PT0051 Glucose Monitoring in Whole Blood (Nova Statstrip Glucose Monitoring System)

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6.0	Approved and Current	First version in Document Control	5/12/2017	1/27/2017	Indefinite

Linked Documents

- PT0051-A1 Interfering Substances

GLUCOSE MONITORING IN WHOLE BLOOD (NOVA STATSTRIP GLUCOSE MONITORING SYSTEM)

SOP Number: PT0051 Version: 6
Author(s): POC Practice Council

SCOPE

This procedure applies to all staff who perform glucose testing using the Nova Glucose Hospital Meter at Point of Care Testing (POCT) sites.

PRINCIPLE/PURPOSE

The Nova StatStrip Glucose Hospital monitoring system is used to obtain a rapid quantitative measure of glucose in whole blood amperometrically, using an enzyme based test strip. The Test Strip is designed with an electrode that measures glucose levels. Glucose in the blood sample mixes with reagent on the test strip that produces an electric current. The amount of current that is produced depends on how much glucose is in the blood. The Nova StatStrip system reports a plasma-calibrated patient glucose result. The Nova StatStrip device has been cleared by the FDA for multiple patient use.

This meter is not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia. The Nova StatStrip device is intended for the quantitative determination of glucose in capillary finger stick, venous, arterial, neonatal arterial and neonatal heel stick whole blood. It is not intended for use in patients with decreased peripheral blood flow.

CLIA classification: Waived

Use: Definitive

DEFINITIONS

Neonatal blood: Blood obtained from an infant less than 25 days old. This does not include cord blood.

DOCUMENTATION/RECORDS

Quality Control (QC) and patient results must be documented in one or more of the following areas:

A. Clinical Information System
B. LIS (Laboratory Information System)
C. Patient Chart or Report Form
D. QC and Patient Log

SAFETY CONSIDERATIONS/PERSONAL PROTECTIVE EQUIPMENT

A. Standard precautions
    1. All parts of the StatStrip Glucose Meter are considered potentially infectious and can potentially transmit blood-borne pathogens between patients and healthcare professionals.
    2. The StatStrip Glucose Meter may only be utilized for testing on multiple patients when the Standard Precautions are followed and when the meter is cleaned and disinfected after use on each patient following the procedure in the Maintenance section.
    3. Only auto-disabling, single use lancing devices may be used with this meter.
B. The battery used in this meter may present a fire or chemical burn hazard if mistreated. Do not disassemble, heat above 100ºC (212º F), or incinerate. Swollen batteries should be replaced.
C. Do not stare into the laser light or point it towards anyone's eyes.

SPECIMEN

A. For patient identification policies, refer to PH0024, PH0026 and / or the Intermountain Patient Identification Policy.

B. Patient preparation

No special patient preparation is necessary unless specifically ordered by a physician.

C. Specimen type(s)

1. Arterial whole blood, venous whole blood, neonate arterial whole blood or neonate heel stick specimens throughout all hospital and all professional healthcare settings. Use only whole blood. Do not use serum or plasma.
2. Capillary blood glucose testing is acceptable except 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.
3. Alternate sites (e.g., forearm) have not been approved by the manufacturer and should not be used.
4. Neonatal cord blood specimens should not be used. System has not been evaluated for use with neonatal venous blood.
5. Only lithium heparin anticoagulant is acceptable when sampling with syringes, vacutainer tubes or capillary tubes. Samples without anticoagulant must be run immediately.

REAGENTS/SUPPLIES/EQUIPMENT

A. Nova StatStrip Glucose Test Strips

1. Keep the test strip vial tightly closed when not in use. Test strips should be stored only in original vial. Store the test strips at room temperature (15 – 40 °C). Do not refrigerate or freeze the test strips.
2. Remove the test strip from the vial only when ready to test.
3. Do not reuse test strips. Strips are designed to be disposed of after a single use.
4. Write the modified expiration date, 180 days after opening or until the manufacturer's expiration date, whichever comes first, on the test strip bottle when it is first opened. Discard any unused test strips if it has passed the modified or the manufacturer’s expiration date.
5. Do not use any test strips that have passed the manufacturer’s expiration date or the modified expiration date.
6. Do not bend, cut or alter test strip in any way.

