Blanchard Valley Health System

Laboratory Servies

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Glucose in Whole Blood on the Nova StatStrip Xpress 2 Hospital Glucose Meter Procedure for POCT (LTR54712)

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Glucose in Whole Blood on the Nova StatStrip Xpress® 2 Hospital Glucose Meter Procedure for Point of Care Testing

Method: Nova StatStrip® Xpress® 2 Hospital Glucose Meter
Test Analyte: Whole Blood Glucose
CLIA Complexity: Waived
The POCT program at BVHS follows manufacturer instructions for all test systems without modification.

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.

INTENDED USE

The StatStrip Xpress® 2 Glucose Hospital Meter 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.

The StatStrip Xpress® 2 Glucose Hospital Meter is also intended for use in the quantitative determination of glucose in venous whole blood, arterial whole blood, neonatal heel stick and neonatal arterial whole blood samples throughout all hospital and all professional healthcare settings.

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

PRINCIPLE

The Nova StatStrip Xpress® 2 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.

THE 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 Xpress® 2 Meter
- 2 Energizer Max AAA Batteries

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

- Frequency- clean and disinfect after EVERY patient test.

Storage Requirements
- StatStrip Xpress® 2 Meter; store at 5ºC to 40ºC (41 to104 ºF)
- StatStrip Test Strips; Open expiration is 180 days or until expiration date printed on label, but not to exceed the manufacturer expiration date; store at 15ºC to 30ºC.
- StatStrip Glucose Control Solutions; Open expiration is **3 months**, or until expiration date printed on label, but not to exceed the manufacturer expiration date; 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 Xpress® 2 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, or 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).
- As required by the institution's quality control policy or local regulatory requirements.

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. Insert a test strip into the meter. Then a blood drop will display.
3. Identify the sample as a Control; use the Left or Right button to find the desired control level: QC1 or QC3.
4. Gently mix the Stat Strip Control solution.
5. Discard the first drop of control solution from the bottle to avoid contamination.
6. 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 meter beeps.
7. Recap the control solution.
8. Glucose quality control test results are available on the screen in 6 seconds.
9. There is one long beep when the results are ready. There are 3 short beeps if test results are outside the measurement range of the test strip. Record the quality control result on the Xpress 2 QC and Maintenance log sheet as required for each specific location.
10. Remove the test strip and discard into an appropriate biohazard container.
11. Repeat procedure for the next level of Quality Control.

The following JC/CAP accredited sites must record quality control results in the Laboratory Information System (LIS):

1. BVH Cardiac Rehab
2. BVH Outpatient Laboratory
3. Bluffton Hospital Outpatient Laboratory
4. Carey Diagnostic Laboratory
5. EWOC Laboratory
6. Ottawa Diagnostic Center
7. Wound Care Solutions

GENERAL INSTRUCTIONS FOR LIS (CERNER) Point of Care Quality Control (QC) Data Entry

Point of Care (POC) QC data entry is a process of recording the requisite Quality Control material so that appropriate documentation and monitoring of device performance can occur. Documentation of POC QC data with Cerner will be accomplished via an option from the User's PowerChart toolbar that link's to the Laboratory's PathNet Accession Results Entry application (with appropriate access limitations).

QC data will have predefined ranges of acceptability and, in some cases, recommend trouble shooting steps for correction. In all cases, QC data falling out of range will require some level of documentation (as to action or corrective action).

Point of Care QC Data Entry Process:

1. Open and log into the PowerChart application. (The link to the Laboratory Accession Results Entry application from PowerChart is role based).
2. Locate the "Extended Toolbar" in the top portion of PowerChart. (This appears like a dropdown arrow at the far right of the toolbar.)
3. Click on the down arrow to view the extended toolbar options.
4. From the list, locate and click Accession Results Entry.
5. For each Point of Care device there will be a QC identifier assigned for each level of quality control performed. For example: a glucose meter will have 2 QC identifiers, QC-1070011 for the High control and QC-1070012 for the Low control. These identifiers are specific to that glucose meter.
6. Enter the appropriate QC identifier in the field labeled Accession.
7. Click the Retrieve button and the data entry fields for the QC will appear.
   NOTE: The control description and the control type information will also appear so the user can see exactly what QC they are entering.
8. Enter the appropriate QC data for that control and hit the Enter key.
   a. Applicable ranges of acceptability will display in the QC Ranges column.

b. Any additional documentation items (i.e. Battery Changed?) can also be documented here. These are not generally required as they are not performed every time QC is done.

9. Once all data has been entered, click the Verify button at the bottom right corner of the screen.
10. If the QC value that is entered falls outside of acceptable limits, it will be flagged ("H"igh or "L"ow) and when the User clicks Verify a QC Correction window opens.
    a. The top 2 sections are statistical and rules information for Laboratory use (**Procedures** And **Rules**).
    b. The **Troubleshooting** section may contain information or instructions to the User regarding what to do as a result of this QC failure.
    c. The **QC result comment** is where an action or corrective action comment will be entered stating what action is being taken to correct the failure. Note: This is a required field.
    d. The **Actions** section will default to Rejected because the QC value was out of limits. Do not change this default. If repeat/rerun of the QC is warranted, begin the QC data entry process again at the Accession number entry level.
11. Click the OK button at the bottom right of the screen when troubleshooting and documentation are complete.
12. Point of Care Quality Control should be performed per protocol for the testing device being used. Test the appropriate QC levels at the appropriate frequencies as needed.

