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Point of Care Testing	Procedure	08/01/2012	POC-8 Revision 8

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Approval and Acknowledgements
Refer to QPulse system and Document Details report for laboratory directors(s)' electronic signature approval, employee acknowledgment and effective date.

1. PRINCIPLE

1.1. The Nova StatStrip Hospital meter system is intended for point of care, in vitro diagnostic, and 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 throughout all hospital and professional healthcare settings, including patients receiving intensive medical intervention/therapy.

1.2. The measurement of glucose is used in the monitoring of carbohydrate metabolism disturbances including diabetes mellitus, idiopathic hypoglycemia, pancreatic islet cell carcinoma and for use in determining dysglycemia.

1.3. This device uploads results into the patient's medical record through a data management system maintained by the point of care clinical laboratory. The Nova StatStrip meter must be used with Nova StatStrip glucose test strips.

1.4. Glucose is measured with an electrode using an enzyme based test strip provided by Nova Biomedical. Glucose in the blood sample mixes with reagent on the test strip that produces an electrical current. The amount of current that is produced depends on how much glucose is in the blood.

1.5. This test is WAIVED for capillary (finger stick), venous, and arterial whole blood according to the Clinical Laboratory Improvements Amendments of 1988 (CLIA). Laboratories with a Certificate of CLIA waiver can perform this test in a waived setting and must follow the manufacturer's instructions for performing the test. If a laboratory or the testing site modifies the test instructions, the test will no longer be considered waived.

2. SCOPE OF DOCUMENT:

2.1. This document applies to all Point of Care Nova StatStrip Glucose OSUWMC testing locations.

3. RESPONSIBILITY:

3.1. The coordinators and manager are responsible for maintaining this document and ensuring biennial review. The laboratory medical director is responsible for establishing and approving all changes before activating a document.

3.2. **https://clinicallabs.osumc.edu/staff/Pages/PointOfCareTesting.aspx**

4. SPECIMEN COLLECTION:

WARNING: BODY FLUID PRECAUTION
Blood is a body fluid capable of transmitting infectious diseases. Universal precautions (OSUMC policies) for the prevention of the transmission of blood borne pathogens must be in effect at all times.

4.1. Identify the patient with two identifiers

4.2. Using Universal / Standard Precautions set up the StatStrip instrument and obtain all needed reagents and supplies:
- 4.2.1. Cotton balls
- 4.2.2. Alcohol wipes
- 4.2.3. Single use lancet
- 4.2.4. Gloves
- 4.2.5. Reagent strips

4.3. Before starting the finger-stick procedure, make sure the daily QC testing has been performed.

4.4. Specimen type: The Nova StatStrip® is designed for use with fresh capillary, arterial, venous, neonatal heel stick or neonatal arterial whole blood. The most common usage is capillary whole blood by finger-stick.

4.5. **Capillary specimen precautions:**
- 4.5.1. Caution should be exercised when testing capillary whole blood due to potential pre-analytical variability in capillary specimen collection.
- 4.5.2. A capillary whole blood specimen relies upon an adequate, non-compromised capillary blood flow.
- 4.5.3. The healthcare provider must be aware that a capillary whole blood specimen glucose result may not always be the same as an arterial or a venous whole blood glucose result, especially when the patient's condition is rapidly changing.
- 4.5.4. If a capillary whole blood glucose result is not consistent with a patient's clinical signs and symptoms, glucose testing should be repeated with either an arterial or venous specimen on the StatStrip meter. You may also send a specimen to the laboratory for glucose analysis.

4.6. Finger-stick(capillary) Procedure https://clinicallabs.osumc.edu/Pages/Laboratory-Policies-and-Procedures.aspx
- 4.6.1. Check the patient's hand and fingers for any sign of edema. Consult the nurse or physician if edema is present. Make sure the puncture site is warm. Do not use the fifth finger, or any hand which has an IV. The puncture site should be on the palmer surface of the distal phalanx and not at the tip of the finger.
- 4.6.2. Select the puncture site and clean well with alcohol. Allow site to dry completely.
- 4.6.3. Using the lancet device, make a quick insertion of the lancet into the finger.

4.6.4. Wipe away the first drop of blood with a cotton ball; alcohol hemolyzes blood and may cause inaccurate results. Obtain a small drop of blood resting on the finger. Consult the nurse or physician if there is difficulty in obtaining the specimen.
4.6.5. Dispose of all biohazard materials according to hospital policy. Dispose of the single use lancets in a sharps container.
4.6.6. After the test has been performed, apply pressure to the finger-stick site with a cotton ball.
4.6.7. See the Point of Care Glucose Specimen Collection Guide for additional instruction.
4.7. When not sampling from a lancet device, whole blood should be analyzed within 30 minutes of collection. Storing samples on ice is not recommended.
4.8. Lithium heparin is the recommended anticoagulant when sampling with a syringe or vacutainer tube.
4.8.1. NOTE: Do not perform specimen collection until the StatStrip glucose meter is ready. See Procedure and Quality Control sections.
4.8.2. NOTE: Do not use EDTA (purple top), or fluoride (gray top).