B. Nova StatStrip Glucose Control Solutions: Levels 1 and 3

1. Keep the Nova StatStrip Glucose Control Solution vial tightly closed when not in use. Store the control solution at room temperature. Do not refrigerate or freeze the control solution.
2. Write the modified expiration date, 3 months after opening or the manufacturer's expiration date whichever comes first, on the control bottle when it is first opened. Discard any unused control if it has passed the modified or the manufacturer’s expiration date.
3. Do not use any controls that have exceeded the manufacturer’s expiration date or modified expiration date.

C. Rechargeable battery

If you have a spare fully charged battery, it can be changed to allow for continuous operation:

1. Press the sleep mode button to enter the Sleep Mode. This will allow the operator approximately 20 seconds to change the battery and not lose date/time settings.

2. Pull back on the cover latch to release the cover. Take the battery cover off the back of the meter.
3. Grab the battery on the sides and remove the drained battery.
4. Replace with a fully charged battery.
5. The battery is keyed to allow only insertion from the bottom first, then push in top.
6. Replace the battery cover.
7. Place the drained battery into the Charging Station.

NOTE: If it takes longer than 20 seconds to change the battery, power up the meter, login, and set the date and time or place in docking station to update date and time.

D. Docking/Charging Station

1. When the meter is not in use, place it into the Docking/Charging Station. This will enable the meter to stay fully charged.
2. The LEFT green light is on if the station is connected to the network.
3. The MIDDLE green light is flashing if data is transferring.
4. The RIGHT light is green for fully charged or amber for charging.
5. The EXTRA BATTERY light is green for fully charged or amber for charging and will not turn on if the battery is inserted incorrectly.

CALIBRATION

Calibration verification is performed by the POCT coordinator or qualified designee before any new meter is put into operation. Thereafter, calibration verification will be performed as required for laboratory accreditation.

QUALITY CONTROL

A. The StatStrip Glucose Control Solutions have known glucose values, which are used to confirm that the meter and test strips are working correctly. Low and High Glucose Control Solutions should be performed:

1. During each 24 hours of testing.
2. If a patient test has been repeated and the blood glucose results are still lower or higher than expected.
3. Before using the StatStrip meter for the first time. QC will be done by each new operator during their training.
4. If there are indications that the system is not working properly.
5. Whenever problems (e.g. storage, operator, instrument) are identified or anytime there is a concern that the accuracy of the meter may have been affected by rough handling, such as dropping the meter.

B. Procedure for running quality control

1. Turn the meter on.
2. From the *Welcome* screen press Login.
3. Enter or scan the operator ID.
4. Press Accept.
5. From the *Patient Test* screen, press QC.
6. The *Enter Strip Lot* screen displays. Enter the strip lot number by scanning the barcode on the vial.

7. Press Accept if the lot number is correct,
8. The *Enter QC Lot* screen displays. Enter the QC lot number by scanning the barcode on the bottle.
9. Press Accept if the lot number is correct,
10. The *Insert Strip* screen displays. Insert a Test Strip as shown on the screen, gold end first.
11. With the test strip correctly inserted, the *Apply Sample* screen displays.
12. Gently mix the StatStrip Glucose Control Solution before each use.
13. Discard the first drop of control solution from the bottle to avoid contamination.
14. 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 and the countdown screen appears.
15. Do not allow quality control solution to run into the strip port. Liquid inside the strip port causes damage to the electronics of the meter.
16. Recap the control solution.
17. The *Testing Sample* screen displays. The screen shows a clock with seconds remaining below the clock.
18. The result will display within 6 seconds.
19. Remove the strip manually or use the ejector button on the back of the meter to eject the test strip.
20. To add a comment to the result, press Comment. Select the comment from the menu and press Accept.
21. To accept the result, press Accept.
22. Repeat steps 5 through 21 for next level of QC.

C. Out of control procedure

If either control is not within acceptable limits, perform the following procedural checks:

1. Verify that the correct QC solution is being used.
2. Check outdates on controls and strips.
3. Make sure controls are at room temperature.
4. Rerun controls once.
5. If still not within acceptable limits, repeat the test with new control material. If new controls pass, discard defective controls.
6. If still not within acceptable limits, open a new bottle of glucose strips, repeat both controls. If new strips pass, discard defective strips.
7. If still not within acceptable limits, contact your facility's Point of Care Testing Coordinator.

