# SUBJECT:
Whole Blood Glucose, Nova Biomedical Statstrip

## DEFINITIONS/SPECIFICATIONS:

<table>
<thead>
<tr>
<th>Instrumentation / Method</th>
<th>Nova Biomedical Statstrip / Enzyme, Amperometric Glucose Enzyme (Aspergillus sp., &gt;1.0 IU)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen requirements</td>
<td>3 μL of whole blood</td>
</tr>
<tr>
<td>Minimal Volume</td>
<td>1.2 μL of whole blood</td>
</tr>
<tr>
<td>Specimen collection /Storage / Special Handling</td>
<td>Puncture clean fingertip/heel with auto-disabling single-use finger stick devices, establish free flow of blood to minimize dilution. Test immediately to prevent clotting.</td>
</tr>
<tr>
<td>Causes for Rejection / Limitations</td>
<td>Sample volume insufficient; samples collected in fluoride. <strong>Do not use plasma or serum for testing.</strong></td>
</tr>
<tr>
<td>Patient Prep / Aftercare</td>
<td>N/A</td>
</tr>
<tr>
<td>Test Code</td>
<td>N/A</td>
</tr>
<tr>
<td>Test Components / CPT codes</td>
<td>Whole blood glucose only; CPT: 82948</td>
</tr>
<tr>
<td>Test Schedule</td>
<td>Hours of operation of patient care area</td>
</tr>
<tr>
<td>Result Turn-around-time</td>
<td>6 Seconds (Analysis time)</td>
</tr>
<tr>
<td>Reference Range</td>
<td>Capillary: 70-99 mg/dL</td>
</tr>
<tr>
<td>Critical / Panic Values</td>
<td>Refer to the Hypoglycemia Protocol procedure parameters.</td>
</tr>
</tbody>
</table>

**PURPOSE:**
To evaluate blood glucose levels in a whole blood sample. This test may be used as a definitive test for patient management, or as a screening test if laboratory confirmation is desired.
### REVIEW BI- ANNUALLY:

<table>
<thead>
<tr>
<th>DATE</th>
<th>BY</th>
<th>PAGE</th>
<th>SUMMARY OF CHANGES</th>
<th>Staff notification of change</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Required?</td>
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</table>
DEFINITIONS:

I. Controls:

Samples that are periodically processed in the same manner as a patient sample in order to validate accuracy of the system.

II. Analytical run:

The interval within which the accuracy and precision of the system is expected to be stable, not to exceed 24 hours.

POLICY:

I. GENERAL:

A. Whole blood glucose determination is performed in accordance with physician's orders and/or an appropriate Standardized Procedure.

B. The person who performs the test is responsible for reviewing the current value and comparing it with previous values and the patient's current condition.

   1. If the values do not correlate, the test is repeated.
   2. If unable to resolve, a lab glucose is ordered.
   3. If the meter is suspect, a different meter can be used.
   4. If access to a different meter is not possible or the second meter yields reliable results, the POCT Manager or Clinical Lab is contacted.

C. The physician will be notified:

   1. When results are critical. Follow the parameters as indicated in the Standardized Procedure for signs/symptoms of hypoglycemia. (Note: The Point of Care testing critical value for the Nova StatStrip meter is less than 50 mg/dL or greater than 400 mg/dL.)
   2. According to the parameters specified in the physician orders.
   3. Documentation of the call will be entered into the HIS. Documentation will include the: Date/Time the call was made; the name of the person receiving the call; read back verification and name of person making the call.

D. Nursing departments performing this test must be approved through the Point of Care Testing (POCT) Committee process.

II. STAFF EDUCATION COMPETENCY/BY WHOM:

A. Whole blood glucose (WBG) determination using the Nova Statstrip (NS) may be performed by:

   1. Clinical Laboratory Scientists (CLS) who have been trained in operation and testing under guidance by designated training personnel.
2. Respiratory Care Practitioners (RCPs) working in the Critical Care Unit (CCU) and Neonatal Intensive Care Units (NICU) only, Registered Nurses, LVNs, and perfusionists, who have completed the following HMH Education requirements:
   a. **Didactic:** HMH Blood Glucose Testing Self Study, with a score of at least 90% on an open book test.
   b. **Orientation Skill Validation:** correctly perform the procedure under the supervision of validated training personnel or designated approved staff.
   c. **Annual Skill Validation:** recertification can be achieved by performing a minimum amount of QC (3 High QC, 3 Low QC) and patient testing (12 patients) in a 12 month period and passing a Recertification Test, or by completing the Recertification Test and direct observation of patient and QC testing by a currently certified user. Once certification lapses, the operator is locked out of the meter until recertification is accomplished and the operator ID is re-activated into the workstation. A passing score of 90% is required for the Recertification Test.

1) QC and patient testing is tracked through the Telcor Server, and reviewed monthly by the POCT Coordinator.

2) If the minimum criteria for recertification cannot be met in a 12 month period, the operator is required to complete the Recertification Test and demonstrate one QC test and one patient test for a certified user. Documents are returned to the POCT Coordinator for evaluation and recertification to active status.

3. The documentation will remain on file in the employee’s credential file.

4. Every certified operator will use their own ID for patient testing. Under no circumstances will an operator use another’s ID for patient testing.

III. **QUALITY ASSURANCE:**

A. The laboratory subscribes to the CAP Whole Blood Glucose, Waived (WB2) proficiency survey on an annual basis.

1. The POCT Coordinator or designee sends the samples to each patient care area and requests an individual who routinely performs WBG testing (RN, LVN, RCP in designated units only, and/or perfusionist) to test the proficiency samples. Each sample is processed in a similar manner as patient samples.

2. Refer to the **POCT: General Policy, III. Proficiency Testing** for specific information regarding policy guidelines for proficiency testing. In order to circulate the samples through all the units providing this test, the survey must be completed promptly and returned to the Point of Care Coordinator in the Clinical Lab.

3. PT is performed twice a year.

4. Failure to return proficiency testing results for a testing event is unsatisfactory.

B. High and low controls are included with each analytic run. This means they are performed (and found to be within acceptable parameters) within the 24 hour period prior to patient testing. The meter’s warning clock announces that QC is due within 2 hours of lockout time, beyond which, patient testing cannot be performed.
C. QC results are reviewed daily by the person conducting the run prior to patient testing. Patient testing is not performed unless QC values are acceptable.

D. If either level of QC is out of tolerance, corrective action is taken and documented, with the appropriate comment, in the meter.

E. When a new test strip or control solution vial is opened, the date put in service and new expiration date is recorded on the vials. Once opened, test strips are stable for 6 months; control solutions for 3 months.

F. Each approved testing individual is identified by entering his/her employee number as the “operator” number. The operator number for traveler and registry nurses is designated by the IT department. For student nurses the ID will be designated by the IT department. The instructor is given barcodes of valid ID numbers for their students by the POCT Coordinator.

G. Test strip and control solutions’ lot numbers are tracked via entry into the meter’s memory. Lot numbers can only be entered at the Nova Net workstation by the POCT Coordinator.

H. Test strips and control solutions are validated prior to releasing to patient care areas for use.

I. The Director of Laboratory Medicine has designated the Point-of-Care Testing (POCT) Coordinator as the person responsible for active surveillance of the Quality Assurance program for point of care blood glucose testing.

J. Quality control records are reviewed by the POCT Coordinator on a monthly basis.

K. Each meter is docked when not actively used for testing. This is to ensure the battery remains charged, test data is transferred in a timely manner and ADT data is updated to the meter’s memory. Data is reviewed and records maintained in the Clinical Laboratory for a minimum of three years.