5. REAGENTS/SUPPLIES:

5.1. Materials:
5.1.1. Nova StatStrip® glucose meter
a. The humidity range required to perform glucose testing on the Nova StatStrip is 10% to 90% relative humidity.
b. The meter has an internal thermometer probe. The meter will only function when the internal thermometer temperature is within 59-104°F (15-40°C).
5.1.2. Nova StatStrip® test strips
a. Test strips should be stored in original vial tightly closed when not in use. Store strips between 34-86°F (1-30°C); between 10-90% relative humidity (non-condensing). Do not freeze the test strips.
b. Once each bottle is opened, the expiration date must be written on the bottle. Once opened, the strips are stable for up to 180 days or until the expiration date, whichever comes first. Do not use beyond the expiration date, for this may cause inaccurate results.
c. Remove the test strip from the vial only when ready to test. Replace cap on vial.
d. Record the daily temperature on the temperature/humidity log for bulk storage.
e. Each strip contains the enzyme glucose oxidase (*Aspergillus sp.*) ≥1.0 IU, mediator ≥20μg, and other nonreactive substances.
5.1.3. Nova StatStrip® liquid control solutions levels 1 (low) and 3 (high)
a. Store the control solutions at room temperature (15-30°C). Do not refrigerate or freeze.
b. Once each bottle is opened, the expiration date must be written on the bottle. Once opened, the expiration is shortened to 3 months at room temperature or until expiration date on the bottle, whichever comes first. Do not use beyond the expiration date.
c. Each control contains a buffered solution of D-glucose, preservative, a viscosity agent and other non-reactive reagents.
5.1.4. Nova StatStrip® liquid linearity solutions five (5) levels
a. Store the linearity material at room temperature (15-30°C). Do not refrigerate or freeze.
b. Once opened, the expiration is shortened to 3 months at room temperature or until expiration date on the bottle, whichever comes first.
c. Each level contains a buffered solution of D-glucose, preservative, a viscosity agent and other non-reactive agents.
5.1.5. Nova StatStrip® docking station
5.1.6. Nova StatStrip® carrying case
5.1.7. Nova StatStrip® lithium battery
a. A battery exhibiting any of the following conditions should be immediately removed from use and properly disposed of in accordance with local regulations
5.1.7.a.1. Has exceeded its expiration date
5.1.7.a.2. Swelling, cracking, or damage to the battery case
5.1.7.a.3. Leakage
5.1.7.a.4. Failure to hold a proper charge

6. SPECIAL SAFETY PRECAUTIONS:

6.1.1. ***WARNING:*** The battery used in this meter may present a fire or chemical burn hazard if mistreated. Do not disassemble the battery, heat above 100°C (212°F), or incinerate.
6.1.2. **CAUTION:** The scanner emits a laser beam when activated. There does not need to be a barcode present for the laser to become active. Lasers must never be stared at directly by the human eye.

7. LINEARITY/CORRELATION (performed by POC Department):

7.1. Linearity materials:
7.1.1. Linearity is run on each meter before being placed into service by Nova or the POC department.
7.1.2. Five (5) levels of linearity are available for the Nova Stat Strip.
7.1.3. Linearity preparation: none; the linearity kit comes prepared directly from the Nova manufacturer.

a. The glucose concentrations in the linearity solution are adjusted to give equivalent results to whole blood samples containing the glucose concentrations printed on the vials.

7.2. Linearity procedure:

7.2.1. Test each level of linearity solution on each new or repaired meter

7.2.2. Linearity testing is done in the same manner as a patient test with the exception that the linearity solution is used rather than patient blood, and you are in the linearity testing function of the meter.

a. From the Home Screen, press "Login"
b. Scan or manually enter the Operator ID. If manually entered, press the Accept key.
c. From the Patient Test screen, press menu and select Linearity.
d. Scan or manually enter the strip lot number. If manually entered, press the Accept key.
e. Scan or manually enter the linearity lot number. If manually entered, press the Accept key.
f. The Insert Test Strip Screen should now be displayed. Take a single test strip out of the vial and insert the gold end into the meter with the NOVA label facing up.
g. Mix the appropriate linearity solution completely by gentle inversion.
h. Discard the first drop of linearity solution from the bottle to avoid contamination.
i. Hold the meter flat then touch a drop from the bottle onto the tip end of the test strip.
j. The test strip must fill completely upon touching the linearity droplet, an audible beep will sound when enough sample has been drawn into the strip. **Do not add a second drop to the test strip. Discard the test strip and repeat the test with a new test strip if an error occurs.**
k. Results will appear in 6 seconds. To accept results, press 'Accept". The meter will result pass or fail.
l. Remove the strip manually or use the ejector button on the back of the meter to eject the strip directly into a biohazard container.
m. Repeat steps c-l for each level of linearity until all 5 have passed.
n. Upload the linearity results in Telcor for each device by docking the meter in the appropriate docking station.

