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Written by: Caylee Cunningham, M(ASCP) 06/2016

Reviewed and Approved by: Kent Lewandrowski, MD 7/2016

Purpose

This document outlines policies and procedures for definitive waived glucose testing at the point of care.
Scope

Level of Personnel: All MD’s, RNs, NPs, PCAs, and MAs, who have successfully completed initial training and maintained annual competency.

Testing Site: All sites approved and on file with the Pathology Services POCT Division

Policy and Procedure Statement

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.

Test 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.

Regulatory Requirements

I. Each testing site must have a documented quality control program, which is developed in collaboration with or has been approved by the MGH Pathology Service.

II. All test results must be maintained in patient records with all required information for four years

   Required information:
   1. Patient’s name
   2. Medical Record Number
   3. Patient’s gender
   4. Patient’s age or date of birth
   5. Date & time test collected, performed and reported
   6. Ordering Physician
   7. Responsible physician (if not 6)
   8. Reference or Target Range
   9. Test Performed
   10. Test units
   11. Lab name

III. Additional information that must be retained for four years:

   1. Testing personnel records
   2. Quality control results
   3. Product information (i.e. serial number, lot numbers, expiration dates, etc.), information on quality control and any remedial action
   4. QC charts, maintenance sheets, reference and critical ranges

IV. Other

   1. Universal precautions must be observed when handling any patient specimen.
   2. A physician’s order or standing order is required prior to performing test.
   3. The Hospital Hand Hygiene policy must be adhered to at all times.
   4. Transcription review for manually documented results – one patient result/test performed/day.

V. Linearity/Calibration Verification

The POCT program will perform and document linearity/calibration verification checks every six months if applicable.

Competency Assessment

All operators must complete the Nova StatStrip HealthStream Module prior to training and the Nova StatStrip Training Checklist during initial training. The procedure is available through the Laboratory Handbook.

Competency is assessed at orientation and annually thereafter using at least two of the following methods:
1. Performing a test on a blind specimen.
2. Supervisor observes performance of routine work.
3. Each user’s quality control performance is monitored.
4. Written testing specific to the method.

Only operators who have been trained and completed yearly competencies will be given access to the meter through a System Administrator.

**Expired Operators:**

Operators that fail to meet competency requirements within 365 days will be locked out of the system. They may be required to undergo retraining and competency assessment according to above.

### Test Kits/Supplies/Equipment

<table>
<thead>
<tr>
<th>Product</th>
<th>Vendor</th>
<th>Part #</th>
<th>O&amp;M #</th>
<th>PeopleSoft#</th>
<th>Distributed by:</th>
<th>Storage requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>StatStrip Glucose Hospital Meter Test Strips</td>
<td>Nova Biomedical</td>
<td>42214</td>
<td>0828042214</td>
<td>493498</td>
<td>Owens and Minor</td>
<td>Open expiration 180 days, or until expiration date printed on label; store at 15ºC to 30ºC.</td>
</tr>
<tr>
<td>Control Solution 1, StatStrip (1 bottle per package)</td>
<td>Nova Biomedical</td>
<td>41741</td>
<td>0828041741</td>
<td>493495</td>
<td>Owens and Minor</td>
<td>Open expiration 90 days, or until expiration date printed on label; store at 15ºC to 30ºC.</td>
</tr>
<tr>
<td>Control Solution 3, StatStrip (1 bottle per package)</td>
<td>Nova Biomedical</td>
<td>41743</td>
<td>0828041743</td>
<td>493496</td>
<td>Owens and Minor</td>
<td>Open expiration 90 days, or until expiration date printed on label; store at 15ºC to 30ºC.</td>
</tr>
<tr>
<td>StatStrip Linearity Kit (5 levels, 1 of each bottle)</td>
<td>Nova Biomedical</td>
<td>42173</td>
<td>0828042173</td>
<td>493497</td>
<td>Owens and Minor</td>
<td>Open expiration 90 days, or until expiration date printed on label; store at 15ºC to 30ºC.</td>
</tr>
<tr>
<td>StatStrip Wireless Meter</td>
<td>Nova Biomedical</td>
<td>54790</td>
<td>Email mghpocctcoordinators</td>
<td>Nova Biomedical</td>
<td>Room Temperature 15ºC to 40ºC (59 to104 ºF)</td>
<td></td>
</tr>
<tr>
<td>Docking Station</td>
<td>Nova Biomedical</td>
<td>53400</td>
<td>Email mghpocctcoordinators</td>
<td>Nova Biomedical</td>
<td>Room Temperature 15ºC to 40ºC (59 to104 ºF)</td>
<td></td>
</tr>
<tr>
<td>Li-Polymer Battery</td>
<td>Nova Biomedical</td>
<td>50346</td>
<td>Email mghpocctcoordinators</td>
<td>Nova Biomedical</td>
<td>Store below 60ºC (140°F). Discard properly after expiration date printed on the label.</td>
<td></td>
</tr>
<tr>
<td>StatStrip Carrying Case</td>
<td>Nova Biomedical</td>
<td>53425</td>
<td>Email mghpocctcoordinators</td>
<td>Nova Biomedical</td>
<td>Room Temperature 15ºC to 40ºC (59 to104 ºF)</td>
<td></td>
</tr>
</tbody>
</table>

**Note:**

- New lot numbers of QC, Linearity and test strips are entered into Nova Net by the POCT Program staff prior to use for tracking purposes.
- All reagents must be dated when opened.

