Blanchard Valley Health System

Laboratory Servies

Blanchard Valley Hospital | **Bluffton Community Hospital**

1900 South Main Street, Findlay, OH 45840 | 139 Garau Street, Bluffton, OH. 45817

Glucose in Whole Blood on the Nova StatStrip System Procedure for POCT (LTR54239)

Last Approved By: Morman, Leslie (POC Coordinator) (Electronic Signature Timestamp: 04/21/2025)

Revision: 3.10

Last Approved Time: 04/21/2025

Attention: Printed copies MAY not be the most current information. Please consult the Lab QMS for the current version.

Glucose in Whole Blood on the Nova StatStrip® System

Procedure for Point of Care Testing

Method: Nova StatStrip® System

Test Analyte: Whole Blood Glucose

CLIA Complexity: Waived

The POCT program at BVHS follows manufacturer instructions for all test systems without modification.

INTENDED USE:

The StatStrip Glucose Hospital Meter System is intended for point-of-care, *in vitro* diagnostic, multiple-patient use for the quantitative determination of glucose in capillary finger stick, venous whole blood, arterial whole blood, neonate arterial whole blood, and neonate heel stick specimens.

It is not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia.

PRINCIPLE:

The Nova StatStrip Glucose Hospital Meter quantitatively measures glucose in whole blood both enzymatically and amperometrically. The test strip is designed with an electrode that measures glucose levels. Glucose in the blood sample mixes with reagent on the test strip and produces an electric current. The amount of current is proportional to the amount of glucose in the blood sample.

In addition to measuring glucose, the meter stores patient test data, QC test data, and other information relating to patient, patient sample, operator, reagents, and the meter. A user interface provides for a self-prompting environment via a color LCD. The charging station recharges the batteries.

THE SPECIMEN:

- Capillary whole blood (finger stick), venous whole blood, arterial whole blood, neonate heel stick, and neonate arterial whole blood specimens.
- Sample size 1.2 µL

Conditions

- When not analyzing from a lancing device, arterial and venous whole blood must be anticoagulated with lithium heparin.
- When not analyzing from a lancing device, whole blood must be analyzed within 30 minutes of collection.
- Alternate site testing (earlobe, forearm) is NOT allowed.
- Storage of samples on ice is not recommended.

EQUIPMENT AND MATERIALS:

Equipment

- StatStrip Meter
- Docking Station
- Lithium Battery

Materials

- StatStrip Glucose Test Strips.
- StatStrip Glucose Control Solutions, Levels 1 and 3.

Cleaning and Disinfection

- Materials - Clorox Healthcare Germicidal Bleach Wipe, EPA Registration# 67619-12, Or any disinfectant product with EPA Registration #67619-12, and Super Sani Disposable Wipes (Sani Wipes) EPA registration #9480-4.
- Frequency-Clean and Disinfect after EVERY patient test.

Storage Requirements

- StatStrip Meter; store at 15ºC to 40ºC (59 to104 ºF).
- Li-Polymer Battery; Store below 60ºC (140ºF). Discard properly after expiration date printed on the label.
- StatStrip Test Strips; Open expiration 180 days, or until expiration date printed on label; store at 1ºC to 30ºC.
- StatStrip Glucose Control Solutions; Open expiration 90 days, or until expiration date printed on label; store at 15ºC to 30ºC.

QUALITY CONTROL TESTING:

Frequency

Run 2 different levels of the StatStrip Glucose Control Solutions during each 24 hours of testing prior to testing of patient specimens and under the following circumstances:

- Each new operator.
- Before using the StatStrip Meter for the first time.
- If a patient test has been repeated and the blood glucose results are still lower or higher than expected.
- If there are other indications that the system is not working properly.
- Whenever problems (storage, operator, instrument) 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).

The meters have a QC Lockout function that prevents patient testing unless the QC is performed successfully by a qualified operator.

Procedure

1. Verify that the strip vial and QC vials are within the open expiration date – not to exceed the printed date on the vials.
2. From the "Welcome" screen, press the <Login> button and enter user ID by scanning ID badge barcode.
3. From the Patient Test Screen, press the QC key.
4. Press <Scan> to enter the Strip lot number and scan the barcode on the vial.
5. Enter the first QC Lot by scanning the barcode on the vial in the same manner.
6. Insert the test strip into the meter's strip port, gold end first.
7. Gently mix the Stat Strip Control solution.
8. Discard the first drop of control solution from the bottle to avoid contamination.
9. Ensure that the "Apply Sample" screen is illuminated.
   Note: If the screen darkens at any time during testing, tap the screen to illuminate it before continuing.
10. 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, maintaining contact until the 6-second countdown begins and a beep sounds.
11. Remove the Test Strip manually or use the strip ejector at the back of the meter.
12. Recap the control solution.
13. If "PASS" is displayed, press the Accept key, and continue with the next control level if required. If "FAIL" is displayed, add a comment as required. A record of corrective action is required when control results exceed defined acceptability limits. Press the <Comment> key. Select up to 3 comments to document corrective action taken. Comments will display on the result screen. Press the <Accept> key. Repeat any failed test.

