

**WHOLE BLOOD GLUCOSE SCREENING USING THE  
ACCU-CHEK INFORM**

**Policy # B 03.0**

**MANUAL: NURSING POLICY/PROCEDURE MANUAL**

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Effective Date: 1/05

Approval /s/ Kathy Hardin

Reviewed/Revised: 10/05, 2/08

Kathy Hardin, RN, JD, CNO

**I. VALUES CONTEXT**

*We work together to be effective and efficient in the uses of resources and to provide a safe environment.*

**II. PURPOSE/EXPECTED OUTCOME(S)**

The enzyme glucose dehydrogenase converts the glucose in the blood sample to gluconolactone. This reaction liberates an electron that reacts with a coenzyme electron acceptor, the oxidized form of the mediator hexacyanoferrate (III), forming the reduced form of the mediator, hexacyanoferrate (II). The Accu-Chek® Comfort Curve® test strips employ the electrochemical principle of biamperometry. The meter applies a voltage between two identical electrodes, which causes the reduced mediator formed during the incubation period to be reconverted to an oxidized mediator. This generates a small current that is read by the meter.

The Accu-Chek Inform workstation and information system software allow you to configure (program) various glucose meter options. Periodically, patient and control results are transferred to the workstation for reporting and archiving.

Patient results determined by this waived testing may be considered definitive for purposes of care and diagnosis unless they fall less than 55 and greater than 400 mg/dl), in which case results must be confirmed by the clinical laboratory.

**EQUIPMENT AND MATERIALS**

The Accu-Chek Inform System works with the following reagents:

- Accu-Chek Comfort Curve Test Strips (Cat. No. 2030365)
- Accu-Chek Comfort Curve Glucose Control Solutions 2 – level (Cat. N. 2030390)
- Accu-Chek Comfort Curve Linearity Test Kit (Cat No. 2030357)
- Accu-Chek RALS plus workstation system software and/or connectivity cradle.

**Reagent Storage Requirements:**

- Normal precautions are exercised when handling laboratory reagents. Follow your facility's infection control guidelines.
- Test strips must be stored at room temperature. Do not freeze.
- Test strips are stored in the same tightly capped vial in which they are packaged. The vial cap is immediately replaced after removal of a test strip.
- Test strips are stable until the expiration date on the vial.
- Outdated test strips are discarded.
- Test strips are used at temperatures between 14° and 40°C (57° and 104° F) and <85% humidity.

**III. POLICY FOR CODING (CALIBRATION) OF THE ACCU-CHEK INFORM SYSTEM**

- Coding is always verified by matching the code on the Accu-Chek Inform display screen with the code number printed on the side of the vial of test strips.
- The meter is “calibrated” when the instrument is turned on with the Code Key inserted. Place the new Code Key in the meter and discard the old Code Key. It is recommended that the Code Key be changed with each new vial of test strips.

**A. PROCEDURE**

1. Gather the following items for calibration:
  - Accu-Chek Inform System
  - Test strips with appropriate Code Key
2. Remove the Code Key from the test strip box.
3. Compare the three digit number on the Code Key with the number on the test strip vial.
4. Remove old Code Key from Accu-Chek Inform meter, if necessary.
5. Snap the new Code Key (slots facing towards the meter) into the Code Key slot with the printed side facing up.
6. Leave the Code Key in the meter.

**IV. Specimen Requirements:**

**POLICY FOR SPECIMEN COLLECTION AND HANDLING**

1. Capillary, venous, neonatal (including cord blood), and arterial whole blood specimens may be used for testing on the Accu-Chek Inform System with Accu-Chek Comfort Curve test strips (Cat. No. 2030365).
2. The capillary sample must be tested immediately after collection.
3. Blood glucose determinations using venous and arterial blood specimens should be performed within 30 minutes of specimen collection to avoid glycolysis. Mix samples thoroughly.
4. For best results with arterial and venous blood, the following anticoagulants/preservatives are recommended: Heparin and EDTA.
5. Serum separator tubes and re-topped tubes are acceptable if blood is used immediately before the clotting process begins.
6. Iodoacetate or fluoride/oxalate should not be used as a preservative.
7. Caution should be taken to clear arterial lines before blood is drawn and dosed on the test strip.
8. Caution is advised in the interpretation of neonate glucose values below 40 mg/dl. Follow the recommendations for follow-up care that have been set by your institution for critical glucose values in neonates.
9. Sufficient sample size is required to ensure accurate results.