### Limitations

- **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.
- 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.

**PRECAUTIONS:**

- Discard used test strips into biohazard waste.
- 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.
- 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 or point it towards anyone’s eyes while scanning a barcode.
- 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.

**Calibration/Linearity**

The Nova StatStrip Meter does not require any calibration. It is not a requirement of the manufacturer to validate new devices, strip lots or QC lots due to lot-to-lot consistency. Additional information is available in vendor documents.

**Quality Control**

**Frequency:**

Two levels of StatStrip Glucose Control Solutions should be run and Pass during each 24 hours of testing prior to testing of patient specimens and under the following circumstances:

- Each new operator
- Each new or replacement meter
- 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. “Enter Operator ID” will appear at the top of the screen.

   **Note:** If the padlock symbol appears with the words “Glu Locked,” QC must be complete in order to perform patient testing.

3. Press <Scan> and scan the user barcode, or enter the user ID manually using the keypad.

   **Note:** Entering the user ID manually will require duplicate entry

4. From the Patient Test Screen, press the QC key.
5. Press <Scan> to enter the Strip lot number and scan the barcode on the vial.
6. Enter the first QC Lot by scanning the barcode on the vial in the same manner.
7. Insert the test strip into the meter’s strip port, gold end first with NOVA facing up.
8. Gently mix the Stat Strip Control solution.
9. Discard the first drop of control solution from the bottle to avoid contamination.
10. 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.
11. 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.
12. Remove the Test Strip manually or use the strip ejector at the back of the meter.
13. Recap the control solution.
14. If “PASS” is displayed, press the Accept key, and continue with the next control level if required. If “FAIL” is displayed, Press the <Accept> key and repeat the level.
    **Note:** If control solution continues to Fail upon repeat, remove test strip vial from use and repeat control solution test with new test strip vial.
15. Repeat procedure for the next level of Quality Control. If both levels do not receive a “PASS” status, patient testing will not be allowed.

### Specimen Collection

- Venous whole blood, arterial whole blood, neonatal heel stick, and neonatal arterial whole blood samples throughout all hospital and all professional healthcare settings
- Capillary whole blood (finger stick)
  - **Note:** Capillary testing should not be done on patients with Arterial lines.
- Sample size 1.2 μL
- Analysis Time: 6 seconds
- Never “milk” the finger to achieve a drop of blood for testing. Warming of hands may be necessary to achieve better capillary flow.
- Wipe away the first drop of blood prior to testing.
- Arterial and venous whole blood must be anticoagulated with lithium heparin.
- Whole blood must be analyzed within 30 minutes of collection
- Alternate site testing (earlobe, forearm) is NOT allowed.

### Test Procedure

**Running a Patient Sample**

1. Verify two forms of patient ID prior to running a test.
2. Verify that the strip vial is within the open expiration date – not to exceed the printed date on the vial.
3. From the “Welcome” screen, press the <Login> button. “Enter Operator ID” will appear at the top of the screen.
4. Press <Scan> , release and scan the user barcode, or enter the user ID manually twice using the keypad.
5. From the “Patient Test” screen, press the <Accept> key.
    **Note:** If the padlock symbol appears with the words “Glu Locked”, proceed to Quality Control Testing section above.
6. When the “Enter Strip Lot” screen displays, press <Scan> , release, and scan the strip lot number. The “Enter Patient ID” screen will appear.
7. Enter Patient ID (CSN) by scanning the patient barcode in the same manner.
    **Note:** Entering the patient ID manually will require duplicate entry and prevent results transmission.
8. **If the patient ID is valid,** the screen will display the patient’s name, DOB, Gender and room/bed number. Verify the patient information on the screen is correct and press <Accept>. The “Insert Strip” screen will appear.
9. **If the patient ID is not in the system or is not a valid patient ID,** verify the patient wristband matches the patient that will be tested and select <Downtime Override>. This will proceed to the “Insert Strip” screen.
    **Note:** If the patient ID is NOT correct in either circumstance, select the <Back> button to rescan/reenter the patient ID. It is possible that the armband or label was printed from the wrong encounter.

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Title (with LTR): Nova StatStrip Glucose Procedure (LTR32210)
Last Approved: Lewandrowski, Kent (Electronic Signature Timestamp: 7/22/2016 10:20:28 AM)
Gregory, Kimberly (Electronic Signature Timestamp: 7/6/2016 2:26:22 PM)
10. Insert the test strip into the meter’s strip port at the bottom of the meter, gold end first with NOVA facing up. The “Apply Sample” screen will appear.
11. Perform the finger or heel stick 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. Gently apply pressure at the site to form a drop of blood. Do not “milk” the finger. Wipe away the first drop of blood.
14. Touch the end of the Test Strip to the next blood drop, maintaining contact until the 6-second countdown begins.
15. Once the result appears, remove the Test Strip manually or use the strip ejector at the back of the meter.
16. Discard the used Test Strip into an MGH approved Biohazard container.
17. Select <Accept>. Once <Accept> is selected, the result will transmit wirelessly to EPIC.
18. Clean and Disinfect the meter according to MGH policy.
19.Dock the meter when not in use to keep the battery charged and to ensure the most up-to-date meter configurations. Make sure the meter is securely seated in the dock and that all lights are illuminated.