L. On a monthly basis (or as needed), meter status is reported to the patient care areas.

M. The rationale behind quality control guidelines is governed by the manufacturer and agencies that regulate the hospital and the clinical laboratory (CLIA, CAP, TJC).

N. Patient self-testing is not permitted. Treatment may only be based on those results obtained from authorized Nova StatStrip meters.

O. STUDENT NURSES:

1. Student nurses are allowed to perform blood glucose testing using the approved HMH policy and procedure after an authorized instructor verifies their competency.

2. The clinical instructor must have current documentation of orientation to the procedure before supervising students. The documentation of this orientation is maintained by the POCT Coordinator, and includes:

   a. Passing the blood glucose certification test.
   
   b. Completion of orientation skill validation signed off by the instructor, workforce development staff member or Point of Care Coordinator.

3. The clinical instructor is responsible for submitting proof of completion of the above to the POCT Coordinator prior to supervising any students.

IV. SAFETY PRECAUTIONS:
A. All specimens should be handled as potential infectious materials using standard precautions as specified in the hospital "Standard Precautions" (Administrative Policies and Procedures, policy number 746).

B. Dispose of auto-disabling single-use finger stick devices and/or needles into an approved sharps disposal container immediately after completion of testing.

V. PRINCIPLE:

When a drop of blood is applied to the test strip and fills the sample well, the glucose in the patient/control sample undergoes a reaction with the modified Glucose Oxidase enzyme that converts it into Gluconic Acid. The reduced form of the enzyme is combined with Ferricyanide and the resulting reaction produces an electronic charge that is proportional to the concentration of glucose in the sample. This charge is measured by the meter, converted and displayed as the glucose concentration.

The glucose measurement is based on the following methodology:

Equation 1: Glucose + Enzymes(oxidized form) ——> Gluconic Acid + Enzymes(reduced form)

Equation 2: Enzymes(reduced form) + Ferricyanide ——> Enzymes(oxidized form) + Ferrocyanide

Equation 3: Ferrocyanide ————> Ferricyanide

Electrode

The current generated at the electrode is proportional to the glucose concentration of the sample.

VI. REAGENTS AND MATERIALS:

A. Equipment:

1. Nova Biomedical StatStrip whole blood glucose meter
2. Auto-disabling single-use finger stick device
3. Alcohol pads (optional)
4. Gauze pads

B. Reagents: (available through HH Receiving and Distribution)

1. Nova Biomedical StatStrip Test Strips (PN 42214): store tightly closed at room temperature below 30°C (86°F). Unopened, stable until expiration date noted on the vial. Once opened, stable for 6 months [180 days] or the manufacturer's expiration date on the vial whichever comes first.
   - Document date opened, initials and modified expiration date (6 months [180 days] after open date).
   - Do not use after expiration date printed on vial. Do not use after 180 days after open date. Each box contains two vials of strips, each containing 50 individual testing strips. Each strip contains glucose enzyme (Aspergillus sp.), >1.0 IU, mediator >20ug and other nonreactive substances.

2. SureStepPro High and Low QC Solutions (PN 41743 & 41741): store tightly closed at room temperature below 30°C (86°F). Unopened, stable until expiration date.
noted on the vial. Once opened, stable for 3 months or the manufacturer’s expiration date on the vial whichever comes first.

- **Document date opened, initials and modified expiration date (3 months after open date).**

**Do not use after expiration date printed on vial. Do not use 90 days after open date.** Each vial contains a buffered, stabilized, aqueous solution of D-glucose containing a preservative, FD&C dye, viscosity adjusting agent and other non-reactive ingredients. The expected range of each solution is listed on each control vial.

VII. **GENERAL INSTRUMENT PROCEDURES:**

A. **Meter Overview**

The meter uses a touch screen and three-button keypad (Back, OK & Forward) for menu navigation and data entry. **NOTE: When there are “Soft keys” (keys at the bottom of the screen in the display) that appear, you may use either the touchscreen or the corresponding hard keys (back, OK & forward) below the display to complete the function.** There are also two Scan/Home buttons, one on each side of the meter, used to activate the barcode scanner or return the display to the “Welcome” screen. The Sleep Mode button will place them meter into a power saving mode or wakes the meter for use.

The Strip Port (top of meter) is the area where the test strip is inserted before testing. The Laser Barcode Scanner (bottom of meter) is where the scanning beam will emanate from when the meter is directed to scan.

**NOTE:** The touch screen is designed to be used by making selections with the finger. Do not use sharp or pointed implements as they will damage the unit.
1. Docking the meter: The meter is designed to be docked when not in use for testing. Once testing is complete and the meter has been disinfected, it must be returned to the dock to ensure:
   - Data is transferred to the patient’s electronic medical record.
   - ADT (admission-discharge-transfer) information is updated.
   - Battery is allowed to recharge.

Spare Battery: In addition to docking the meter, there is a slot that allows a spare battery for the Nova StatStrip to be charged. The slot is keyed to accept the battery in a specific orientation. The label on the battery should be facing toward you when it’s placed in the slot. The side with the metal contacts should be inserted into the dock. The led near the slot will indicate charge of the battery when it is inserted properly and the charging process is taking place.
   - Amber=charging
   - Green=fully charged

There are three indicator lights on the dock:
   - Left=is green if the dock is connected to the network.
   - Middle=flashing green when data is transferring on the network.
   - Right=Green if meter is fully charged. Amber if charging.

2. Changing Rechargeable Batteries:
WARNING: The Lithium battery may present a fire or chemical burn hazard, if mistreated. Do not disassemble, heat above 100°C (212°F), or incinerate.

All rechargeable Lithium batteries have a finite useful life that will vary depending upon use and handling conditions. A Lithium battery exhibiting any of the following conditions should be immediately removed from use and properly disposed of in accordance with local regulations.
   - Swelling, cracking, or damage to the battery case
   - Leakage
   - Failure to hold a proper charge
   - Has exceeded its expiration date and fails to hold proper charge

To replace the battery:
   a. Put the meter to sleep using the “Sleep Mode” button.
   b. Turn the meter over to access the battery door.
   c. At the top of the door, there is a latch. Press down on the latch to open and remove the door.
   d. Remove the battery by pressing the white latch up while moving the top of the battery away from the meter.
   e. Put a freshly charged battery into the empty battery compartment. Since it is keyed it will only go in if oriented properly. The bottom must be inserted first then the top.
   f. Replace the battery door carefully. NOTE: If the battery is swollen and the door will not close. Use another battery and notify the Point of Care Coordinator.
   g. The meter will boot up in 20 seconds.
h. Return the discharged battery to the charging station in the dock.

3. **Storage memory:** The meter stores patient test data and control test data. The operator can recall and review test data stored in the meter. Test data information is stored in a non-volatile memory to prevent data loss if the battery loses charge or is replaced. Memory has the capacity to store: 1000 patient tests, 200 qc tests and 4000 operators.

4. **Display Keypad:** The keypad has 2 formats: numeric and alphanumeric.

