Clinical Laboratory Department POLICY AND PROCEDURE

POLICY NUMBER: 804
VERSION: 3

SUBJECT: Blood Glucose Monitoring: Use of Nova Stat Strip Glucose Meter

PURPOSE:

To provide guidelines for the safe and accurate monitoring and/or treatment of blood glucose levels in patients with diseases, conditions, and/or receiving treatments that may alter/affect blood glucose levels. This test can be used as definitive or for screening purposes. The Nova StatStrip Glucose Hospital Meter System is intended for in vitro diagnostic use by health care professionals and for point-of-care usage in the quantitative determination of glucose in whole blood. It is indicated for use in a clinical setting by healthcare professionals as an aid to monitor the effectiveness of diabetes control.

POLICY:

This test is WAIVED for finger stick whole blood, venous, and arterial whole blood under the Clinical Laboratory Improvements Amendments of 1988 (CLIA). Blood glucose testing will be used in the monitoring and/or treatment of identified patients with diseases, conditions and/or receiving treatments that may potentially alter blood glucose levels.

An order is required for the procedure. Authorized personnel who have demonstrated competency with the blood glucose point of care procedure and have completed the Adult Acute Complaints protocol training may perform the procedure:

1. Patients who present with dizziness/lightheadedness and are a known diabetic.
2. Known diabetics reporting an abnormal blood sugar at home of less than 70 mg/dL or greater than 300 mg/dL.

SPECIMEN:

Patient Preparation:

Capillary blood can be obtained from piercing the fingertip or heel using a safety-lancing device. The puncture site should be cleaned with soap and water, and then thoroughly dried before obtaining the sample. ***DO NOT USE ALCOHOL***

Type:

Nova StatStrip Test Strips may be used to test capillary, venous, arterial, and neonate blood samples. Venous and capillary blood may differ in glucose concentration by as much as 70 mg/dL, depending on the time of blood collection after food intake. Shock, administration of vasoactive agents, and other factors affecting the peripheral circulation may also cause discrepancies between venous and capillary glucose results. Do not use serum or plasma samples. Blood samples in anticoagulants and preservatives (sodium, lithium and ammonium heparin) may be used, but must be analyzed within 30 minutes. Capillary blood glucose testing may not be appropriate for persons with decreased peripheral blood flow, as it may not reflect the true physiological state. Examples include, but are not limited to, severe hypotension, shock, hyperosmolar-hyperglycemia (with or without ketosis) and severe dehydration.

Handling Conditions:

- The operating temperature range for meter operation: 59˚F to 104˚F (15˚C to 30˚C)
- The relative humidity range for meter operation: up to 90% non-condensing
- The maximum altitude for meter operation: up to 15,000 feet (4500 meters)

If using fresh whole blood in the absence of an anticoagulant, test immediately to prevent clotting from affecting the results. When whole blood in a test tube is used; care should be taken to uniformly distribute red cells throughout the tube before testing. This can be accomplished by gently inverting the capped tube 10 times. Test the blood sample as close as possible to the time the sample was collected. The test should be performed within 30 minutes of sample collection to minimize glycolysis. The blood glucose concentration decreases over time, because red blood cells continue to consume glucose.

EQUIPMENT AND MATERIALS:

Equipment:

1. NOVA StatStrip meter and operator's guide.
2. Safety, single-use lancing device.

Materials:

1. StatStrip Testing Strips.
2. StatStrip High and Low Glucose Control Solutions.
3. Cotton Balls or gauze pad.
4. Clean gloves.
5. Facility approved surface disinfectant.

Reagent Storage Requirements:

1. Store test strips tightly capped in their original container in a cool, dry place, at 15-30°C. Keep away from heat and direct sunlight. Do not refrigerate or freeze. Discard any unused portion 180 days (6 months) after opening. Do not use after the manufacturer's expiration date printed on the container label.

2. Store control and linearity solutions at 15- 30°C. Do not freeze or refrigerate. Discard any unused portion 3 months after opening. Do not use after the manufacturer's expiration date printed on the container label.

QUALITY CONTROL:

The Nova Stat Strip Glucose Hospital Meter includes several quality control mechanisms that detect errors due to system failures and operator performance. External controls (NOVA StatStrip Level 1 and Level 3 Glucose Control Solutions) should be used to verify the integrity of the Nova Stat Strip Glucose Hospital Meter:

1. Each day the clinic is open to patients.
2. When troubleshooting the system.
3. If a patient test has been repeated and the blood glucose results are still lower or higher than expected
4. Whenever problems (storage, operator, and instrument, etc.) are identified or anytime there is a concern the accuracy of the meter may have been affected by rough handling (such as dropping the meter).

