Laboratory Procedure

SUBJECT Glucose in Whole Blood on the Nova StatStrip® System							
FORMER SUBJECT	DATE REVISED 2/20/23		DATE EFFECTIVE 8/3/16			PAGE 1 OF 1	
OWNER: Laboratory	INIT/DATE 8/3/16						
DATE ORIG. WRITTEN 8/2/16	DATE REVIEWED:						
APPLIES TO: All staff using the Nova StatStrip System							

Glucose in Whole Blood on the Nova StatStrip® System

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 60ºC (140ºF). 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
- Venous whole blood, arterial whole blood, neonatal heel stick, and neonatal arterial whole blood samples throughout all hospital and all professional healthcare settings
- 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
- For venous specimens only:
    - S-Monovette lithium heparin tube
    - Multi-Adapter Luer-Lock

Cleaning and Disinfection

- Materials– PDI Super Sani-Cloth Germicidal Wipes
- 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 15ºC to 30ºC.
- StatStrip Glucose Control Solutions: Open expiration 90 days, or until expiration date printed on label; store at 15ºC to 30ºC.

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.

The following criteria must be evaluated every time a blood glucose is performed on a patient in the ED or ICU. If a patient meets any of these criteria, a venous or arterial specimen must be tested. MAP less than 65mmHG

1. 2 or more vasopressor infusions
2. Volume resuscitation with fluids infusing at greater than 500 ml/hr. to maintain MAP>65mmHG for more than 3 hours.
3. Gross edema on the extremity from which the capillary blood is being obtained.
4. Any of the above in combination with hypoxemia (defined as arterial PaO2 of less than 80mmHG). Low PaO2 levels in patients with known lung disease should not be used to restrict use of capillary blood in isolation of other listed parameters.

Note: Venous and arterial specimens will be collected into a Lithium Heparin S-Monovette and applied from the S-Monovette to the test strip.

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. DO NOT take vials of strips into the patient room. Only take a single strip after scanning the strip lot number and pressing <Accept>.
7. Enter Patient ID (F Number) by scanning the patient wristband in the same manner.

    i. In the event that a patient barcode 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.
    ii. In the event that a "Patient Not Found Dock Meter and Re-scan" message appears, first dock the meter then re-scan wristband. If message still displays, verify that the patient Account Number that is displayed matches the patient you

are to be performing the test on. If correct, then proceed by selecting Downtime Override. If incorrect, select <Back> and rescan the patient's wristband.

8. Verify the patient information on the screen and press <Accept>. The "Select Sample Type" screen will appear.
9. Select appropriate sample type and press <Accept>. The "Insert Strip" screen will appear.
10. Insert the test strip into the meter's strip port, gold end first. The "Apply Sample" screen will appear.
11. Perform the finger stick, heel stick or venous collection procedure, ensuring that the site is clean and dry.
12. 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.
13. 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.

    i. If performing a test using a venous or arterial sample, collect sample in a lithium heparin S-Monovette, mix sample by inverting several times, and apply a drop of blood to the test strip.
    ii. Please note that performing bedside glucose testing on patients with venous draws or line draws may result in significant blood loss with frequent glucose testing and therefore, may lead to iatrogenic anemia.

14. Touch the end of the Test Strip to the blood drop, maintaining contact until the 6-second countdown begins and a beep sounds.
15. Alternatively, apply a drop of well-mixed heparinized whole blood from a syringe.
16. Once the result appears, remove the Test Strip manually or use the strip ejector at the back of the meter.
17. Discard the used Test Strip into appropriate waste container.
18. Select <Reject>, <Accept>, or <Comment>.

    i. If "Reject" is selected, add comments, and repeat the test as necessary.
    ii. If "Accept" is selected, the meter will be ready for the next patient test.
    iii. 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.

19. Clean the meter by wiping the external surface of the meter thoroughly with a fresh PDI Super Sani-Cloth Germicidal Wipe.
20. 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.
21. 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.

Comment Codes

Code	When to Use
Questionable Result	Reject first test. Repeat test or send to lab
Instrument Cleaned	Add comment after each test indicating that you are cleaning and following the cleaning and disinfecting procedure.

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 >400 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 59-104ºF	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

Troubleshooting Results

- Contact the Point of Care Coordinator at x6704 between the hours of 8am-4:30pm Monday-Thursday, or the Nursing Supervisor outside of these hours for the following issues:
    - Result does not cross to the patient chart
        - This can usually be resolved by the Point of Care Coordinator or Nursing Supervisor releasing the result.
    - Wrong sample type chosen
        - Result will cross over to the patient chart as long as the result was accepted and downtime override was not chosen.
        - If the result crosses to the patient chart, you will need to contact the Point of Care Coordinator (x6704) with the patient name, F number, date/time of test. At this point the Point of Care Coordinator will add a note indicating the correct sample type.
        - If the result has NOT crossed to the patient chart, the Point of Care Coordinator or Nursing Supervisor can go in and change the sample type and then send the result to the patient chart.

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 device insert, August 2015.

2/20/23