<table>
<thead>
<tr>
<th><strong>Numeric Keypad:</strong></th>
<th><strong>Title Bar:</strong> Description of the screen, Time of day, Operator ID, Meter Name and sound status</th>
<th><strong>Alphanumeric Keypad:</strong> To select a particular character, press the key where the letter is found the appropriate number of times to cycle through. For example, to select “B” press the key that contains “ABC” twice. Press “0..9” to go to Numeric Keypad</th>
</tr>
</thead>
<tbody>
<tr>
<td>Press “ABC…” to go to Alphanumeric</td>
<td><strong>Body:</strong> data entries, selections and screens</td>
<td><strong>Soft Buttons:</strong> confirmation of data entry and screen navigation. Duplicates the function of the Left, OK and Right meter hard buttons.</td>
</tr>
</tbody>
</table>

B. **The Welcome Screen:** This screen appears after the unit is awakened from standby or sleep mode. It gives you basic information about the status of the meter, the department it’s from and the operator that’s logged in.
Messages or Alerts – You may see on the welcome screen and how to respond.

<table>
<thead>
<tr>
<th>Message</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Memory Full</td>
<td>Dock the meter.</td>
</tr>
<tr>
<td>Dock Meter Immediately</td>
<td>Dock the meter.</td>
</tr>
<tr>
<td>Battery Low</td>
<td>Dock the meter for charging or replace the battery with a freshly charged spare.</td>
</tr>
<tr>
<td>Charge/Replace Battery</td>
<td>Dock the meter for charging or replace the battery with a freshly charged spare.</td>
</tr>
<tr>
<td>QC Due: xx:xx hrs</td>
<td>Run QC before the meter locks.</td>
</tr>
<tr>
<td>Download Due: xx:xx hrs</td>
<td>Dock the meter.</td>
</tr>
<tr>
<td>LOCKED</td>
<td>Run QC.</td>
</tr>
<tr>
<td>Perform QC before Patient Testing</td>
<td>Run QC.</td>
</tr>
<tr>
<td>QC Required</td>
<td>Run QC.</td>
</tr>
<tr>
<td>Memory Low</td>
<td>Dock the meter.</td>
</tr>
<tr>
<td>Need to Dock Soon</td>
<td>Dock the meter.</td>
</tr>
<tr>
<td>Other messages</td>
<td>If there is a question, contact Nova Biomedical: 1-800-545-NOVA or the Point of Care Coordinator.</td>
</tr>
</tbody>
</table>

C. Operator Login:

2. From the Home or Welcome Screen, press the “OK/Enter” button or “Login” soft key at the bottom middle of the screen.

3. The “Enter Operator ID” screen appears.
   a. Scan your operator ID barcode by pressing the “OK/Enter” button or “Scan” soft key on the meter display. You can also use either side buttons to activate the barcode scanner.
   b. If the display shows your proper ID, press the “OK/Enter” button or “Accept” soft key at the bottom of the screen.
c. Although it is highly recommended that you scan in your ID, you can manually enter your ID by using the numeric keypad.

4. After the Operator ID is accepted, the Patient Test screen will display after pressing “OK/Enter” button or “Accept”.

5. **NOTE:** After completion of testing, log yourself out of the meter to prevent your ID from being used by someone else. Your ID will remain logged in the meter for up to 3 minutes after you complete your testing. To log out, press the “Logout” soft key.

6. **NOTE:** If an invalid, erroneous, or fictitious operator ID is entered, the meter WILL NOT allow further testing until a valid number is input.

D. **SCANNING A BARCODE:** The barcode scanner allows for scanning operator ID, patient ID, QC, Strip Lot Numbers, and Linearity Lot Numbers.

   *Caution: This product contains a laser. Do NOT stare into the laser light or point it towards anyone’s eyes while scanning.*

   1. Hold the barcode label parallel to and approximately 2 to 6 inches from the unit’s scanner.

   2. Press the “OK/Enter” button or “Scan” soft key or the left or right “SCAN” button and direct the beam at the barcode.

   3. Look at the top of the display (Screen Title). After a successful scan, the information from the barcode appears in the display field and the bedside unit beeps.

   4. Press the “OK/Enter” button to confirm entry.

E. **Patient Test Screen:** Once the operator is logged in the “Patient Test “ Screen will be displayed. If controls need to be run, there will be a message indicating this on the screen; and there will be a “lock” symbol next to “Glu”, indicating that the meter is “locked” from patient testing until controls are run. To run controls, you may press the “QC” soft key.

**VIII. SPECIMEN COLLECTION:**

A. **PATIENT IDENTIFICATION:**

   1. Ask the patient his/her name and have him/her spell it, if possible.

   2. Check the I.D. bracelet. Verify that the spelling of the name, medical record number, and financial number matches the order.

   3. If the bracelet does not match the order form or the patient's spelling, corrections must be made before collecting/testing the specimen.
B. PRE-COLLECTION:
1. Identify yourself and explain the procedure.
2. If possible, have patient wash his/her hands in warm water.
3. Wash your hands and put on gloves.
4. Check date-opened expiration dates on test strips; discard any expired material.

C. COLLECTION:
1. IMPORTANT NOTE: The Nova StatStrip meter must be set up for testing before the sample is drawn.
2. Select a puncture site (finger or infant heel). Do not select a finger with a ring on it as the ring may constrict blood flow resulting in an insufficient volume collected for testing.
3. Clean area with soap and water or alcohol wipe. Wipe the area with clean gauze, or allow to air dry. Site must be completely dry before puncturing.
4. Collect sample following established protocol for capillary collection.
5. Establish free flow of blood to minimize dilution with tissue fluid. Do not use excessive pressure to squeeze blood out of the site.
6. Immediately proceed with: TESTING PROCEDURE, B. ANALYSIS.

IX. TESTING PROCEDURE:
A. PRE-ANALYSIS:
1. PREVENTIVE MAINTENANCE (PM):
   a. NOTE: When using bleach wipes on the meter:
      • Squeeze excess liquid from the wipe.
      • Avoid wetting the barcode reader and electrical contacts.
      • Prevent any liquid from entering the Test Strip Port.
      • To remove dried bleach residue, a water dampened lint free tissue can be used to wipe the meter down.
      • Dry the meter with a soft lint free tissue or cloth.
      • Never Dock a wet meter.
   b. Ensure that the daily PM has been performed. If so, continue to QUALITY CONTROL section. If not, proceed as follows:
   c. The meter is cleaned with a 10% bleach wipe on a daily basis.
   d. After patient testing, the meter is cleaned with a 10% bleach wipe after each test is completed. Allow solution to remain on the meter for 2 minutes for disinfection.

Caution: Do not use alcohol, cleaners with ammonia, Windex® or other glass cleaners, abrasive cleaners or phenol.
2. **QUALITY CONTROL**: Must be acceptable before patient results are released. They are generally run in the following situations:

- Routinely, once every 24 hours.
- If results are questionable
- If there are indications that the system is not working properly
- If the meter is dropped

a. Obtain Nova StatStrip Test Strips and both levels (High and Low) of QC solutions.

b. Ensure that both strips and QC solutions are within their amended expiration dates. If not, discard expired vials obtain new reagents; label with date opened, modified expiration date and initials.

c. Wake the glucose meter.

d. From the “Welcome” Screen, check for battery status. If necessary swap battery with the spare in the dock.

e. Scan in your operator ID.

f. After login, the meter proceeds to the “Patient Test” Screen. **NOTE**: If Controls have not been run and found to be acceptable within the previous 24 hours, the meter will display a prompt to run controls. If there is no such message, patient testing can be performed. Proceed with the next steps if you intend to run controls.

g. Press the “QC” soft key.

h. From the “Enter Strip Lot” screen, scan the barcode on the strip container by pressing the “OK/Enter” button or “Scan” soft key. Press the “OK/Enter” button or “Accept” soft key if the lot number on the display is correct. **NOTE**: If the message, “is not a valid Strip Lot# Try again”, scan once more. If the message appears again, contact the Point of Care Coordinator and try a different lot of strips.

