicians, providing care within the hospital. Current training must be commensurate with the category/class for which they would normally apply. | ___ | ___ |
| CATEGORY 1:<br>Illness or problem requiring skills usually acquired after one year of pediatric training or the equivalent in experience. | ___ | ___ |
| CATEGORY 2:<br>Complex or severe illness or potentially life-threatening problems usually requiring skills acquired after pediatric training sufficient for board eligibility/certification or the equivalent in experience.(Includes requirements as outlined in Category 1.) | ___ | ___ |
| CATEGORY 3:<br>Intensive care of children including ventilator care and advanced life support.(Includes requirements as outlined in Category 2.) | ___ | ___ |
| CATEGORY 4:<br>Illness or problem requiring expertise acquired only during subspecialty training or similar experience. (This category does not necessarily include all others. Please check other categories desired.) | ___ | ___ |
| **NEONATAL CATEGORIES:**<br>Please check *one* class which best describes your level of expertise and training | | |
| CLASS A:<br>(For those requesting category 1.) Normal care of newborn infants greater than 2,000 grams. | ___ | ___ |
| CLASS B:<br>(For those requesting category 2 or 3.)Care of preterm or low birth-weight infants with non-life threatening illness and not requiring special care nursery or intensive care nursery status. Board certification or board eligibility with certification achieved within four (4) years of obtaining initial privileges in neonatology or pediatrics.(Includes class A.) | ___ | ___ |
| CLASS C:<br>(For those requesting category 2 or 3.) Care of all newborn infants, including those with potentially life-threatening illnesses but excluding ventilator care and advanced life support aspects. Board certification or board eligibility with certification achieved within four (4) years of obtaining initial privileges in neonatology. (Includes class A.) | ___ | ___ |
| CLASS D:<br>Neonatology intensive care of all newborn infants, including ventilator advanced life support. Board certification or board eligibility with certification achieved within four (4) years of obtaining initial privileges in neonatology. (Includes class A, B, C.) Evidence of successful completion of NRP course by the AAP or AHA. | ___ | ___ |
| **CHECK PRIVILEGES REQUESTED** | | |
| Admit and treat patients to the hospital, ER and outside clinics | ___ | ___ |
| Consultations | ___ | ___ |
| Laser Tattoo Removal<br>(Documentation of 1 hour training with dermatologist required) | ___ | ___ |
| Venous Access | ___ | ___ |
| Arterial Access | ___ | ___ |
| Arterial Lines | ___ | ___ |

# Delineation Of Privileges

Pediatrics Privilege Checklist

Name:

| Privilege | Requested | Granted |
|---|---|---|
| **WAIVED TESTING** | | |
| Rapid STREP A Test | ___ | ___ |
| Amnio Test | ___ | ___ |
| Dipstick for urine | ___ | ___ |
| Urine pregnancy test | ___ | ___ |
| Fecal occult blood by *Hemoccult* | ___ | ___ |
| **PROVIDER-PERFORMED MICROSCOPY (PPM)** | | |
| Wet mount for presence/absence of bacteria, fungi, parasites and human cellular elements; KOH preparations, urine sediment examinations - **Annual competence assessment required* | ___ | ___ |
| Pinworm examination - **Annual competence assessment required* | ___ | ___ |
| **SURGICAL PROCEDURES** | | |
| Nasal cautery for recurrent nosebleeds - * A minimum of 1 case evaluated | | |
| Partial nail removal for ingrown toenails - * A minimum of 1 case evaluated | | |
| Venipuncture | ___ | ___ |
| Laceration Repair | ___ | ___ |
| Incision and drainage of superficial abscesses | ___ | ___ |
| Neonatal circumcisions<br>Mogen Clamp- evaluate 1<br>Gomco – evaluate 1 | ___ | ___ |
| Myringotomy | ___ | ___ |
| Simple fractures and dislocations<br>(One procedure to be evaluated) | ___ | ___ |
| Exchange transfusions | ___ | ___ |
| Removal of foreign bodies | ___ | ___ |
| Umbilical vein catheterizations | ___ | ___ |
| Umbilical artery catheterizations | ___ | ___ |
| Venous cutdowns | ___ | ___ |
| Endotracheal intubations | ___ | ___ |