List of BVHS Glucose Meter Quality Control Identifiers:

BVH Cardiac Rehab
CR - High: QC-1070391, Low: QC-1070392

BVH Laboratory
OPL A (Outpatient Lab A) - High: QC-1070441, Low: QC-1070442
OPL B (Outpatient Lab B) - High: QC-1070451, Low: QC-1070452

Bluffton Laboratory
XLAB - High: QC-1070611, Low: QC-1070612

Carey Diagnostic Center:
CDS: High: QC-6070002, Low: QC-6070001

Eastern Woods Outpatient Center
EW - High: QC-1070541, Low: QC-1070542

Ottawa Diagnostic Center
ODC - High: QC-2070621, Low: QC-2070622

Wound Care Solutions
WC A - High: QC-1070531, Low: QC-1070532
WC B - High: QC-1070681, Low: QC-1070682

PATIENT TESTING

Patient Preparation
Follow Standard Procedures for collecting a venous, arterial, or capillary specimen.
Follow Standard Procedures for recording the fasting or non-fasting status of the patient.

Running a Patient Sample

1. Insert a test strip into the meter. Verify that all segments of the screen display. If the display is incomplete, discontinue use for diagnostic testing. A test strip with a blood drop will display.
2. Perform the finger or heel stick procedure, ensuring that the site is clean and dry.

3. Squeeze the site gently to form a drop of blood. Wipe away the first drop of blood then squeeze the finger again to form a second drop of blood.
4. Touch the end of the Test Strip to the blood drop, maintaining contact until the beep sounds.
5. There is one long beep when the results are ready. There are 3 short beeps if test results are outside the range of the test strip.
6. Once the result appears, remove the Test Strip. Discard the used Test Strip into appropriate waste container.

When patient testing is complete, the StatStrip Xpress 2 Glucose Hospital Meter should be cleaned and disinfected after use prior to testing with a new patient.

1. Clean the meter by wiping the external surface of the meter thoroughly with a fresh germicidal disinfecting wipe.
2. Disinfect the meter. Using a new, fresh 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. 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)** and is allowed to air dry for an additional 1 **minute**.
   Note: For patients with a known diagnosis of C. diff, the meter surface must stay wet for **3 minutes**.
3. Remove any residue with soft cloth dampened with water.

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)

TROUBLESHOOTING

E1 System Hardware Error: A system hardware error has been detected**.**
Action: Perform the test again. If you get the same error, call Nova Technical Support.

E2 Operating Temperature Error: The Meter temperature is outside of the range for testing. A blood glucose result will not be obtained**.**
Action: Move the meter to an area where the temperature is acceptable (41-104°F or 5-40°C), allow meter to adjust to the temperature. Repeat the test.

E3 Used Strip Error: The test strip was previously used.
Action: Repeat the test with a new test strip. If the error persists, perform the test using an alternate test strip vial or alternate method.

E4 Short Sample Error: An insufficient sample volume (control or blood) was drawn into the test strip.
Action: Repeat the test with a new test strip. If the error persists, perform the test using an alternate test strip vial or alternate method.

E5 Strip Not Recognized Error: The test strip is not recognized.
Action: Repeat the test with a new test strip. If the error persists, perform the test using an alternate test strip vial or alternate method.

E8 Bad Strip Error: The test strip is defective or bad.
Action: Repeat the test with a new test strip. If the error persists, perform the test using an alternate test strip vial or alternate method.

TECHNICAL ASSISTANCE

For technical assistance, call Nova Biomedical Technical Services at 1.800.545.NOVA, 1.781.894.0800.

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.
- 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.

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.

MONTHLY ROUTINE BATTERIES CHECK

Nova recommends using AAA Alkaline or Lithium (Iron Disulfate) batteries from well-known manufacturers such as Duracell and Energizer. Ideally, use of batteries that have a “No Leak” guarantee is preferred, such as the Energizer MAX. Zinc-Carbon batteries are NOT recommended to use with Xpress 2 meters. Because of the potential to leak, it is recommended that Xpress 2 meter batteries be inspected on a monthly basis and findings recorded on the Xpress 2 QC and Maintenance log sheet. Never install or use any batteries that are past their listed expiration date, and immediately replace any batteries that show swelling, cracking, leaking, or exhibit any white powder on the outside of the batteries or in the battery case.

The battery provides sufficient power to operate for approximately 600 tests. A battery low warning will alert the user to replace the battery. Test results are stored in non-volatile memory to prevent test result loss. Replacement Energizer Max AAA batteries are to be ordered as needed from Friends Office Supplies.

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 or heel stick lancing devices are used to assisting 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 cleaned and 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® Xpress® 2 Hospital Glucose Meter by M. Krasnoff 3/8/2017.
CAP Point-of-Care-Testing Checklist 08.21.2017.
CAP Point-of-Care Testing Checklist 08.22.2018.
Nova Biomedical Customer Information Bulletin No: 01-21SS for Product: Nova StatStrip and StatSensor Meter Systems, January 2021.
"Nova StatStrip Xpress-2 Battery Recommendations", Nova Biomedical Customer Information Bulletin No: 08-21SS for Product: Nova StatStrip Xpress 2, October 2021.
Nova Biomedical Customer Information Bulletin No: 01-25SS for Product: Nova StatStrip and StatSensor Meter Systems, March 2025.