Refer to the test strip package insert for the most current information.

**V. PATIENT PREPARATION POLICY**

1. The purpose of the test and steps of the procedure will be explained to the patient prior to performing the test.
2. The operator's hands must be washed before and after testing.
3. Universal precautions must be observed and disposable gloves must be worn when the operator is handling blood products.
4. If the patient is able, the patient should wash his/her hand prior to testing with capillary samples taken from the fingertip.
5. Fresh capillary whole blood samples for use with the Accu-Chek Inform System are to be taken from the fingertip or heel (neonates).

6. Venous, neonatal, and arterial blood samples may also be used with the Accu-Chek Comfort Curve test strips (Cat. No. 2030365).

## **VI. PATIENT TESTING POLICY**

The Accu-Chek Inform System is set up to store the following information about each patient test:

Test Result

Operator ID

Patient ID

Test Strip Information

Test Time and Date

Comment(s)

Meter Serial Number

- Any patient result that exceeds the critical range established by the facility is followed-up by the operator (repeat test, lab verification, physician notification, other...) according to policy.
- The appropriate comment(s) is/are entered in the Accu-Chek Inform System by the operator.
- Only a certified operator may perform a blood glucose test on the Accu-Chek Inform System.
- Blood glucose tests with the Accu-Chek Inform System must be ordered by a physician unless the patient is experiencing symptoms of hypoglycemia or hyperglycemia, and quality care dictates a STAT test.
- A physician will be notified according to parameters specifically ordered. A STAT blood glucose test performed by the laboratory is ordered whenever the blood glucose result is less than 55 or greater than 400 mg/dl.

### **A. PROCEDURE**

The following equipment should be at the patient's bedside prior to testing:

- Accu-Chek Inform System
- Accu-Chek Comfort Curve test strips (Cat. No. 2030365)
- Single-use, disposable lancets (or lancets and lancet device with disposable platforms/tips if used with multiple patients)
- Alcohol swab
- Cotton ball, tissue or gauze for wiping finger after stick
- Disposable latex gloves

1. Press power ON button.

2. Enter (or scan) your operator ID. Press the forward arrow button.

3. Select Patient Test.
  4. Enter (or scan) the patient ID. Press the forward arrow button.
  5. Verify that the code number on the test strip vial corresponds to the code number on the Accu-Chek Inform System.
    - Select YES if the code numbers correspond.
    - Select NO if the code numbers do not correspond. *See Entering Test Strip Codes on page 7.*
  6. Remove a test strip from the vial. Immediately replace the cap on the vial.
  7. When the flashing strip icon appears on the meter display, gently insert test strip with the yellow target area or test strip window facing up. (Insert the end with the silver bars.) **Note: Insert test strip BEFORE dosing.**
  8. When the flashing drop icon appears on the meter display, obtain a blood sample. You may use a whole blood capillary, venous, arterial or neonatal (including cord) blood sample. (Follow the manufacturer's instructions if using a lancet device.)  
If using the Accu-Chek Comfort Curve test strip:
    - Touch and hold drop of blood to the curved edge of the yellow target area.
    - The blood is drawn into the test strip automatically.
- Important:** If you see any yellow color in the target area or test strip window after you have applied the initial drop of blood, a second drop of blood may be applied to the strip within 15 seconds of the first drop. If more than 15 seconds have passed, the test result may be erroneous, and you should discard the test strip and repeat the test.
9. An hourglass will appear on the display while waiting for the result.
  10. Enter up to three preprogrammed comments and one custom comment, if necessary. Then press the forward arrow button to record the test and return to the Main Menu screen in order to run the next test.
  11. Remove the test strip from the meter and discard it according to facility's infection control policy.
  12. Press the power OFF button to turn the Accu-Chek Inform System off.
  13. Remove gloves and dispose of them according to facility's infection control policy. Wash hands thoroughly with soap and water.
  14. Document the blood glucose result according to facility policy.