i. From the “Enter QC Lot” screen, scan the barcode on the control vial by pressing the “OK/Enter” button or “Scan” soft key. Press the “OK/Enter” button or “Accept” soft key if the lot number on the display is correct. **NOTE**: If the message, “is not a valid QC Lot# Try again”, scan once more. If the message appears again, contact the Point of Care Coordinator and try a different lot of control.

j. The “Insert Strip” screen displays. Insert a test strip as shown on the screen.

k. Insert the “gold” end of the test strip into the meter with the “Nova” label facing upward.

l. The “Apply Sample” screen displays. Gently mix the control vial before use.

m. **IMPORTANT NOTE**: Before applying control solution to the strip, always have the meter on a level surface or with the strip end lower than the meter (pointed downward). Never have the strip angled up when applying the control solution. Preventing the solution from
entering the meter is very important and a key to maintaining the meter in good working order.

n. When ready, place a drop from the control vial onto the end of the test strip and allow the solution to draw into the strip well by capillary action.

o. When enough of the solution is drawn into the strip the screen changes and the analysis countdown begins from 6 to 0.

p. When analysis is complete the display will indicate a “Pass” or “Fail”.

q. To accept the results, press the “Accept” soft key.

r. Repeat the procedure for the Low Control Solution.

s. If either control FAILS, a list of possible corrective actions will be displayed when “COMMENT” is pressed: (repeat test, mix ctrl, procedure error, etc.). Select one of these and take appropriate corrective action.

1) Repeat the control that failed.
2) If the control fails a second time. Verify the correct control is being used and it’s not expired.
3) Open a new set of strips and/or control and rerun the control.
4) If the third run does not PASS, contact the Point of Care Coordinator or the PFC.

t. Once both control levels are within tolerance, patient testing can begin.

B. ANALYSIS: If Controls have not been run, proceed back to “2. PREANALYSIS” to complete the QC run.

1. Wake the Nova StatStrip meter.
2. Confirm adequate battery reserves.
3. Log in your operator ID. (Refer to C. Operator Login)
4. Ensure that test strips are within their amended expiration dates. If not, discard expired vials obtain new reagents; label with date opened and initials.
5. From the “Patient Test” Screen, press “Accept”.
6. From the “Enter Strip Lot” Screen, scan in the lot number of strips from the strip container barcode. Once the lot # is displayed and verified against the container, press the “OK/Enter” button or “Accept” soft key. NOTE: If the lot already displayed on the meter matches the StatStrip lot you are using, press the “OK/Enter” button or “Accept” softkey.
7. From the “Enter Patient ID” Screen, scan in the ID wristband barcode then press “OK/Enter” button or “Accept”.
8. READ the information on the “Confirm Patient ID” Screen. Verify the correct patient has been identified. Press the “OK/Enter” button or “Accept” softkey if the information is correct.

• IMPORTANT NOTE: As the operator, you are responsible for verifying this information. It must match the patient’s wristband. Any discrepancy found here must be resolved before continuing to prevent results from posting to the wrong patient’s records.
NOTE: If the meter is unable to display the patient’s demographic information, verify the ID entered matches the ID wristband. If it does, press “Downtime/Override” and proceed.

9. Retrieve a StatStrip and insert it into the Strip Port of the meter (Gold end inserts into the port and “Nova” is facing up).

10. Collect patient sample as outlined in 0. SPECIMEN COLLECTION.

11. Ensure that the meter is level or positioned so that the strip end is lower than the barcode scanner end of the meter (this will prevent damage by keeping the sample from dripping into the meter).

12. When blood appears from the capillary puncture, touch the end of the strip to the blood drop. The sample will travel and fill the wells in the strip.
   - The test strip must fill completely upon touching the test strip. If the strip does not fill the first time, do not touch the blood drop a second time. Discard the strip and repeat with a new strip.
   - Do not let blood flow into the meter Test Strip Port.
   - Do not apply blood to the top of the strip.

13. When sufficient sample has been drawn up the meter display will start the countdown from 6 to 0.

14. After 6 seconds the results will be displayed.

15. Results with a blue background are in the normal range. If the background is red, the results are abnormal. Arrow orientation indicates if the abnormal result is high ↑ or low ↓. Critical results are indicated by two arrows ↑↑ (highr) or ↓↓ (low).

16. A comment can be added by pressing the “Comment” softkey and selecting the appropriate comment, then press “Accept”.

17. To accept the results, press the “OK/Enter” button or “Accept” softkey. To reject the results press the “Reject “ softkey. NOTE: Accepting the result will send them to the patient’s record.

C. POST-ANALYSIS:
1. Remove and discard the strip and auto-disabling single-use finger stick devices in sharps container.
2. Check the puncture site to ensure bleeding has stopped before leaving the room.
3. Verify that the StatStrip container lid is securely snapped shut.
4. Clean meter as, outlined in E.A.1. Preventive Maintenance, with 10% bleach wipe, allow the solution to remain for 2 minutes for disinfection.
5. Dock the meter to transmit the results, charge batteries and update meter memory.

D. RECALLING RESULTS:
1. QC and patient results can be reviewed by recalling them from the meter’s memory.
2. Press the “Review” softkey and the list of reviewable results will be displayed.
3. You may sort the results by pressing the available soft keys for ID, Date/Time or Type.
4. Once you find the result you’d like to review, highlight the result by touching it then place the “View” soft key.

X. TEST REPORTING:

A. Reference range: Capillary: 70 - 99 mg/dL.

B. If results must be manually documented (computer downtime or automated transfer of results is not available), results are immediately, legibly documented onto the Inhouse Point of Care Testing, Medication Administration Record or other appropriate flowsheet or Electronic Medical Record. Record the date and time, result, initials of tester. Note specimen source, if indicated. Include signature and title where indicated.

C. Critical Value: Refer to the Standardized Procedure: Treatment of Hypoglycemic Reactions (“Hypoglycemia Protocol”) in the Clinical Policy and Procedure Manual for parameters established for the treatment of sign/symptoms of hypoglycemia as determined by using the blood glucose meter. (Note: the Hypoglycemia Protocol procedure parameters differ from the Point of Care Testing parameters which are set at less than 50 mg/dL or greater than 400 mg/dL.) Followed the parameters as indicated in the Standardized Procedure for signs/symptoms of hypoglycemia.

1. For results greater than 400 mg/dL and/or if the meter displays HI, and in the absence of physician notification parameters or an order indicating treatment, the physician will be notified as soon as possible. Documentation of the date, time, and physician's name and initials of who notified the physician will be written in the progress record. The meter will display HI (without an accompanying numerical value) if the result is greater than 600 mg/dL. If “HI” is displayed and the physician requests a numerical value, a plasma/serum glucose should be ordered through HIS for performance in the Clinical Laboratory.

2. If the meter displays a result of 20 mg/dL or less, do one (or more) of the following:

   a. If the patient has symptoms of hypoglycemia:
      1) Repeat the whole blood glucose test.
      3) If the results do not match, confirm the patient’s blood glucose level by ordering a plasma/serum glucose level in HIS for performance in the Clinical Laboratory. Contact physician for approval.

   b. If the patient does NOT have symptoms of hypoglycemia:
      1) Repeat the test.
      a) If the patient’s blood glucose continues to be very low, run both the High and Low Control solutions. If the control results indicate that the meter and test strips are working properly (both tests should “PASS”), the low glucose result is likely to be correct. If either one of the control solutions “FAIL”, contact Nova Biomedical Technical Services: 1-800-545-NOVA or 1-781-894-0800, to obtain assistance.
D. If at any time, a result is significantly different, questionable, or unexpected from previous values or trends on a given patient, consider ordering a plasma/serum glucose level in HIS for performance in the Clinical Laboratory (with physician approval).

