

Glucose in Whole Blood on the Nova StatStrip® System (Practices)

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.

This glucose meter is approved for the determination of dysglycemia with:

- Capillary finger sticks in **STABLE** patients only.
- Venous whole blood or arterial whole blood in **UNSTABLE** patients as delineated below.
- Heel sticks and arterial whole blood (but not venous whole blood) in neonates.

The StatStrip Glucose Hospital Meter System is not approved for the screening or diagnosis of diabetes mellitus.

CLIA WAIVER:

This test is “Waived” for finger stick whole blood, venous and arterial whole blood, neonatal infant heel sticks and neonatal arterial specimens under the Clinical Laboratory Improvements Amendments of 1988 (CLIA). Laboratories with a Certificate of CLIA waiver can perform this test in a waived setting. If the manufacturer’s instructions are modified in any way, the test will no longer be considered waived.

LIMITATIONS:

- Capillary whole blood specimens (e.g. obtained by finger stick) should not be used in patients receiving intensive medical intervention/therapy because of the potential for pre-analytical collection error and specifically in patients with decreased peripheral blood flow, as it may not truly reflect the patient’s true physiological state. Examples include, but are not limited to, severe hypotension, shock, hyperosmolar-hyperglycemia (with or without ketosis) and severe dehydration.
- 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.
- Altitudes above 15,000 feet (4500 meters) above sea level have not been evaluated.
- 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.

CAUTION: *Capillary whole blood specimens (e.g. obtained by finger stick) should not be used in patients receiving intensive medical intervention/therapy because of the potential for pre-analytical collection error and specifically in patients with decreased peripheral blood flow, as it may not truly reflect the patient's true physiological state. Examples include, but are not limited to, severe hypotension, shock, hyperosmolar-hyperglycemia (with or without ketosis), and severe dehydration.*

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.

PRECAUTIONS:

- Prior to use, read the Instructions for Use Manual.
- DO NOT reuse test strips. Test strips should be disposed after a single use.
- Discard used test strips according to local regulations.
- Remove the test strip from the vial only when ready to test.
- Do not use the test strip if the expiration date has passed, for this may cause inaccurate results.
- Do not tamper with the test strip.
- 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 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 60°C (140°F). Do not incinerate. Do not use if damaged. Follow proper disposal procedures.

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.

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.

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:

- 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– PDI Super Sani-Cloth Germicidal Wipes

- Frequency-Clean and disinfect after EVERY patient test

Storage Requirements

- StatStrip Meter: store at 15°C to 40°C (59 to 104 °F)
- Li-Polymer Battery: Store below 60°C (140°F). 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 15°C to 30°C.
- StatStrip Glucose Control Solutions: Open expiration 90 days, or until expiration date printed on label; store at 15°C to 30°C.

CALIBRATION: The Nova StatStrip Meter does not require any calibration

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)
- At least once every 365 days to maintain competency to perform testing

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 employee badge.
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. Verify that the lot number is correct and press <Accept>.
6. Enter the first QC Lot by scanning the barcode on the vial in the same manner.
7. Verify that the lot number displayed is correct and press <Accept>.
8. Insert the test strip into the meter’s strip port, gold end first.
9. Gently mix the Stat Strip Control Solution.
10. Discard the first drop of Control Solution from the bottle to avoid contamination.
11. 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.
12. 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.
13. Remove the Test Strip manually or use the strip ejector at the back of the meter.
14. Recap the Control Solution.
15. If “PASS” is displayed, press the Accept key, and continue with the next control level if required. If “FAIL” is displayed, repeat test with a new strip.
16. Repeat procedure for the next level of Quality Control.

PATIENT TESTING:

Patient Preparation

Follow Standard Procedures for collecting a venous, arterial, or capillary specimen.

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. Verify that the strip lot number displayed is correct and press <Accept>. The “Enter Patient ID” screen will appear.
6. Enter Patient ID (M Number) by manually entering the patient’s M number.

6.1 In the event that a patient M Number is not available, please use the next available number on the Emergency Blood Glucose Monitoring Log. A copy of the completed log should be sent to the attention of the Point of Care Coordinator as soon as all information on log sheet is complete.

7. 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 stick, heel stick or venous collection 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. If performing a capillary or heel stick, squeeze the site gently to form a drop of blood. Wipe away the first drop and test the second drop.
12. Touch the end of the Test Strip to the blood drop, maintaining contact until the 6-second countdown begins and a beep sounds.
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. Clean the meter by wiping the external surface of the meter thoroughly with a fresh PDI Super Sani-Cloth Germicidal Wipe.
16. Disinfect the meter. Using a new, fresh PDI Super Sani-Cloth Germicidal 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 2 minutes** and is allowed to air dry for an additional **1 minute**. Remove any residue with a soft cloth dampened with water.
17. 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 20 mg/dL will display “LO”

Results above 600 mg/dL will display “HI”

Reference Ranges

Adults: 74-106 mg/dL

Neonates: 45-110 mg/dL

Procedure for Critical Results

All results that fall within the critical range should be repeated. If the repeat result is still >600 mg/dL for adults or >300mg/dL for neonates, then a venous sample should be collected and sent to the main lab for testing.

Adults: <50 mg/dL or >400 mg/dL

Neonates: <40 mg/dL or >300 mg/dL

Procedure Notes/Troubleshooting

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 59-104°F	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

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.

REFERENCE:

Nova Biomedical StatStrip Glucose Hospital Meter System Instructions for Use. 01/2020

StatStrip Glucose Hospital Meter Test Strips package insert. 03/2019