## **VII. QUALITY CONTROL TESTING POLICY**

A. Quality control records will be retained for a minimum of two years. The Accu-Chek Inform System is set up to store the following information about each quality control test:

- Test Result
- Operator ID
- Control Level
- Control Lot Information
- Test Strip Information
- Comment(s), if appropriate
- Meter Serial Number

Control tests are performed at the following times in this facility:

- If the Accu-Chek Inform System has been dropped
  - Each \_\_24 hour shift as determined in Setup
- Any corrective action may be recorded as a comment in the Accu-Chek Inform System.
  - If a quality control tests result falls within the acceptable control range, it is acceptable to proceed with patient testing.
  - If a quality control test result falls outside of the acceptable control range, the Troubleshooting section of the Accu-Chek Inform Operator's Manual is referenced, if needed, and the problem is corrected before proceeding with patient testing.
  - Glucose control solutions must be stored at room temperature. Do not freeze. Glucose control solutions are stable for three months after opening or until the expiration date, whichever comes first. The date the vial is opened should be written on the vial label.
  - Any outdated glucose control solutions will be discarded.
  - Test strips must be stored at room temperature. Do not refrigerate or freeze. Test strips are stable until the expiration date listed on the bottle. Test strips must be stored in the same capped vial in which they were packaged, and the vial cap must be immediately replaced after removal of a test strip.

## **B. PROCEDURE**

1. The following equipment is needed for quality control testing:
  - Accu-Chek Inform System
  - Accu-Chek Comfort Curve test strips (Cat. No. 2030365) with Accu-Chek Comfort Curve Glucose Control Solutions 2 – level (Cat. No. 2030390)

2. Put on disposable gloves .
3. Press power ON button.
4. Enter (or scan) your operator ID.
5. Select Control Test.
6. Scan the bar code on the vial.
7. Verify that the strip code number on the test strip matches the code number on the Accu-Chek Inform System by scanning the bar code on the vial.
8. Remove a test strip from the vial and replace the vial cap immediately.
9. When the flashing strip icon appears on the meter display, gently insert test strip with the yellow target area or test window facing up. (Insert the end with the silver bars.) **Note: Insert test strip BEFORE dosing.**
10. If using the Accu-Chek Comfort Curve test strip:
  - Touch and hold drop of glucose control solution to the curved edge of the yellow target area.
  - The glucose control solution is drawn into the test strip automatically.
11. An hourglass will be displayed on the Accu-Chek Inform meter while waiting for the result.
12. Enter the appropriate comment(s). Then press the forward arrow button to record the test and to test the next level of control (if other levels are required) or to proceed to patient testing.
13. Remove the used test strip(s) and disposable latex gloves and discard them according to your facility's infection control policy.
14. Document the result(s) per policy.

#### **VIII. DOCUMENTATION OF QUALITY CONTROL RESULT POLICY**

1. The date, time, ID of the operator, meter serial number, and quality control result are recorded according to facility policy.
2. If a quality control test result falls within the acceptable control range, it is acceptable to proceed with patient testing.
3. If a quality control test result falls outside the acceptable control range, the *Troubleshooting* section of the Accu-Check Inform System Operator's Manual is referenced, if needed, and the problem is corrected before proceeding with patient testing.
4. Any quality control result that falls outside the acceptable control range, along with any corrective action to restore that result to acceptable range, is recorded according to facility policy.

The Lab Point of Care Testing Personnel will review the quality control records for completion, as well as note any trends that may indicate potential problems. These trends include gradual drifting of values, sudden shifts in glucose control values while using the same lot of strips, and operator performance.

**IX. LINEARITY TESTING POLICY**

A. The Accu-Chek Inform System stores the following information about each linearity test:

- Test Result
- Operator ID
- Linearity Level
- Linearity Lot Information
- Test Time and Date
- Strip Information
- Comment(s)
- Meter Serial Number

- Linearity tests are performed by Lab point of Care Testing personnel.
- Linearity is determined:
  - Before a blood glucose meter is put into use
  - With each new lot of test strips
  - At least every six months
  - When controls begin to reflect an unusual trend or are consistently out of range.
- The reportable range of each instrument is verified by Lab Point of Care Testing personnel.
- If a patient test result falls outside of the linear range, it is verified by the laboratory by an alternative method and is reported as less than (<) or greater than (>) the linear limits.
- The Linear reporting range of each Accu-Chek Inform System is \_\_10mg/dL to \_\_600mg/dL.
- The linearity results of each Accu-Chek Inform System are recorded per facility policy.
- Linearity records are retained for two years if required.
- The correct linearity test kit is used: Accu-Chek Comfort Curve Linearity Test Kit (Cat. No. 2030357) is used with Accu-Chek Comfort Curve test strips (Cat. No. 2030365).