XI. TEST LIMITATIONS:
A. Nova StatStrip reportable range is 10 – 600 mg/dL. Results greater than 600 mg/dL will be displayed as “HI”.
B. Venous and capillary blood may differ by as much as 70 mg/dL, depending on the time of blood collection after food intake.
C. Shock, administration of vasoactive agents, and other factors affecting the peripheral circulation may also cause discrepancies between venous and capillary blood glucose results.
D. Whole blood glucose testing performed at the bedside and serum and/or plasma glucose testing performed in the clinical lab may differ due to preanalytic variables. Most notably continued glycolysis by red blood cells directly proportional to the amount of time the cells and plasma remain unseparated.
E. Extremes in hematocrits can affect test results. The StatStrip is not affected when the Hematocrit is within 20% to 65%.
F. Results may be affected if excessive water loss or dehydration occurs. Severe dehydration can lead to many serious medical complications. One complication which is of particular importance in diabetes management is a hyperglycemic-hyperosmolar state, with or without ketosis, which may be life-threatening if left untreated. If the patient is known to be in this condition, a plasma/serum glucose should be performed as whole blood glucose testing may not be accurate.
I. Glucose Interferences: The StatStrip Glucose Hospital Meter exhibits NO interference from the following substances up to the following concentration levels:

<table>
<thead>
<tr>
<th>Tested Interfering Substances</th>
<th>Tested Concentration Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>10.0 mg/dL</td>
</tr>
<tr>
<td>Ascorbic Acid</td>
<td>10.0 mg/dL</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>15.0 mg/dL</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>500.0 mg/dL</td>
</tr>
<tr>
<td>Creatinine</td>
<td>6.0 mg/dL</td>
</tr>
<tr>
<td>Dopamine</td>
<td>10.0 mg/dL</td>
</tr>
<tr>
<td>Ephedrine</td>
<td>0.9 mg/dL</td>
</tr>
<tr>
<td>D(+) Galactose</td>
<td>350.0 mg/dL</td>
</tr>
<tr>
<td>Hematocrit (RBC)</td>
<td>20% - 65%</td>
</tr>
</tbody>
</table>
Ibuprofen 48.0 mg/dL 2.33 mmol/L
L-Dopa 100.0 mg/dL 5.07 mmol/L
D(+) Maltose Monohydrate 240.0 mg/dL 6.66 mmol/L
D(+) Maltotetraose 240.0 mg/dL 3.6 mmol/L
D(+) Maltotriose 240.0 mg/dL 4.76 mmol/L
Methyl-Dopa 1.0 mg/dL 0.042 mmol/L
Salicylate 30.0 mg/dL 1.87 mmol/L
Tetracycline 30.0 mg/dL 0.62 mmol/L
Tolazamide 15.0 mg/dL 0.48 mmol/L
Tolbutamide 45.0 mg/dL 1.67 mmol/L
Triglycerides 750.0 mg/dL 8.78 mmol/L
Uric Acid 20.0 mg/dL 1.05 mmol/L

XII. PROCEDURAL NOTES:
A. Test strips which come in contact with excessive air and moisture may cause inaccurate results. After removing a strip, immediately replace the bottle cap. Use each strip immediately after removing from bottle. **Never transfer strips to a new bottle or container.** Do not bend, cut or alter a test strip in any way.
B. Samples collected in Lithium or Sodium heparin are acceptable for use.
C. **If an Analysis Error screen is encountered, it usually can be remedied by removing the strip, inserting a new one and repeating the sampling process.** Displayed are different Analysis Errors. Movement of the strip can interrupt the electrical contact causing an error. A “Flow Error” may be caused by insufficient sample or movement of the strip before the countdown begins. If “Bad Sample” is displayed and returns after repeating with a new strip, try a new strip vial. If the error code persists an alternative testing method (main lab) may need to be utilized.
D. Docking Transfer Failed Error: If a meter is removed before data transfer is completed, the “Transfer Failed” Error will appear. If the network and dock are working properly the transfer will continue at a later time when the meter is returned to the docking station. If this error refers to problems with the server (broken connection or server refuses to communicate with the meter) then the Point of Care Coordinator should be contacted.

XIII. TEST INTERPRETATION / CLINICAL SIGNIFICANCE:
Glucose is the energy currency of the body. Under normal, fasting conditions, the body is able to maintain blood glucose concentrations at 70-99 mg/dL by hormones that regulate the rate of production and consumption.

When glucose is not being absorbed from the gastrointestinal tract, it must be produced by the liver. The major sites of glucose consumption are the muscles, adipose tissue and brain. When blood glucose concentrations fall below 40 mg/dL for more than a few minutes, the brain does not function properly, and the patient experiences lethargy, drowsiness, seizures or coma. Respiratory arrest and death may occur if untreated.

The primary hormonal regulators of glucose production and consumption are insulin and glucagon, which are produced by the islets of Langerhans in the human pancreas. Insulin secretion is stimulated by elevated, and suppressed by low blood glucose concentrations, while glucagon is stimulated by low, and suppressed by high blood glucose concentrations. Within the islet, insulin suppresses glucagon, glucagon stimulates insulin and both are suppressed by somatostatin. Elevated glucagon concentrations promote excessive rates of ketogenesis that can lead to diabetic ketoacidosis.

The fundamental pathophysiology in all forms of diabetes is diminished insulin action. Type I diabetes is an autoimmune condition that results from a failure to produce insulin while type II results from a combination of insulin resistance and the production of insufficient amounts of insulin to prevent hyperglycemia. Type II becomes more common with advancing age, and 80% of its victims are obese.

Diabetes can also develop secondarily from any condition that severely damages the pancreas or significantly interferes with insulin action, and there are a variety of drugs (e.g., thiazide diuretics, glucocorticoids and hGH) that can cause insulin resistance.

Complications of diabetes include atherosclerosis, coronary heart disease, ischemic stroke, poor wound healing, skin ulceration, claudication, neuropathy, nephropathy and retinopathy.

In addition to women with preexisting diabetes, hyperglycemia is of concern to those who develop diabetes during pregnancy (gestational diabetes). Maternal hyperglycemia results in fetal hyperglycemia. This fosters more rapid growth of the fetus, but is also accompanied by inhibited maturation in response to fetal hyperinsulinism. There is increased risk of fetal lung immaturity due to inhibition of surfactant production. In addition, when the umbilical cord is cut, the newborn is at risk of developing hypoglycemia due to the instant removal of the supply of glucose, without a concomitant decrease in insulin production.

APPENDIX:
I. Nova StatStrip Whole Blood Glucose Meters
A. Validation of New Meters:
   1. Precision (performed new or as required):
      a. Materials required:
         1) StatStrip Glucose Control Solution Level 3 (High) and Level 1 (Low): store unopened at RT until expiration date indicated on vial or 3 months after opening.
         2) StatStrip Glucose Test Strips: store unopened at RT until expiration date indicated on the vial or 6 months after opening.
b. Testing:
   1) Perform 5 replicates of the High and Low Glucose Control Solutions, following the protocol defined in the Nova StatStrip procedure.

c. Data Analysis:
   1) Print a Meter QC Log report.
   2) Enter the data into the XL program, StatStrip-meter verification, to calculate the mean, standard deviation and coefficient of variation.
   3) Data is evaluated by a licensed Clinical Laboratory Scientist. All values must be within the ranges established by the manufacturer and CVs should be ≤5%.
      a) If the CV is ≥ 6%, run additional replicates for a total n of 20.
      b) Consult with the Nova representative if a meter does not appear to meet our criteria.

d. Results of precision testing are maintained on site while the meter is in service, or for a minimum of three years.