# Delineation Of Privileges

Pediatrics Privilege Checklist

Name:

| Privilege | Requested | Granted |
|---|---|---|
| Pediatric Procedural Sedation<br><br>Initial Criteria:<br>a. Current PALS (NICU Providers only require NRP)<br>b. Completion of Sedation Module (minimum score of 80%)<br><br>**Evaluation Criteria:** A minimum of 3 cases evaluated<br><br>Renewal Criteria:<br>a. Current PALS (NICU Providers only require NRP)<br>b. Completion of Sedation Module (minimum score of 80%)<br>c. A minimum of 6 cases within the previous 24 months<br>- If volume not met, the next case evaluated | ___ | ___ |
| Thoracentesis & Chest tube placements<br>(One procedure to be evaluated) | ___ | ___ |
| Subdural taps<br>(One procedure to be evaluated) | ___ | ___ |
| **DIAGNOSTIC PROCEDURES** | | |
| Lumbar punctures | ___ | ___ |
| Bladder taps<br>(One procedure to be evaluated) | ___ | ___ |
| Arthrocentesis<br>(One procedure to be evaluated) | ___ | ___ |
| Skin biopsies | ___ | ___ |
| Abdominal paracentesis<br>(One procedure to be evaluated) | ___ | ___ |
| **PEDIATRIC SUBSPECIALTY PROCEDURES**<br>Retrospective review of documented procedures from other institutions. Evaluation at discretion of Chief of Pediatrics | | |
| Central venous catheter (CVC) | ___ | ___ |
| Percutaneous lines (PICC) | ___ | ___ |
| Bronchoscopies | ___ | ___ |
| Bone marrow aspiration | ___ | ___ |
| Rectal biopsy | ___ | ___ |

# Delineation Of Privileges

Pediatrics Privilege Checklist

Name:

| Privilege | Requested | Granted |
|---|---|---|
| I hereby request the Pediatric Department Chief to consider my application for the procedures requested above. I am willing to provide documentation of my current clinical competence for the requested privileges. Applicant's electronic signature on file.<br><br>TEMPORARY PRIVILEGE APPROVAL<br><br>_____<br>Chief, Department of Pediatrics Date<br><br>Evaluator Assignment:_____<br><br>[ ] PROVISIONAL [ ] RENEWAL APPROVAL<br><br>_____<br>Chief, Department of Pediatrics Date | | |

VENTURA COUNTY MEDICAL CENTER

# DEPARTMENT OF MEDICINE

## Focused Professional Practice Evaluation/***Specific Privilege***

*Formerly known as Proctoring*

**(Please forward to Medical Staff Administration when completed)**

Practitioner under evaluation: _____ Medical Record #: _____

Name of Evaluator: _____ Admission Date: _____

Diagnosis/Procedure: _____

Complications if any: _____

Review Type: ☐ Concurrent ☐ Retrospective ☐ Inpatient ☐ Outpatient

*procedures must be proctored concurrently

| AREA OF PERFORMANCE | YES | NO | N/A |
|---|---|---|---|
| Was there adequate evidence to support diagnosis or the need for the invasive procedure? | | | |
| Was the practitioner's documentation appropriate and informative? If NO,<br>☐Documentation not present<br>☐Documentation does not substantiate clinical course & treatment<br>☐Documentation not timely | | | |
| Was the practitioner's proposed use of diagnostic services (ie. Lab, x-ray, etc.) appropriate? | | | |
| Was the quality of the H&P (inpatient) or SOAP note (outpatient) satisfactory, complete and timely? | | | |
| Was the initial plan and level of care appropriate? | | | |
| Were the practitioner's initial orders appropriate? | | | |
| Was there adequate evidence to support diagnosis or the need for the invasive procedure? | | | |
| Were invasive procedures performed in a satisfactory manner? | | | |
| Was an inpatient consultation called promptly or outpatient referral placed appropriately (if needed)? | | | |
| Was practitioner cooperative with colleagues and staff? | | | |
| Was behavior ethical at all times? | | | |
| Did the practitioner interact and communicate appropriately with the patient and family? | | | |
| If the patient spoke a language other than English, was a qualified interpreter used? This can include the practitioner if they speak another language. | | | |
| Did the physician abide by all rules and regulations of the hospital and Medical Staff in the care of this patient? | | | |

| AREA OF PERFORMANCE FOR INPATIENT PROCTORING | YES | NO | N/A |
|---|---|---|---|
| Was the patient seen daily? | | | |
| Was the patient discharged to an appropriate level of care? | | | |
| Was patient's length of stay appropriate? | | | |

| AREA OF PERFORMANCE FOR OUTPATIENT PROCTORING | YES | NO | N/A |
|---|---|---|---|
| If this was an outpatient specialty consultation, are the recommendations to the PCP clear and easy to understand? | | | |
| Were any medications, labs, or imaging ordered (not just recommended in the note) | | | |
| If this was an outpatient primary care visit, was health maintenance addressed? | | | |

Practitioner under evaluation: _____ Medical Record #: _____

| BASIC ASSESSMENT | Satisfactory | Unsatisfactory | N/A | BASIC ASSESSMENT | Satisfactory | Unsatisfactory | N/A |
|---|---|---|---|---|---|---|---|
| Basic Medical Knowledge | | | | Communication Skills | | | |
| Technical/Clinical Skills | | | | Professionalism | | | |
| Clinical Judgement | | | | Use of Consults | | | |
| Interpersonal Skills | | | | | | | |

**PERFORMANCE**

❒ OUTSTANDING. Unusually well qualified.