**B. PROCEDURE**

To be performed by Lab Point of Care Testing Personnel. To record a linearity test in the Accu-Chek Inform System:

1. Press Power ON button
2. Enter (or scan) your operator ID, then press the forward arrow button.
3. From the Main Menu screen, press the forward arrow button.
4. Select Admin...
5. Select Linearity Test
6. Verify the linearity lot displayed on the Accu-Chek Inform System:
  - Select YES if the linearity lot number in the display is the same as the linearity lot you wish to use. Continue with step 8.
  - Select NO to enter the linearity lot for the solution you wish to use.
7. Enter the expiration date of the linearity solution.
8. Verify the strip code number by scanning the bar code on the vial.
9. Select the linearity solution number for the first test
10. Perform linearity test

11. Select comment(s), if necessary, and press the forward arrow button to return to the Linearity Test screen.
12. Press the forward arrow button to record the test

### **C. REPORTING RESULTS**

1. Reference Ranges:

Blood glucose levels for people without diabetes <sup>1</sup> are as follows:

<u>Time</u>	<u>Range</u>
Before meals	less than (<) 100mg/dL
One hour after meals	less than (<) 160 mg/dL

Expected values for neonates: 40-90 mg/dL for neonates (0-2 days)

**CAUTION is advised for the interpretation of neonate glucose values below 40 mg/dL.**

2. Critical Values: Values less than (<) 55 and greater than (>) 400 mg/dL
  - a. All blood glucose values less than (<) 55 or greater than (>) 400 mg/dL must be repeated and double-checked with the clinical laboratory.
    - If a “HI” display appears, the blood glucose is above the linear limit (600 mg/dL) of the instrument or the test has not been performed correctly.
  - b. **Double check the result** with another finger stick sample
  - c. If results remain outside the panic value range, draw a venous blood sample from the patient.
  - d. **Order the Accu-Chek verification test in MEDITECH, the test is called GLUA.**
    - Be sure to enter the whole blood glucose result from the Accu-Chek in the space provided.
    - The laboratory will double check the Accu-Chek value, and enter the laboratory result in the computer.
  - e. The results from the Accu-Chek and from the laboratory confirmation must be written in the patient’s chart.
  - f. Notify the appropriate physician and /or nurse with the results.
  - g. Once a patient’s high glucose level is confirmed by the laboratory, *subsequent high results need only be confirmed by the laboratory if:*
    - The new glucose reading is significantly higher than the previous laboratory confirmed result.
    - The patient has been treated for hyperglycemia, and the Accu-Chek results remain over the panic or linear range.
    - There has been a clinically significant increase or decrease in the Accu-Chek glucose results.
    - Results remain over panic range and the results have not been confirmed by the laboratory in the past 24 hours.
    - Patient’s condition is inconsistent with the Accu-Chek glucose results.

i.e., a known diabetic appears to be in shock or is unconscious, but the finger stick glucose is 150 mg/dL. This glucose result is inconsistent with the patient's apparent condition and should be double-checked with the clinical laboratory.

**Additional Precautions for Neonatal Testing:**

All abnormal neonatal values should be confirmed by a clinical laboratory test method. All neonates exhibiting hypoglycemic symptoms, regardless of blood glucose monitoring results should have their glucose tested by a clinical laboratory test method. When *monitoring neonatal samples, laboratory confirmation is recommended for all results less than 30 mg/dL.*

Use caution when interpreting neonatal blood glucose results that are less than 40 mg/dL.

**X. CRITICAL VALUES POLICY**

- Physician notification and treatment for hypoglycemia will be initiated if the blood glucose value is less than (<) 55 mg/dL for adults
- Physician notification and treatment for hyperglycemia will be initiated if the blood glucose value is greater than (>) 400mg/dL for adults.
- Physician notification and treatment for neonatal critical value will be initiated if the blood glucose is less than (<) 30 and greater than (>) 400 mg/dL.