2. **Accuracy or Linearity or Calibration Verification (performed new or as required):**
   a. Materials required:
      1) StatStrip Linearity Kit: (Lifescan PN 42173) Store unopened at RT until expiration date on box. Once opened, stable for 3 months at RT.
      2) StatStrip Glucose Test Strips: store unopened at RT until expiration date indicated on the vial or 6 months after opening.
   b. Entering Linearity reagent data into the NovaNet Workstation.
      1) To set up Linearity on NovaNet, you must have NovaNet priveledges.
      2) Log onto NovaNet.
      3) Select Device
      4) Select Reagents
      5) Select Linearity
      6) Enter Lot# and Level values.
   c. Testing:
      1) From the Patient Test screen, press the Menu softkey.
      2) From the Menu screen, press the Linearity softkey.
      3) Scan (or enter) the Strip Lot Number from the container barcode and press the “OK/Enter” button or “Accept” softkey.
      4) Scan (or enter) the Linearity Lot Number from the barcode on vial and press the “OK/Enter” button or “Accept” softkey.
      5) When prompted, insert a test strip into the Test Strip port.
      6) When the “Apply Sample” screen displays, gently mix the linearity solution that is indicated on the screen (1 through 5).
      7) Discard the first drop.
8) Place a drop of linearity solution onto the end of the test strip until a beep is sounded, indicating that sufficient sample has been drawn into the well.

9) Recap the linearity solution.

10) The display will count down.

11) The result will display, along with PASS or FAIL, after the test is completed.

12) If a comment is needed, press the “Comment” softkey.

13) To accept the result, press the “OK/Enter” button or “Accept” softkey.

14) Repeat the process as needed to analyze levels 1 through 5.

d. Accuracy Data or Calibration Verification Analysis:

1) After testing, dock the meter to transfer the data, then print the data from the Telcor QML workstation.

2) Data is evaluated by a licensed Clinical Laboratory Scientist.
   a) Values must be within 15% of expected values, or
   b) 15 mg/dL for values less than 100 mg/dL.
   c) Consult with the Nova representative if a meter does not appear to meet our criteria.

e. Linearity Data Analysis:

1) After testing, dock the meter to transfer the data, then print the data from the Telcor QML workstation.

2) Data is evaluated by a licensed Clinical Laboratory Scientist.
   a) Correlation coefficients must be > 0.95.
   b) Optimal slopes are 0.95 - 1.05.
   c) Consult with the Nova representative if a meter does not appear to meet our criteria.

f. Results of accuracy testing are maintained on site while the meter is in service, or for a minimum of three years

B. Continual Quality Assurance:

1. Accuracy Verification / Analyzer Correlation: (performed as required)

Two meters are tested at 3 different levels. All meters are compared to these two meters through comparison of CAP proficiency testing results performed three times per year.

a. Materials required:

1) D-glucose:
   a) D10W: store at RT until expiration date on bottle, or
   b) 10% glucose solution: prepare by dissolving 10 grams of anhydrous D-glucose in 100 mL of deionized water. Prepare at least 24 hours prior to use. Store at RT for up to 3 months. Discard if evidence of contamination is present (e.g., cloudy).
2) Minimum of 3.5 mL of whole blood in heparin. *Incubate at room temperature for at least 16 hours to deplete the glucose in the sample. Discard after one day's use.*

3) Nova StatStrip Test Strips: store unopened at RT until expiration date indicated on the vial or 6 months after opening.

4) 12 x 75 mm test tubes and parafilm.

5) Test tube rocker.

6) Variable volume automatic pipets.

7) Chemistry analyzer

b. Testing:

1) Prepare spiked blood samples:
   a) Using a glucose meter that has been previously verified for accuracy, determine the glucose level of the depleted heparin sample. Record on the Nova StatStrip worksheet. **NOTE:** This value should be < 50 mg/dL to appropriately assess the low end capabilities of the meter. If > 50 mg/dL, it may be necessary to allow more time for glucose depletion.
   b) Place 1 mL of the glucose-depleted heparinized whole blood sample in each of three tubes, labeled 1, 2, and 3.
   c) Do not add any 10% glucose to tube 1.
   d) Add 20 μL of 10% glucose to tube 2.
   e) Add 40 μL of 10% glucose to tube 3.
   f) Approximate target concentrations of tubes 2 and 3 may be calculated by:
      \[
      \text{Target} = 200 \text{ (or 400)} + \text{initial glucose concentration}
      \]
   g) Place tubes 2 and 3 on a rocker for a minimum of 10 minutes.

2) To minimize the effect of glycolysis, plasma samples for comparison testing should be prepared within 10 minutes of meter testing.

3) Run tube 1 in duplicate on the meter(s) to be verified.
   a) Record results on the Nova StatStrip worksheet.
   b) Immediately centrifuge the sample and have the plasma tested in duplicate on the chemistry analyzer.

4) Remove tube 2 from the rocker and run it in duplicate on the meter(s) to be verified.
   a) Record results on the Nova StatStrip worksheet.
   b) Immediately centrifuge the sample and have the plasma tested in duplicate on the chemistry analyzer.

5) Remove tube 3 from the rocker and run it in duplicate on the meter(s) to be verified.
   a) Record results on the Nova StatStrip worksheet.
   b) Immediately centrifuge the sample and have the plasma tested in duplicate on the chemistry analyzer.
6) Record the chemistry analyzer results on the Nova StatStrip worksheet.

7) Dock the meters and print the data from the the workstation.

c. Data Analysis:
1) Enter the data into the XL program, SSF-CALVER, to calculate the slope, y-intercept and correlation coefficient.
2) Data is evaluated by a licensed Clinical Laboratory Scientist.
   a) All values must be within 15% of the chemistry analyzer values.
   b) Correlation coefficients must be ≥ 0.95.
   c) Optimal slopes are 0.95 - 1.05.
   d) Consult with the Nova representative if a meter does not appear to meet our criteria.

c. Results of accuracy testing are maintained on site while the meter is in service, or for a minimum of three years.

3. Proficiency Testing: (two challenges per calendar year)
a. Follow CAP instructions for storage and handling of the specimens.

c. Notify each of the patient care area managers that the samples will be sent to their area (time/date) for proficiency testing. Request that an individual who normally performs patient whole blood glucose testing be available to perform the testing.

d. Label each CAP sample with the appropriate sample ID. (WB01, WB02, etc.)
e. Send samples with instruction sheet for each unit to the assigned individual and have them perform the following:
   1) Use the assigned sample ID for the Patient ID (WB01, etc.)
   2) Run each of the samples as they would any patient.
   3) Have the individual sign the attestation page.
f. Compile data and send results to CAP within 10 working days.

III. Nova StatStrip Reagents
A. Test Strip Validation: (performed with each new lot of test strips)
   1. Point of Care Coordinator or designee will enter Test Strip data into the NovaNet workstation.
   2. Select two or more meters to perform the strip validation, then dock to transfer data for each of the meters so that the strip information can be downloaded from each of the meters.
   3. Test both the high and low levels of controls a total of 20 times each (i.e., 10 times on one meter, ten times on another meter).
   4. To be validated:
      a. CVs should be <5% and
      b. All values must be within the ranges on the strip vial.
5. Notify Receiving and Distribution when the new lot # can be released to the patient care areas.