Procedure:

Check the battery status to ensure adequate power. After initial power up, an operator can login to have access to all the assigned functions of the meter. To login, proceed as follows: From the Home screen, press the Login soft key at the bottom middle of the screen. The Enter Operator ID screen displays. Enter or scan the 6-digit employee number. Press the Accept soft key at the bottom of the screen. After the Operator ID is accepted, the Patient Test screen displays. The meter is now ready to run.

- From the Patient Test screen, press the QC soft key. The Enter Strip Lot screen displays.
- Enter the Strip Lot Number or scan the barcode. To scan the barcode, press the Scan soft key. Press the Accept soft key if the lot number is correct. The Enter QC Lot screen displays.
- Enter the QC lot number, select from the QC Lot List screen (press the List soft button), or scan the barcode. To scan the barcode, press the Scan soft key. Press the Accept soft key if the lot number is correct. The Insert Strip screen displays.
- Insert a Test Strip. With the test strip correctly inserted, the Apply Sample screen displays.
- Gently, but thoroughly, mix the StatStrip Glucose Control Solution before each use.
- Place a drop of control solution from the bottle at the end of the test strip until the solution is drawn into the well of the test strip. When enough sample has been drawn into the strip, an audible beep is sounded by the meter. Recap the control solution. The Testing Sample screen displays. The screen shows a clock with seconds remaining below the clock. When the meter completes the test, the QC Result screen displays with the results in mg/dL.

- The result is displayed with either PASS or FAIL. Control solution test results should fall within the ranges entered into the glucose meter if the system is working properly and the correct test procedure is followed. If control solution test results fall outside the expected range, the system is not functioning properly. Repeat the test with a new test strip. DO NOT use the system to test patient blood glucose levels until the control solution results fall within the expected range.
- To accept the result, press the Accept soft key.
- "Back-to-Back" QC passes are required to unlock the meter for patient testing. This means that both QC level 1 and QC level 3 must both pass back to back, one after another, without a fail between the two levels for the meter to unlock, thus allowing patient testing to be performed.

Results that fall outside the expected range may indicate:

1. Procedural error.
2. Old, unmixed, or contaminated glucose control solution.
3. Incorrect lot number or code number entered in the meter.
4. Test strip deterioration.
5. Meter malfunction.

   If a QC test does not fall within the specified range, verify that the Nova Glucose Stat Strips and Control Solutions are not past their expiration dates. Repeat the test with a new strip. If the second test fails, inspect and clean the meter. If the third test fails, contact the POCT coordinator.

If the result FAILED, you MUST add at least one comment to the result each and every time QC fails.
To add a comment to a result, press the Comment soft key on the Result screen. The Add Comment screen displays with preformed comments. Select one of the comments from the comments list on the Add Comment screen. There are Page Up and Page Down soft keys to scroll through the comments. Once selected, press the Accept soft key to place the comment onto the QC result. This will be recorded with the failed result. Then press the Accept key again to record the result with the attached comment.

Dispose the strip in the appropriate waste disposal, then repeat the QC test with a new test strip. If the second test fails, inspect and clean the meter. If the third test fails, contact the POCT Coordinator or the Laboratory. Do not use the meter to test patients until QC has passed.

PATIENT TEST

Procedure:

1. Must have a provider's order either in Orchid or as a written protocol order.
2. Gather the appropriate equipment.
3. **Identify patient with at least 2 unique/acceptable identifiers.**
4. **Follow infection control guidelines using aseptic technique, and take care not to contaminate reagent supplies.**
5. Explain the procedure to the patient.