**XI. PROFICIENCY TESTING**

- The Accu-Check Inform System stores the following information about each proficiency test:

- Test Result
- Operator ID
- Sample ID
- Test Time and Date
- Strip Information
- Comment(s)
- Meter Serial Number

- Proficiency tests are performed by qualified operator
- Proficiency tests are performed at the following time:

Every four (4) months

- This facility is enrolled in an external proficiency program provided by \_\_ College of American Pathologist (CAP) or American Association of Bioanalysis (AAB) – dependent on facility.

**A. PROCEDURE**

To record a proficiency test in the Accu-Chek Inform System:

1. Press the power ON button
2. Enter (or scan) your operator ID, then press the forward arrow button
3. Press the forward arrow button to display the Main Menu 2 screen
4. Select Proficiency
5. Enter (or scan) the sample ID and press the forward arrow button
6. Verify the strip code information by scanning the bar code on the vial
7. Perform the proficiency test
8. Enter comment(s), if necessary
9. Press the forward arrow button to return to the Main Menu 2 screen to run the next sample. Or press the power OFF button to turn the Accu-Chek Inform System off.
10. Remove the strip and discard it according to facility's infection control policy.

**XII. STORAGE/MAINTENANCE OF THE ACCU-CHEK INFORM SYSTEM POLICY**

1. The Accu-Chek Inform System is handled with care. Sudden shocks caused by dropping or rough treatment may affect performance. If the Accu-Chek Inform System is dropped, performance is verified by quality control testing.
2. The Accu-Chek Infor System is stored away from direct sunlight and extreme temperatures.
3. Cleaning and maintenance of the Accu-Chek Inform System is performed at the following times:
  - Daily
  - As needed
4. Disposable gloves are worn when performing preventive maintenance and cleaning on the Accu-Chek Inform System and blood glucose testing equipment.
5. If personnel are unable to correct a problem with the Accu-Chek Inform System, it is removed from service and sent to the Clinical Lab for repair/replacement.

**A. PROCEDURE**

Wipe the surface of the Accu-Chek Inform System with a soft cloth slightly dampened (not well) with one of the following solutions:

(Note: Do not spray the Accu-Chek Inform System directly with solution, as this could cause solution to enter the case and damage the electronic components).

- Sani Wipes
- Glucor-Chlor

**B. LIMITATIONS OF THE METHOD**

Test strips give dependable test results if the following limitations are understood:

1. Use only Accu-Chek Comfort Curve test strips (Cat. No. 2030365) for testing capillary, venous, neonatal (including cord), and arterial whole blood samples.
2. Blood glucose determinations using venous and arterial blood specimens should be performed within 30 minutes of specimen collection to avoid glycolysis. Avoid air bubbles if dosing with pipettes. Air bubbles may cause erroneous results.
3. For best results with arterial and venous blood, the following anticoagulants/preservatives are recommended: heparin and EDTA.
4. Serum separator tubes and red-topped tubes are acceptable if blood is used immediately before the clotting process begins.
5. Iodoacetate of fluoride/oxalate should not be used as a preservative.
6. Caution should be taken to clear arterial lines before blood is drawn and dosed on the test strip.
7. Caution is advised in the interpretation of neonate glucose values below 40 mg/dL. Follow the recommendations for follow-up care that have been set by your institution for critical glucose values in neonates.
8. Do not use during xylos absorption testing.
9. No effect was found at 20% to 65% hematocrit and glucose concentrations up to 200 mg/dL.
10. At glucose concentrations above 200 mg/dL, low hematocrits (below 20%) may cause elevated results and high hematocrits (above 55%) may cause reduced versus a whole blood reference.
11. System measurement range is 10 - 600 mg/dL.
12. The Accu-Chek Inform System has been tested at altitudes ranging from sea level to 10,150 feet.
13. The following compounds, when determined to be in excess of their limitations, may produce elevated glucose results:

<b>Compound</b>	<b>Limitation</b>
Galactose	>10 mg/dL
Maltose	>16 mg/dL
Bilirubin (unconjugated)	>20 mg/dL
Lipemic Samples	>5000 mg/dL
Acetaminophen	>8mg/dL
Uric Acid:	
Hypoglycemic range	>10 mg/dL
Euglycemic range	>12 mg/dL
Hyperglycemic range	>16 mg/dL

14. In situations of decreased peripheral blood flow, finger stick blood testing may not be appropriate, as it may not reflect the true physiological state. Examples would include but are not limited to: severe dehydration caused by diabetic ketoacidosis or the hyperglycemic hyperosmolar nonketotic state, hypotension, shock, or peripheral vascular disease.
15. Refer to the test strip package insert for updated information.