*If test result is higher or lower than expected, run a control solution test to confirm test strip performance.*

*If a patient test result is higher or lower than expected after verifying the test strip performance, perform glucose test using an alternate method and consult healthcare professional.*

### Cleaning and Disinfecting

The StatStrip Glucose Meter must be cleaned and disinfected after each patient use to minimize the risk of transmission of blood-borne pathogens between patients and healthcare professionals. To ensure proper disinfection, it is important to clean the meter (Step 1) prior to disinfecting the meter (Step 2).

1. Clean the meter by wiping the external surface of the meter thoroughly with a MGH approved disinfecting wipe (i.e PDI Super Sani-Cloth, Dispatch or Medtrol Bleach wipe).
2. Using a new 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.
3. 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 at least 2 minutes with Super Sani-Cloths and 5 minutes with Bleach wipes and is allowed to air dry for an additional 1 minute.
4. Remove any residue with a soft cloth dampened with water.

**Note:**
- DO NOT allow the liquid to enter the strip port connector or allow pooling of liquid on the touch screen. If liquid does get into the strip port or connector, immediately dry the components with a dry cloth or gauze.
- DO NOT spray the meter directly with cleaning solutions.
- DO NOT immerse the meter or hold the meter under running water.

### Interpretation of Results

**Reference Range**

The normal range reported for plasma glucose collected in a gray top tube in a fasting patient is reported to be 70-100 mg/dl. Plasma glucose values are compared to the reference range in the context of criteria of the American Diabetes Association for the diagnosis of diabetes mellitus. However, we do not report a non-fasting glucose level, as this varies widely depending on a variety of factors. Additionally, the sample collected for blood capillary glucose is a capillary specimen, which differs from the corresponding values of a plasma sample. Therefore, the BCG test does not correlate exactly with the plasma glucose level collected in a gray top tube. Furthermore, the CBCG test is designed for monitoring known diabetic patients in the hospital setting and is not indicated for the diagnosis of diabetes mellitus or related conditions. The BCG value should be evaluated in the context of the individual patient, their prior BCG glucose values, underlying medical conditions, pharmacological interventions, and a variety of other patient-specific criteria.

As a general guideline, the reference range values are:

- Adult fasting, 70 - 140 mg / dL  
- Non-fasting, 70 - 200 mg / dL

Please refer to pediatric and neonatal protocols for reference ranges.
Results within the Reference Range of 70 to 100 mg/dL will display in blue. Results outside of the Reference Range will display in red and will display a single up arrow (↑) or a single down arrow (↓).

**Measurement Range**

The meter’s measurement range is 10 mg/dL to 600 mg/dL.

- Results below 10 mg/dL will display “LO” in red with a double down arrow (↓↓).
- Results above 600 mg/dL will display “HI” in red with a double up arrow (↑↑).

**Docking the Meter and Results Transmission**

Results are transmitted to EPIC via the wireless network once the result is accepted. This transmission also occurs every time the meter is docked. If the wireless network goes down, users should utilize the hard wired bases for docking the meter for results transmission. Every base unit has Ethernet connection and therefore has the capabilities of transmitting and receiving data if the wireless system is down. Every glucose meter has a charging/downloading base. The meter should reside in the base when not in use, to ensure the battery is charged for testing and to receive the most up-to-date information (i.e. new/recertified operators, meter configurations, reagent lot number/expiration dates).

![Docking the Meter and Results Transmission Diagram]

**Battery Change or Replacement**

**Routine Battery Change:**

A backup battery is kept in the charging station. If the meter should lose its charge, but needs to be used, exchange the discharged battery with the backup. Be sure to put the discharged battery into the charging station so a back up will be available later.

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. Place discharged battery in docking station with label facing towards back of dock and bump on top.
Correct battery charging

Incorrect battery placement

NOTE: Batteries are RECHARGEABLE; please do not discard into trash!!

Battery Replacement:

Frequency
- If battery won’t hold a charge
- When the Li-polymer battery has reached its expiration date
- When the Li-polymer battery shows any visible signs of damage

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 and contact POCT program.

Help needed? Contact pager 35058 or email mghpoctcoordinators

Troubleshooting

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

Meter Replacement Procedure

In the event of a problem with the meter, the operator should:

1. Review the troubleshooting section of this procedure.
2. During normal business hours page the POCT Coordinator at 35058 or email MGHPOCTCoordinators
3. Off-shift, weekends or holidays – Contact Nursing Supervisor

References

3. Stat Strip Glucose Hospital Meter Test Strips package insert, 12/18/2014