6. Turn on the meter.
7. Check the battery status to ensure adequate power.
8. From the Patient Test screen, press the Accept soft key.
9. The Enter Strip Lot screen displays. Enter or scan the strip lot number. Once the Lot Number has been added, press the Accept soft key.
10. From the Enter Patient ID screen, scan the patient's 10 digit FIN umber. NEVER enter the number manually Press the accept key.
11. Verify the Positive Patient ID feedback in the meter. If it cannot find the patient, you can press the downtime override button, but be aware, it is telling you there is a problem. If it is because the FIN number is not correct, the result will never chart, or it will chart to the wrong patient. Please recheck the FIN number. It could also be due to the patient not being registered (or that the meter has not caught up with registration, or registration is not caught up with the patient).
12. In cases in which the patient does not have a FIN record number, you must use a "fake" patient ID (situations like when a patient needs an emergency glucose and they are not registered), use all 1's (1111111111) -It will need 10 of them. If you get a second situation the same day from the same clinic, then use all 2's, etc. You must also document manually in Power Chart under patient notes the number you used for that patient as a cross reference. Use the log provided in the urgent cares for these cases. Then you MUST call or email the Point of Care Coordinator to convey the true ID of the patient, the date and time this was done, and the reason why it was done.
13. Wear gloves and pierce the patient's fingertip (or heel) using a safety lancing device.
14. Wipe away the first 1-2 drops of blood with a gauze pad.
15. The Apply Sample screen should be displaying. When the blood drop appears, touch the end of the test strip to the blood drop until the well of the test strip is full and the meter beeps.
16. WARNING: The test strip must fill completely upon touching the blood droplet. If the test strip does not fill completely, do not touch the test strip to the blood droplet a second time. Discard the test strip and repeat the test with a new strip. The test results will appear in 6 seconds. Do not remove the test strip while the countdown is in progress. To accept the result, press the Accept soft key. To reject the result, press the Reject soft key. To add a comment, press the Comment soft key
17. Give the patient a cotton ball or gauze pad and apply light pressure to the puncture site.
18. Dispose of the safety lancet device in a sharps container.
19. Results within the normal range are displayed in Blue.
20. Results outside the normal range are displayed in Red.
21. A Single up arrow (↑) is displayed for a result if the value is higher than the upper end of the normal range but within the critical range.
22. A double up arrow (↑↑) is displayed for a result if the value is higher than the upper end of the critical range.
23. A Single down arrow (↓) is displayed for a result if the value is lower than the lower end of the normal range but within the critical range.
24. A double down arrow (↓↓) is displayed for a result if the value is lower than the lower end of the critical range.
25. Critical values are programmed into the meter. For any critical result obtained, repeat the test. Any repeated results that fall above or below the limits of the critical range are considered critical values and the patient's physician/caregiver must be notified immediately. At the physician's discretion or request, a venous specimen may be collected and sent to the laboratory for confirmation.

26. All critical values must have a comment added. To add a comment, press the Comment soft key on the Result screen. The Add Comment screen displays with preformed comments. Select one of the comments from the list. Once selected, press the Accept soft key to place the comment onto the result. This will be recorded with the patient's critical result. Then press the Accept key again to record the result with the attached comment.
27. Remove the test strip and dispose of it in the appropriate waste container.
28. If the test result is >600 mg/dL, the Glucose Meter will read "HI." The result is above the operating range of the meter. Retest using a new test strip.
29. If the test result is <10 mg/dL, the Glucose Meter will read "LO." The result is below the operating range for the meter. Retest using a new test strip.
30. Remove gloves and wash hands.
31. Dock the meter. Once the meter is docked, and the above steps were followed, the results will chart in Cerner.
32. NEVER enter the glucose result manually into ORCHID. If this is done, TWO results will post to ORCHID (the one that was entered manually, and the one that was sent electronically by the meter.)

REVIEWING DATA

All results can be recalled and reviewed: Patient Results, QC Results, and Linearity results. The Review Results screen can be sorted by ID, Time/Date, or Type.

- From the Patient Test screen, press the Review soft key.
- The Review Result screen displays.
- Select how to sort the results by pressing ID, Time/Date, or Type.
- Select the result that you want to review.
- Press the Page Down or Page Up soft key to scroll through the stored results.
- Press the View soft key to view the selected result.
- Press the Previous soft key to view the previous result.
- Press the Next soft key to view the next result.

DOCKING/CHARGING STATION/BATTERIES

A rechargeable battery provides power to operate the meter. A low-battery warning on the meter display alerts the operator to recharge the battery. An auto sleep feature conserves power when the meter is not in use. Test data information are stored in a non-volatile memory to prevent data loss.

1. When the meter is not in use, place it into the Docking/Charging Station. This will enable the meter to stay fully charged.
   • The green left light is on if the station is connected to the network.
   • The green middle light is on if data is transferring.
   • The right light is green for fully charged or amber for charging.

   When the Battery LOW symbol displays on the screen, place the meter into the Charging Station. If you have a spare battery that is already fully charged, change the battery to allow for continuous operation

   Changing the Batteries:

1. If you have a spare fully charged battery, it can be changed to allow for continuous operation.
2. Push down on the 2 cover latches to release the cover. Take the battery cover off the back of the meter.
3. Push up on the battery latch. Remove the drained battery.
4. Replace with a fully charged battery.

NOTE: The battery is keyed to allow only insertion from bottom first then push in top.

6. Replace the battery cover.
7. Place the drained battery into the Charging Station.

WARNING: Replace the battery with Nova Biomedical battery only. Using another battery may present a risk of fire or explosion. If discarding, dispose of the battery promptly. Keep the battery away from children.

CLEANING, DISINFECTION, AND MAINTENANCE:

Cleaning the Outside of the Meter:

1. The meter exterior is to be cleaned and disinfected after every patient use.
2. Use an intermediate level disinfectant (combination quaternary ammonium/alcohol solution) approved for use at this facility. Disinfectant is to remain wet on surface of meter for the designated contact time per manufacturer. Dry thoroughly.