Repeat procedure for the next level of Quality Control.

PATIENT TESTING:

Patient Preparation

Follow Standard Procedures for collecting a venous, arterial, or capillary specimen. For neonates, collect a heel stick or arterial specimen.
Follow Standard Procedures for recording the fasting or non-fasting status of the patient.

Running a Patient Sample

1. From the "Welcome" screen, press the <Login> button. "Enter Operator ID" will appear at the top of the screen.
2. Press <Scan> and scan the user barcode.
3. Press <Accept>. The "Patient Test" screen will appear.
   Note: If the padlock symbol appears with the words "Glu Locked", proceed to Quality Control Testing section above.
4. From the "Patient Test" screen, press the <Accept> key.
5. When the "Enter Strip Lot" screen displays, press <Scan> and scan the strip lot number. The "Enter Patient ID" screen will appear.
6. Scan the Patient ID armband barcode by scanning the patient barcode in the same manner.
   Note: Follow the accepted procedure for processing invalid samples (unregistered patient, unreadable barcode, system downtime) in the event that an "Invalid Patient" message appears. The 8 digit FIN number can be entered manually if needed.
7. Verify the patient information on the screen and press <Accept>. The "Insert Strip" screen will appear.
8. Insert the test strip into the meter's strip port, gold end first. The "Apply Sample" screen will appear.
9. Perform the finger or heel stick procedure, ensuring that the site is clean and dry.
10. Ensure that the "Apply Sample" screen is illuminated.
    Note: If the screen enters sleep mode and darkens at any time during testing, tap the screen to illuminate it before continuing.
11. Squeeze the site gently to form a drop of blood.
12. Touch the end of the Test Strip to the blood drop, maintaining contact until the 6-second countdown begins and a beep sounds.
    Alternatively, apply a drop of well-mixed heparinized whole blood from a tube or syringe.
13. Once the result appears, remove the test strip manually or use the strip ejector at the back of the meter.
14. Discard the used test strip into appropriate waste container.
15. Select <Reject>, <Accept>, or <Comment>.

    15.1. If "Reject" is selected, add comments as required, and repeat the test as necessary.
    15.2. If "Accept" is selected, the meter will be ready for the next patient test.
    15.3. If "Comment" is selected, choose the comment by touching it on the screen. It will highlight in black. Press <Accept>. You may select up to three

comments per sample. Providers must be notified immediately of critical results and detailed documentation of action taken is required.

16. Clean the meter by wiping the external surface of the meter thoroughly with a fresh germicidal disinfecting bleach wipe.
17. Disinfect the meter. Using a new, fresh germicidal bleach wipe, thoroughly wipe the surface of the meter (top, bottom, left, and right sides) a minimum of 3 times horizontally followed by 3 times vertically avoiding the bar code scanner and electrical connector. Gently wipe the surface area of the test strip port making sure that no fluid enters the port. Ensure the meter surface stays wet for 1 minute (Clorox wipes) or 2 minutes (Sani Wipes) and is allowed to air dry for an additional 1 minute. For patients with a known diagnosis of C. diff, the meter surface must stay wet for 3 minutes.
18. Remove any residue with a soft cloth dampened with water.
19. Once testing is complete, return the meter to the docking station. Ensure that the meter is securely seated in the dock and that all lights are illuminated.

Measurement Range

10 mg/dL to 600 mg/dL
Results below 10 mg/dL will display "LO"
Results above 600 mg/dL will display "HI"

Reference Ranges with Critical Values listed by age:

0 hours – 4 hours:	41-60 mg/dL	(< 25 and > 250 critical)
4 hours – 1 day:	46-60 mg/dL	(< 35 and > 250 critical)
1 day - 2 months:	51-90 mg/dL	(< 45 and > 250 critical)
2 months - 16 years:	60-99 mg/dL	(< 54 and > 250 critical)
16 years - 150 years:	70-99 mg/dL	(< 54 and > 400 critical)

Procedure Notes/Troubleshooting

Note: Most problems can be solved by removing the battery. Wait 1 full minute. Replace battery. Put meter back in dock.

Condition	Explanation	Action
Low Battery	Battery charge too low to continue	Replace battery or return meter to docking/charging station
Analysis Error-Analysis Cancelled	Test Strip was removed or loosened	Repeat test with new Test Strip. Leave strip in place until result is displayed on screen.
Analysis Error-Temperature Error	Temperature must be 59-104ºF	Re-locate the meter to an environment within specified temperature range.
Analysis Error-Bad Sample	Sample not accepted	Repeat the test with a new strip. If the error recurs, use alternate testing method.