NOTE: Do not report patient results until meter or QC problem is resolved. Send a blood sample to the lab for glucose testing.

PROCEDURE

A. Turn the meter on.

B. From the *Welcome* screen press Login.

C. Enter or scan the operator ID.

D. Press Accept.

E. From the *Patient Test* or *Menu* screen, press Accept.

F. The *Enter Strip Lot* screen displays. Enter the strip lot number by scanning the barcode on the vial.

G. Press Accept if the lot number is correct.

H. The *Enter Patient ID* screen displays. Enter or scan the patient ID.

I. Press Accept if the patient ID is correct.

J. The *Insert Strip* screen displays. Insert a test strip as shown on the meter screen, gold end first.

K. Collect sample using one of the following methods:

1. Finger/heel stick
    a. Wash patient's hand/heel with water then dry thoroughly. Alternatively, use alcohol pads to clean area; dry thoroughly after cleaning.
    b. Puncture the fingertip or heel using a suitable lancing device. Lancing devices should be single-use and auto-disabling. Fingerstick devices should never be used for more than one person.
    c. GENTLY squeeze the finger/heel to form a drop of blood. Wipe away the first drop of blood using a dry gauze pad or cotton ball. **DO NOT** use an alcohol wipe.
2. Venous or arterial samples
    a. If using fresh whole blood in the absence of an anticoagulant, test immediately to prevent clotting.
    b. Heparinized anticoagulated whole blood should be analyzed within 30 minutes of collection. Storing samples on ice is not recommended.
    c. When using heparinized anticoagulated whole blood from a tube or syringe, be sure to distribute red blood cells uniformly by gently inverting several times to mix. Do not shake.
    d. All syringe and tube draws must be labeled properly with the patient's name and a second patient identifier (e.g., SS #, Medical Record # or patient's birth date) if removed from the presence of the patient.

L. The *Apply Sample* screen displays. Touch the end of the test strip to the blood drop until the well of the test strip is full; the meter beeps and begins testing. Do not allow blood to run into the strip port. Liquid inside the strip port causes damage to the electronics of the meter.

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*.

M. The test results will appear in 6 seconds.

NOTE: Do not remove the test strip while the countdown is in progress.

1. Results within the normal range are displayed in blue.
2. Results outside the normal range are displayed in red.
3. If the value is outside the technical range of *the meter, t*he low or high end of the technical range will display along with < or >, accordingly.
4. A single up arrow (↑) is displayed with a result if the value is higher than the upper end of the normal range, but is not a critical result.
5. A double up arrow (↑↑) is displayed with a result if the value is a high critical result.
6. A single down arrow (↓) is displayed with a result if the value is lower than the lower end of the normal range, but is not a critical result.
7. A double down arrow (↓↓) is displayed with a result if the value is a low critical result.
8. Remove the strip manually or use the ejector button on the back of the meter to eject the strip.

N. If the meter displays a very **low** blood glucose result (<20 mg/dL), it is recommended that a blood sample be sent to the lab for confirmation.

O. No numerical result will appear if the glucose is <10 or > 600 mg/dL. The instrument will flag the result as “LO” or “HI”, respectively. Send a blood sample to the lab for confirmation.

P. To add a comment to the result, press Comment. Select the appropriate comment from the list of comments on the screen. Comments should be added prior to accepting or rejecting the result.

Q. To accept the result, press Accept.

R. To reject the result, press Reject.

S. Each result must be accepted or rejected before the meter is placed in the docking station; otherwise the results will remain in a pending state.

T. All data is stored into memory.

U. Log out of the meter after use. This can be done by docking the meter, pressing the operator information on the screen, or pressing logout on the Patient Test screen.

V. When patient testing is completed, the StatStrip Glucose meter should be cleaned and disinfected. Refer to Maintenance for cleaning and disinfecting instructions.

MAINTENANCE

A. Non critical care/Point of Care instruments or devices must be cleaned and disinfected when visibly soiled, after each use in an isolation room, and after each patient use if the device is going to a different patient.

B. Clean and disinfect the meter with a fresh Clorox® Germicidal Wipe, or an alternate germicidal product selected from the EPA’s Registration #67619-12

1. Clean the meter by wiping the surface of the meter with a Germicidal Wipe, making sure that no fluid enters the strip port.