CAUTION: DO NOT immerse the meter or hold the meter under running water. DO NOT spray the meter with a disinfectant solution. Avoid harsh solvents such as benzene and strong acids. A 10% solution of household bleach (Sodium Hypochlorite) may be used. 70% Isopropyl (rubbing) Alcohol may also be used.

PROCEDURE NOTES:

1. The Glucose Meter is calibrated to provide plasma equivalent results to laboratory methods.
2. Test Strips are for testing outside the body (in vitro diagnostic use only).
3. WARNING: Healthcare professionals and others using this system should be aware that all products or objects that come into contact with human blood should be handled as if capable of transmitting viral diseases, even after cleaning.
4. Do not stare into the Laser light or point it towards anyone's eyes while scanning a barcode.
5. The Meter is designed such that the Operator uses his or her finger when dealing with the touch screen. A PDA-style pen may be used as a replacement for finger input. Any other type of implement with a sharp or abrasive end may damage or disable the meter.

LIMITATIONS OF THE PROCEDURE:

1. Capillary blood glucose testing may not be appropriate for persons with decreased peripheral blood flow, as it may not reflect the true physiological state. Examples include, but are not limited to, severe hypotension, shock, hyperosmolar-hyperglycemia (with or without ketosis) and severe dehydration.
2. The test result range for the StatStrip Glucose Meter is 10 to 600 mg/dL for glucose.
3. The StatStrip Glucose Hospital Meter exhibits no interference from the following substances up to the following concentration levels:
    a. Acetaminophen 10.0 mg/dL 0.66 mmol/L
    b. Ascorbic Acid 10.0 mg/dL 0.57 mmol/L
    c. Bilirubin 15.0 mg/dL 0.26 mmol/L
    d. Cholesterol 500.0 mg/dL 12.9 mmol/L
    e. Creatinine 6.0 mg/dL 0.53 mmol/L
    f. Dopamine 10.0 mg/dL 0.53 mmol/L
    g. Ephedrine 0.9 mg/dL 0.055 mmol/L
    h. D(+) Galactose 350.0 mg/dL 19.4 mmol/L
    i. Hematocrit (RBC) 20% - 65%
    j. Ibuprofen 48.0 mg/dL 2.33 mmol/L
    k. L-Dopa 100.0 mg/dL 5.07 mmol/L
    l. D(+) Maltose Monohydrate 240.0 mg/dL 6.66 mmol/L
    m. D(+) Maltotetraose 240.0 mg/dL 3.6 mmol/L
    n. D(+) Maltotetriose 240.0 mg/dL 4.76 mmol/L
    o. Methyl-Dopa 1.0 mg/dL 0.042 mmol/L
    p. Oxygen All Concentrations
    q. Salicylate 30.0 mg/dL 1.87 mmol/L
    r. Tetracycline 30.0 mg/dL 0.62 mmol/L
    s. Tolazamide 15.0 mg/dL 0.48 mmol/L
    t. Tolbutamide 45.0 mg/dL 1.67 mmol/L
    u. Triglycerides 750.0 mg/dL 8.78 mmol/L
    v. Uric Acid 20.0 mg/dL 1.05 mmol/L

ERROR MESSAGES

ERROR MESSAGE	SOLUTION
Battery Low .	Change the battery or place the meter onto the Charging/ Docking Station
Test Strip Was Removed	The test has been cancelled, repeat the test with a new test strip. Leave the test strip in place until the result is displayed on the screen.
Temperature	Meter will only work within the temperature range of 59°F to 104°F (15°C to 40°C). Return the meter to an environment within the specified temperature range of 59°F to 104°F (15°C to 40°C).
Bad Sample	Insert a new strip and rerun the test. If the error code persists, perform the test using an alternate test strip vial or alternate method.
Replace Strip	Occurs after insertion of strip or occurs during analysis. Insert another strip and retest. If the error code persists, perform the test using an alternate test strip vial or alternate method.
Flow Error	The specimen was incorrectly drawn into the test strip due to either insufficient or incorrect sample application. Repeat the test with a new strip. If the error code persists, perform test using an alternate method.
Transfer Failed (with an arrow pointing away)	Server refuses to allow dialog with meter, or Connection to server was broken. Please check the network settings, status of your network, or contact your administrator for assistance.
Transfer Failed (with an arrow pointing in)	The meter was removed before data transfer was complete. Please re-dock the meter.

REFERENCES:

Nurse Practice Act, Business and Professions Code Section 2725, Scope of Registered Nursing Practice
Taylor, Lillis, & LeMone, Fundamentals of Nursing – The Art & Science of Nursing Care. 2001. Lippincott:
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