Analysis Error-Replace Strip	Strip damaged	Repeat the test with a new strip.
Analysis Error- Flow Error	Insufficient sample or incorrect sample application	Repeat the test with a new strip. If the error recurs, use alternate testing method

LIMITATIONS:

- The system has not been evaluated for use with neonate venous blood.
- Blood source - use only whole blood. Do not use serum or plasma.
- Temperature and humidity extremes - Test results may be inaccurate when test strips are stored outside of the storage and handling conditions.
- Specimens - only fresh whole blood or whole blood collected in lithium heparin collection devices should be used for arterial and venous specimens.
- Fluoride, EDTA, sodium, and ammonium blood collection devices should not be used for arterial and venous specimens.

PRECAUTIONS:

- DO NOT reuse test strips. Test strips should be disposed after a single use.
- Remove the test strip from the vial only when ready to test. Do not tamper with test strip.
- Do not use the test strip if the expiration date has passed, for this may cause inaccurate results.
- If test result is higher or lower than expected, run a control solution test to confirm test strip performance.
- If control solution result is out of range, remove test strip vial from point of use and repeat control solution test with new test strip vial.
- If control solution test is within expected range, repeat patient test.
- If patient test result is higher or lower than expected, perform glucose test on alternate method by ordering a Laboratory blood draw for glucose and consult healthcare professional.
- Universal Precautions, including the use of Personal Protective Equipment (PPE) must be followed when handling the StatStrip meter or any blood products.
- The StatStrip Glucose Meter uses a Class 2 laser that can cause retinal damage. Do not look into the beam of light.
- The StatStrip Glucose Meter uses a rechargeable lithium ion battery. Do not store above 60ºC (140ºF). Do not incinerate. Do not use if damaged. Follow proper disposal procedures.

CLINICAL SIGNIFICANCE:

Glucose serves as the principal fuel of all tissues. Insulin facilitates its entry to the cells where a series of chemical reaction occur to produce energy. Lack of insulin or resistance to it causes diabetes, characterized by elevated glucose levels. Some patients may develop metabolic acidosis and ketosis caused by the increase of the metabolism of fat, the alternate energy source.

Hyperglycemia is also seen in gestational diabetes, pancreatic disease, pituitary and adrenal disorders. Hypoglycemia, a decreased level of blood glucose, is seen in starvation, hyperinsulinemia, and in patients on insulin therapy.

Tight glucose control is essential for prevention of complications in people with diabetes. Lowering blood glucose toward normal levels drastically decreases the development and progression of diabetes-related

complications in the eyes, kidneys, and nerves in persons with type 1 diabetes. Monitoring of blood glucose is a critical tool in providing that information to a person with diabetes.

CALIBRATION:

The Nova StatStrip Meter does not require any calibration. Linearity Levels 1-5 (REF 42173) are available for purchase from Nova Biomedical.

ROUTINE BATTERY REPLACEMENT:

Frequency

- When the Li-polymer battery has reached its expiration date.
- When the Li-polymer battery shows any visible signs of damage.
- If the battery becomes drained, and there is a spare battery available.

Procedure:

1. Pull back on the back cover latch and remove the cover.
2. Grasp the battery and remove it.
3. Replace the battery with the new one, bottom first.
4. Discard expired battery properly, or recharge a discharged battery in the docking station.

Batteries are available for purchase from Nova Biomedical in 4 pack or 5 pack.

SAFETY INCLUDING INFECTION CONTROL / PREVENTION:

All associates and providers are to follow the BVHS safety policies and procedures when performing point of care testing. The POCT program's goal is to assure the safety of patients and health care personnel commensurate with the scope of its activities, particularly those concerning infection control, hazardous waste, and chemical hygiene.

Standard precautions are used for point of care testing by testing personnel. Gloves must be worn during testing events, hand hygiene performed, and gloves changed between patients, according to Standard Precautions. Hands must be cleaned using an effective antimicrobial method.

Only auto-disabling single-use finger stick devices are used to assist monitoring of blood glucose and other point of care testing. These devices are designed to be used only once, after which the blade is retracted, capped, or otherwise made unusable. All waste sharps are to be discarded in puncture resistant containers that are easily accessible, located in areas where needles are commonly used, and properly labeled to warn handlers of the potential hazard.

The BVHS Infection Control/Prevention Policy is in effect to prevent transmission of infection. Compliance with the manufacturer's guidelines (when provided) is required. POCT handheld or portable testing devices must be disinfected after each patient use. Devices and materials designed for single use must not be disinfected and reused. Every attempt should be made to allow only the glucose test strip to come in contact with the patient's skin.

REQUIRED TRAINING AND COMPETENCY ASSESSMENTS:

Refer to the Point of Care Testing Policy for more information concerning required records of training and competency assessments, as directed by the BVHS Laboratory Point of Care Testing Coordinator.

REFERENCES:

CLSI Procedure for Glucose in Whole Blood on the Nova StatStrip® System by Nancy Cataldo 12/31/2014.

CAP Point-of-Care-Testing Checklist 08.21.2017.

CAP Point-of-Care Testing Checklist 08.22.2018.

Nova Biomedical Customer Information Bulletin No: 01-25SS for Product: Nova StatStrip and StatSensor Meter Systems, March 2025.