2. Disinfect the Meter using a new, fresh Germicidal Wipe ensuring the meter surface stays wet for 1 minute if using Clorox® Germicidal Wipes. If using an alternate germicidal product, ensure the surface stays wet for the length of time recommended by the manufacturer. Use an additional wipe as needed to ensure disinfecting time.

C. DO NOT immerse the meter or hold the meter under running water. DO NOT spray the meter with a disinfectant solution. Do NOT use a dripping Germicidal Wipe.

RESULTS/INTERPRETATION

A. See lab-established reference intervals.

B. Neonatal fasting reference ranges have not been established on this instrument.

C. Critical values: Refer to nursing protocol for identification of clinical decision limits.

D. If the clinician receiving the report indicates that the results don’t match the patient’s symptoms, offer to repeat the test or send it to the lab.

E. Reportable range

20 – 600 mg/dL. Report a result less than 20 as “<20”. A result greater than 600 is displayed as “HI” by the meter; report as “>600”.

F. Results review

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.

1. From the *Patient Test* screen, press Review.

2. The *Review Result* screen displays.

3. Select how to sort the results by pressing ID, Time/Date or Type.

4. Press Page Down or Page Up to scroll through the stored results.

5. Select the result that you want to review.
6. Press View.
7. Press Previous to view the previous result. Press Next to view the next result.

   NOTE: The scroll bar shows the position in the results field: beginning, middle or end.

PROCEDURE NOTES

A. The LCD display turns off to conserve battery power (sleep mode) after a defined time of no activity. When the meter "wakes up" it will return to the last screen displayed before it went to sleep. Any of the following will "wake up" the analyzer:

   1. Touching the screen
   2. Placing the meter into the Docking/Charging Station
   3. Inserting a test strip

B. If the meter is placed into the docking station, the following conditions should be expected:

   1. If *Patient Result* screen is the current screen when docking occurs, the results are auto-saved.
   2. If the current screen is a *Setup* screen, any unconfirmed input data or menu selection is discarded upon docking.

C. The meter displays a number of alerts:

   Note: When performing a blood glucose test on the StatStrip meter, if the same error code is presented upon repeat testing of a patient sample, an alternative blood glucose test method should be performed on a new sample from the patient.

   A. Battery Low – Change the battery or place the meter onto the Charging / Docking Station.
   B. Analysis Cancelled- 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.
   C. Temperature – Meter will only work within the temperature range of 59°F to 104°F (15°C to 40°C).
   D. Bad Sample – Insert a new strip and rerun the test.
   E. Replace Strip – Occurs after insertion of strip or occurs during analysis. Insert another strip.
   F. Flow Error – Either insufficient sample was applied to the strip to fill the measuring well or the sample was applied incorrectly. Repeat the test with a new strip.
   G. Transfer Failed (Communication Errors) – Server refuses to allow dialog with meter, or connection to server was broken. This alert will be displayed if the meter was removed before data transfer was complete. Re-dock the meter. If problem persists, contact the POCT Coordinator.

LIMITATIONS

A. 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.

B. The StatStrip Glucose Meter results should agree with a laboratory result within 20%. A test result within this range is considered accurate when testing with the Nova StatStrip Meter. However, there are factors that may cause results to differ by more than 20% in some situations.

C. Blood source - Use only whole blood. Do not use serum or plasma.

D. 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.

E. Humidity extremes - Test results are best obtained when Nova StatStrips are used within an operating relative humidity of 10-90% (non-condensing).

F. Altitude -There is no effect of altitudes up to 15,000 feet above sea level.

G. Glucose results may be affected by dilution of sample by improper collection technique e.g. ‘milking’ the collection site, failure to allow collection site to dry prior to puncture, failure to obtain and wipe away a proper sized first drop of blood.

ATTACHMENTS

PT0051-A1 Interfering Substances

REFERENCES

A. StatStrip Glucose Hospital Meter System for USA Only, REF 55848 E. Waltham, MA: Nova Biomedical.

B. StatStrip Glucose Hospital Meter Test Strips, REF 55890. Waltham, MA: Nova Biomedical.

C. StatStrip Glucose Control Solution, REF 41741, 41742, and 41743. Waltham, MA: Nova Biomedical.

D. StatStrip Glucose Linearity Kit, REF 42173. Waltham, MA: Nova Biomedical.