B. **Control Validation:** (performed with each new lot of controls)
   1. Point of Care Coordinator or designee will enter Test Strip data into the NovaNet workstation.
   2. Select two or more meters to perform the control validation, then dock to transfer data for each of the meters so that the strip information can be downloaded from each of the meters.
   3. Test each new lot of control material a total of 20 times each (i.e., 10 times on one meter, ten times on another meter).
   4. To be validated:
      c. CVs should be <5% and
      d. All values must be within the ranges on the strip vial.
   6. Notify Receiving and Distribution when the new lot # can be released to the patient care areas.

IV. **INFORMATION SYSTEMS**
A. **Telcor Server:**
   1. After docking, data transfers from the meters occur over the network to the Telcor Server.
   2. The Telcor Server is maintained by the Information Technology (IT) Department.
   3. Any problems with the Server should be directed to the IT Department.
   4. There is a client of the server set up in the Point of Care Coordinator’s office. From this client the server can be accessed and the Telcor Server Software, QML, can be accessed to review data, perform operator certification maintenance and print reports.

B. **NovaNet:**
   1. NovaNet is on a server maintained by the IT Department.
   2. There is a client of this server set up in the Point of Care Coordinator’s office. It resides in the same terminal that the Telcor Server can be accessed.
   3. NovaNet is used for changes (adding, deleting, modifying) the following:
      a. glucose meters (bedside units)
      b. control solutions
      c. linearity kits
      d. nursing units
      e. operators
      f. sites
      g. test strips

C. **Terminal Hosting the Server Clients:**
   If there is a problem with QML or NovaNet, the terminal that contains the clients for both programs can be rebooted.
   1. To turn off:
a. Close any programs that are running.
b. Click on the Windows “Start” icon and select “Shut Down”.
c. The Windows Logo will appear with a message indicating that it is safe to turn off the terminal.
d. Locate the On/Off button of the PC and turn it off.
e. Wait for a minute.
f. Turn the PC on.
g. The system will boot and display a Log In Screen, prompting to enter a password. Press the ENTER key.
h. The system will continue to boot and show a desktop.
i. From the desktop you can click the QML icon.
j. If the problem persists, contact the IT helpdesk to report the problem.

REFERENCES:
CLIA ’88 Laboratory Legislation and HCFA Reporting Chapter 4.
Nova StatStrip Glucose Meter
Certification Test (rev.1)

Using the answer sheet at the end of this test, indicate the correct answer. There is only one answer for each question unless indicated. Each question is worth 5 points and you must score a minimum of 90%.

1. What is the function of the Nova StatStrip meter?
   a. To measure a patient’s blood glucose level from a urine sample.
   b. To diagnose diabetes
   c. To measure a patient’s blood glucose level from a whole blood sample.
   d. To provide qualitative indication of a high glucose level.

2. Indicate the major components of the meter in the following diagram: (each 1 pt)
   a. Bar Code Scanner
   b. Sleep Mode Button
   c. Test Strip Port
   d. Touch Screen
   e. OK/Enter Button

3. If an erroneous, invalid, and/or fictitious operator ID is entered into the meter, the operator:
   a. may continue using the meter, and will show up as a non-valid operator (NVO).
   b. will NOT be able to continue any type of testing until a valid operator ID is entered.
   c. may do QC testing ONLY.
   d. may continue with testing, but cannot use the bar code scanner.

4. What critical precaution relates to the bar code scanner?
   a. Do not expose test strips to the laser light.
   b. Do not stare into the scanner or point it towards anyone’s eyes while the scanner is activated.
   c. Do not point the bar code scanner at a computer screen.
   d. Do not scan patient armbands.

5. When cleaning the glucose meter between patients you should:
   a. Use hydrogen peroxide and follow with a distilled water rinse.
   b. Use a dry, soft cotton swab, followed by a bleach rinse
   c. Use a 10% bleach solution and allow it remain on the meter for 2 minutes.
   d. Never use bleach.
Nova StatStrip Glucose Meter Certification Test (rev.1)

6. Which of the following applies to the Nova StatStrip test strips?
   a. Opened test strip vials are only valid for 6 months, therefore it is important to **always** label the opened vials with the date opened.
   b. DO NOT use test strips after the expiration date on the vial, or 6 months after the opened date.
   c. Test strips are sensitive to, heat, air and moisture. Keep them **tightly** closed in the original bottles and store in a dry place below 86°F (30°C). Do not refrigerate or freeze.
   c. Use each strip immediately after removing it from the bottle then replace the cap on the vial tightly and immediately.
   d. Do not use strips that are bent, torn, cut or damaged in any way.
   e. All of the above.

7. Match the following descriptions with the test strip: (each 1 pt)
   a. faces up during insertion  ____ Gold End
   b. area where sample is applied  ____ Barcode
   c. side inserted into meter  ____ Capillary
   d. Indicates Lot # of strip on container  ____ End away from meter
   e. Action that pulls sample into strip  ____ “Nova” label

8. Which of the following **DOES NOT** apply to the Nova StatStrip Glucose Control Solutions?
   a. Opened control vials are only valid for 90 days, therefore it is important to **always** label the opened vials with the date opened.
   b. DO NOT use control solutions after the expiration date on the vial, or 90 days after the opened date.
   c. Control solutions are sensitive to evaporation. Keep them **tightly** closed in the original bottles and store in a dry place below 86°F (30°C). Do not refrigerate or freeze.
   d. Mix gently before using.
   e. Barcode on the vial is the expiration date.
   f. All of the above.

9. After scanning in and accepting the patient ID from the wristband barcode, what is the most important safety procedure you can do for the patient in your care?
   a. Stop; verify the information displayed in the meter matches the patient wristband.
   b. Complete testing as fast as I can.
   c. Continue testing without verifying, I know I put in the right ID.
   d. Stop, verify the information from a facesheet, someone has left in the room.
10. The best reason for preventing any liquid from dripping into the meter’s Strip Port is:
   a. Causes a FAIL  c. Prolongs test time
   b. Damages the meter d. Decreases test time

11. If either control result is unacceptable, a FAIL message will be displayed. If this occurs, you must:
   a. Turn off the meter and try again
   b. Change the battery
   c. Press COMMENT, select your corrective action. Repeat the QC level in question.
   d. Call the POCT Mgr.

12. Which are true? When applying control solution to the strip…
   • The strip end of the meter is level or pointed down below the meter.
   • Pointing the strip end up, can cause the control to enter and damage the meter.
   • Extreme care must be taken to prevent damage to the meter by contamination with control solution.
   a. One of the above
   b. Two of the above
   c. Three of the above
   d. None of the above

13. **Critical Value:** The physician should be notified immediately following the parameter as indicated in the Standardized Procedure. The critical value set for the meter is less than ______ mg/dL or greater than ______ mg/dL. The meter will display ________ without a numerical value if the result is greater than ______ mg/dL.
   a. 400, 500, HI, 600
   b. 50, 500, HI, 600
   c. 0, 400, HI, 600
   d. 50, 400, HI, 600

14. A patient’s glucose result reads 15 mg/dL. He has no symptoms of hypoglycemia. You should:
   a. Document the result. Treat for hypoglycemia.
   b. Repeat the test 3 more times to ensure accuracy.
   c. Repeat the test. If still low, run controls to verify that the meter is in proper operating condition. Have a sample run by the main lab if results are still questionable.
   d. Immediately call the POCT Coordinator.
15. New lot numbers for test strips and / or control solutions can be entered:
   a. by each individual patient care area.
   b. by department managers only.
   c. by the POCT manager at the Nova workstation only.
   d. by personnel in Receiving and Distribution only.