❒ GOOD to AVERAGE. His/her knowledge and level of practice is quite satisfactory

❒ LESS THAN AVERAGE. The physician has displayed weakness in knowledge, conduct and/or performance.

Please provide specific information regarding any unusual strengths or weaknesses you may have observed on the back of this form. ❒ Additional comments below.

_____

Signature of Evaluating Physician Date

Recommend release from further evaluation, as noted above.

_____

CHIEF, DEPARTMENT OF MEDICINE DATE

MEC: _____ BOARD APPROVAL: _____

VENTURA COUNTY MEDICAL CENTER

# DEPARTMENT OF PEDIATRICS

Focused Professional Practice Evaluation/***Specific Privilege***

*Formerly known as Proctoring*

**(Please forward to Medical Staff Administration when completed)**

Practitioner under evaluation: _____ Medical Record #: _____

Name of Evaluator: _____ Admission Date: _____

Diagnosis/Procedure: _____

Complications if any: _____

Review Type: ☐ Concurrent ☐ Retrospective ☐ Inpatient ☐ Outpatient

*procedures must be proctored concurrently

| AREA OF PERFORMANCE | YES | NO | N/A |
|---|---|---|---|
| Was there adequate evidence to support diagnosis or the need for the invasive procedure? | | | |
| Was the practitioner's documentation appropriate and informative? If NO,<br>☐Documentation not present<br>☐Documentation does not substantiate clinical course & treatment<br>☐Documentation not timely | | | |
| Was the practitioner's proposed use of diagnostic services (ie. Lab, x-ray, etc.) appropriate? | | | |
| Was the quality of the H&P (inpatient) or SOAP note (outpatient) satisfactory, complete and timely? | | | |
| Was the initial plan and level of care appropriate? | | | |
| Were the practitioner's initial orders appropriate? | | | |
| Was there adequate evidence to support diagnosis or the need for the invasive procedure? | | | |
| Were invasive procedures performed in a satisfactory manner? | | | |
| Was an inpatient consultation called promptly or outpatient referral placed appropriately (if needed)? | | | |
| Was practitioner cooperative with colleagues and staff? | | | |
| Was behavior ethical at all times? | | | |
| Did the practitioner interact and communicate appropriately with the patient and family? | | | |
| If the patient spoke a language other than English, was a qualified interpreter used? This can include the practitioner if they speak another language. | | | |
| Did the physician abide by all rules and regulations of the hospital and Medical Staff in the care of this patient? | | | |

| AREA OF PERFORMANCE FOR INPATIENT PROCTORING | YES | NO | N/A |
|---|---|---|---|
| Was the patient seen daily? | | | |
| Was the patient discharged to an appropriate level of care? | | | |
| Was patient's length of stay appropriate? | | | |

| AREA OF PERFORMANCE FOR OUTPATIENT PROCTORING | YES | NO | N/A |
|---|---|---|---|
| If this was an outpatient specialty consultation, are the recommendations to the PCP clear and easy to understand? | | | |
| Were any medications, labs, or imaging ordered (not just recommended in the note) | | | |
| If this was an outpatient primary care visit, was health maintenance addressed? | | | |

Practitioner under evaluation: _____ Medical Record #: _____

| BASIC ASSESSMENT | Satisfactory | Unsatisfactory | N/A | BASIC ASSESSMENT | Satisfactory | Unsatisfactory | N/A |
|---|---|---|---|---|---|---|---|
| Basic Medical Knowledge | | | | Communication Skills | | | |
| Technical/Clinical Skills | | | | Professionalism | | | |
| Clinical Judgement | | | | Use of Consults | | | |
| Interpersonal Skills | | | | | | | |

**PERFORMANCE**

❒ OUTSTANDING. Unusually well qualified.

❒ GOOD to AVERAGE. His/her knowledge and level of practice is quite satisfactory

❒ LESS THAN AVERAGE. The physician has displayed weakness in knowledge, conduct and/or performance.

Please provide specific information regarding any unusual strengths or weaknesses you may have observed on the back of this form. ❒ Additional comments below.

_____

Signature of Evaluating Physician Date

Recommend release from further evaluation, as noted above.

_____

CHIEF, DEPARTMENT OF PEDIATRICS DATE

MEC: _____ BOARD APPROVAL: _____