### **XIII. INFECTION CONTROL GUIDELINES POLICY**

1. Because of the hazardous nature of handling blood products, it is recommended that disposable latex gloves be used when collecting specimens, performing test procedure, and cleaning blood glucose meter equipment.
2. Gloves are to be removed and hands washed thoroughly with soap and water after completing the test procedure and prior to handling equipment not related to the procedure. Used disposable latex gloves should be discarded according to facility's infection control policy.
3. Universal precautions should be observed for all blood specimens. They should be handled at Biosafety Level 2 as recommended for any potentially infectious material in the Centers for Disease Control National Institutes of Health manual, *Biosafety in Microbiological and Biomedical Laboratories*, 1998 or in the National Committee for Clinical Laboratory Standard Document M29, *Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids and Tissue*, 1991.
4. The Accu-Chek Inform meter will be disinfected if contaminated with blood.
5. Only disposable single-use lancets used.

### **XIV. OPERATOR CERTIFICATION/RECERTIFICATION POLICY**

1. A certified Accu-Chek Inform System Instructor may be a Diabetes Clinical Specialist, QA Nurse, Roche Diagnostics Account Manager, or another designated individual who is trained in the use of the Accu-Chek Inform System.
2. Each operator will be appropriately in-serviced to perform blood glucose testing on the Accu-Chek Inform System.
3. Each operator must successfully complete a Knowledge Test and Skills Checklist to be certified to perform blood glucose testing on the Accu-Chek Inform System.
4. An initial certification roster and in-service training roster will be maintained for each nursing unit.
5. Each operator will be evaluated for competency according to the facility policy.

**TITLE: WHOLE BLOOD GLUCOSE SCREENING USING THE ACCU-CHEK INFORM SYSTEM AND ACCU-CHEK TESTING STATIO**

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Author/Department: Laboratory Services	
<ol style="list-style-type: none"> <li>1. References: Mor, Juan-R and Guarnaccia, Rocco: Assay of Glucose Using an Electrochemical Enzymatic Sensor, <i>analytical Biochemistry</i>, 79:319-328 (1977)</li> <li>2. D’Costa, E.J. Higgins, I.J.,et al., Quinoprotein Glucose Dehydrogenase and its Application in an Amperometric Glucose Sensor, <i>Biosensors</i>, 2:71-87 (1986)</li> <li>3. Hauge, J.G., Glucose Dehydrogenase of Bacterium Anitratum: an Enzyme with a Novel Prosthetic Group, <i>Journal of Biological Chemistry</i>, 239:3630-3639 (1964)</li> <li>4. Tietz, N.W., <i>Textbook of Clinical Chemistry</i>, p. 2190 (1994)</li> <li>5. American Diabetes Association Position Statement, <i>Diabetes Care</i>, Vol. 19 (suppl. 1) p. S4 (1996)</li> <li>6. Atkin, S.H.; Dasmahapatra, A.; Jaker, M.A.; Chorost, M.I.; Reddy, S., Fingerstick Glucose Determination in Shock, <i>Annals of Internal Medicine</i>, 114;1020-1024 (1991)</li> <li>7. Sandler, M.; Low-Ber, T., Misleading Capillary Glucose Measurements, <i>Practical Diabetes</i>, 7:210 (1990)</li> <li>8. Wickham, N.W.R.; Achar, K.N.; Cove, D.H.; Unreliability of Capillary Blood Glucose in Peripheral Vascular Disease, <i>Practical Diabetes</i>, 3:100 (1986)</li> </ol>	
<p><sup>1</sup>Krall LP, Bleaser RS, <i>Joslin’s Diabetes Manual</i>. Lea &amp; Febiger, 1989:138.  <sup>2</sup>Tietz, Norbert W. <i>Clinical Guide to Laboratory Tests, Second Edition</i>, 1990:246.  <sup>3</sup>Tietz,, Norbert W. <i>Fundamentals of Clinical Chemistry, Fifth Edition</i>, 2001: 439</p>	
Reviewed/Revised by: Sharon Okada, Area Wide POCT Supervisor	
<p>Approvals:  Nursing Practice Council 5-05  Medical Executive Committee 6-05  Board of Trustees 6-05</p>	Distribution: Nursing Division