16. Many ID errors are made when using a patient facesheet. If a facesheet is used how can you ensure that the ID is the same as the current one for your patient?
   a. Verify the print date
   b. Check the patient name
   c. Verify it against the wristband
   d. Show it to the patient

17. Which of the following sample types is unacceptable for use with the Nova StatStrip meter?
   a. capillary
   b. venous
   c. serum / plasma
   d. arterial
   e. neonatal

18. If a meter does not turn on when the power button is pressed, the most likely reason is ___________. You should ___________.
   a. delayed data transfer, perform a data transfer
   b. discharged battery, replace with a freshly charged battery
   c. an invalid operator, become validated
   d. broken scanner, call technical services

19. Which of the following groups of signs and symptoms would require treatment as defined in the Standardized Procedure for Hypoglycemia?
   a. Hyperactive state, flushed skin, palpitations.
   b. Glucose meter reading of 178, hunger, Kussmaul respirations
   c. Glucose meter reading of 45, diaphoresis, hunger, nervousness
   d. Extreme thirst, warm dry skin, pallor

20. Which of the following statements about the Standardized Procedure is NOT true?
   a. The RN must prove annual competency
   b. It authorizes HMH RNs to perform point-of-care blood glucose testing and treat confirmed hypoglycemia before obtaining a physician’s order.
   c. It states that treatment may be initiated by an RN or LVN who observes a patient with the signs and symptoms of hypoglycemia.
   d. It authorizes the RN to treat the hypoglycemia without obtaining a specific order first
Nova StatStrip Glucose Meter
Certification Test (rev. 1)

ANSWER SHEET

NAME: ________________________________ TITLE: _______ UNIT: ____________

EMPLOYEE / student ID: (6 digits): __________ DATE: ______ TEST SCORE: ______
(RETAKE SCORE: ______)

Enter the appropriate letter into the designated space.

1. ______

2. ______

3. ______

4. ______

5. ______

6. ______

7. ______ Gold End
   ______ Barcode
   ______ Capillary
   ______ End away from meter
   ______ "Nova" label

8. ______

9. ______

10. ______

11. ______

12. ______

13. ______

14. ______

15. ______

16. ______

17. ______

18. ______

19. ______

20. ______

Novatest13(12/06/13)

P 5 OF 5
Skills Validation Checklist Nova StatStrip (Rev.11/13)

Student has read and understands technical procedure: ____________________________

Instructions to Validator:
Observe whether the critical behaviors listed below are performed correctly as noted in the procedure for this test. If so, initial the “Competent” column. If the trainee does not perform the task correctly, indicate the deficiency and appropriate action to correct it in the “Staff Development Plan.”

Evaluator Validation

Method of Evaluation: DO-Direct Observation VR-Verbal Response
WE-Written Exam OT-Other

<table>
<thead>
<tr>
<th>Daily Quality Control</th>
<th>Method of Validation</th>
<th>Competent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Cleans meter according to procedure.</td>
<td>VR/DO</td>
<td></td>
</tr>
<tr>
<td>• Squeezes excess fluid from wipe.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Avoids barcode reader and electrical contacts.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Prevents solution from entering Strip Port.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Wipes dry with soft tissue/cloth.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Wakes meter; verifies adequate battery/memory.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Scans <strong>APPROPRIATE</strong> operator I.D. number.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Selects QC test from Patient Test Menu.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. TEST STRIP vial. Verifies strips are not expired.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Scans barcode lot on strip container.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. CONTROL (QC) vial. Verifies controls are not expired.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Scans barcode lot on control container</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. If opening new strip/QC vial, labels appropriately.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Runs QC. Applies solution to strip end level or below meter.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Runs both QC. Takes appropriate action if QC values are out of range and documents all aspects of corrective action.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient Testing</th>
<th>VR/DO</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Employs standard precautions. Performs patient preparation, as indicated.</td>
<td></td>
</tr>
<tr>
<td>3. If required on meter, scans in their operator ID.</td>
<td></td>
</tr>
<tr>
<td>4. From Patient Test screen, initiates strip lot sequence.</td>
<td></td>
</tr>
<tr>
<td>5. Scans / verifies TEST STRIP lot number. Checks Expiration.</td>
<td></td>
</tr>
<tr>
<td>6. Patient ID screen, scans proper patient ID (V#, FIN#).</td>
<td></td>
</tr>
<tr>
<td>7. Verifies information on screen matches your patient.</td>
<td></td>
</tr>
</tbody>
</table>
## Patient Testing

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
<th>Method of Validation</th>
<th>Competent</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.</td>
<td>Inserts strip in correct orientation.</td>
<td>VR/DO</td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>Selects appropriate puncture site. Obtains blood sample.</td>
<td>VR/DO</td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Applies sample to end of strip, allows sample to fill test well.</td>
<td>VR/DO</td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td>Accepts test result from display and documents.</td>
<td>VR/DO</td>
<td></td>
</tr>
<tr>
<td>12.</td>
<td>Can enter a “Comment”.</td>
<td>VR/DO</td>
<td></td>
</tr>
<tr>
<td>13.</td>
<td>Removes strip and discards appropriately.</td>
<td>VR/DO</td>
<td></td>
</tr>
<tr>
<td>14.</td>
<td>States that meter must be cleaned after each patient with 10% hypochlorite solution and allowed to air-dry for 2 minutes.</td>
<td>VR/DO</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Squeezes excess fluid from wipe.</td>
<td>VR/DO</td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
<td>• Wipes dry with soft tissue/cloth.</td>
<td>VR/DO</td>
<td></td>
</tr>
<tr>
<td>15.</td>
<td>If result is outside patient's usual range, or if outside of critical values reports to appropriate caregiver / MD.</td>
<td>VR/DO</td>
<td></td>
</tr>
<tr>
<td>16.</td>
<td>Discards auto-disabling lancet in appropriate container.</td>
<td>VR/DO</td>
<td></td>
</tr>
<tr>
<td>17.</td>
<td>Verify puncture site has stopped bleeding.</td>
<td>VR/DO</td>
<td></td>
</tr>
<tr>
<td>18.</td>
<td>Docks meter for download and charging.</td>
<td>VR/DO</td>
<td></td>
</tr>
</tbody>
</table>

## Miscellaneous

1. Able to recall and review previous test data.  
2. Replaces battery with spare.  
3. Changes the Date and Time.

## CBL Completion

<table>
<thead>
<tr>
<th>Task</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Score-Please attach printout from test</td>
<td>WE</td>
</tr>
</tbody>
</table>

## Signature & Title of RN validating skill

<table>
<thead>
<tr>
<th>Signature &amp; Title of RN validating skill</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

I have received training and agree with the above validation of competency. I will adhere to performance of the test according to the guidelines established in the policy and procedure. I will contact my supervisor, manager or director if I require additional training in the future.

(Student signature)______________________ Date:____________

**Final Step:** Forward this completed competency, along with a transcript or “Congratulations, you passed” page of the associated CBL with a test score of \( \geq 90\% \), to the Point-of-Care Coordinator in the Clinical Laboratory, **Glenn Saita**. Use inter-departmental mail or fax to x2121.

## Development Plan