7.2.3. Corrective action for failed linearity

a. Outliers (failing) must be repeated.
b. Troubleshoot the cause of the outliers by following these steps:
   - 7.2.3.b.1. Verify linearity ranges listed with each kit
   - 7.2.3.b.2. Make sure the correct level being tested matches the level entered or scanned into the StatStrip®
   - 7.2.3.b.3. Ensure that the linearity ranges entered into Nova Net match the package insert
   - 7.2.3.b.4. Make sure the linearity kit has not expired
   - 7.2.3.b.5. Ensure no bubbles are present
   - 7.2.3.b.6. Ensure sufficient sample volume was used
   - 7.2.3.b.7. Repeat linearity using a fresh kit
   - 7.2.3.b.8. If linearity data points are unacceptable upon repeated testing, remove the meter from service

7.2.4. Data is reviewed in Telcor. Acceptability is determined and reviewed by the manufactures' guidelines, manager and division director

7.3. Correlations - performed quarterly

7.3.1. Refer to Point of Care Testing (POCT) Quality Management Policy.

8. CLEANING THE METER AND TROUBLESHOOTING:

8.1. Cleaning the Meter

8.1.1. Clean the Nova analyzer surface after each use with a hospital approved disinfectant sanitizing wipe (Super Sani-Cloth Plus or for C diff patients only the Sani bleach cloth). DO NOT use solvents or strong cleaning solutions as they may damage the instrument's plastic components.

8.1.2. When using a Sani-Cloth Plus for cleaning, make sure the excess liquid has been squeezed from the cloth to eliminate any possibility of fluids entering the meter's internal components.

8.1.3. DO NOT immerse the meter or hold the meter under running water.

8.2. Troubleshooting:

8.2.1. Handle the meter with care. Test the meters performance using control solutions if the meter is dropped.

8.2.2. Storage: Store the meter at ambient temperatures. Do not expose the meter to sources of excessive heat.

a. Do not leave the meter under a bilirubin light or photo therapy light during testing.
b. Do not leave the meter on a bed warmer during testing.
c. Do not leave the meter in an isolette during testing.
d. In situations where the patient is in a bed warmer or isolette, after performing a fingerstick or heelstick procedure, obtain the sample as quickly as possible and return the meter to ambient temperature.

8.2.3. Check the meters battery, expiration date and that it is charged.

8.2.4. If the meter fails to turn on, or gives errors upon testing, contact the point-of-care testing department by email at path.glucose@osumc.edu. For more urgent concerns call the point-of-care testing department at 685-6610.
8.2.5. Meters may be required to be returned to the vendor for repairs. If available, loaner meters may be given to the department while their meter is out for repairs.

9. QUALITY CONTROL: StatStrip function check

9.1. Quality Control Information:
9.1.1. All persons authorized to perform bedside glucose testing must perform 2 levels of quality control at least annually. If you do not run your controls annually you will be locked out of the meter.
9.1.2. Contact the POC department at path.glucose@osumc.edu to be reactivated
a. If you change locations, you will not have access to the meters in the new unit. Contact the POC department with your new location.
b. Once you are reactivated in the system, the meter must be docked to accept the new information.
9.1.3. The StatStrip® analyzer has 2 quality control levels (Level 1 LO & Level 3 HI) with known concentrations of glucose. The control solution test results will report as pass or fail on the instrument. Both levels of control solution must be within acceptable range (every 24 hrs) before patient testing can be performed.
9.1.4. If QC Fails, a reason and corrective action must be documented on the meter by selecting a comment and pressing accept.
9.1.5. QC testing is done in exactly the same manner as a patient test with the exception that the control solution is used rather than patient blood, and you are in the QC testing function of the meter.
9.1.6. In addition to daily QC testing, QC should be performed under the following circumstances:
a. Before using the StatStrip Meter for the first time (new user)
b. To investigate possible instrument damage (meter dropped)
c. When test strip lot numbers change
d. To practice using the system to improve or verify operator technique, competency assessment
e. To certify and recertify an operator
f. To check the function of the StatStrip
g. If a patient repeat (confirmatory test) result does not match the clinical presentation or expected results
h. Before the meter is put in use

9.2. Running Quality Control (Testing Personnel):
9.2.1. Check the expiration dates of the strips and QC solutions.
9.2.2. From the Home Screen, press “Login”
9.2.3. Scan or manually enter the Operator ID. If manually entered, press the Accept key.
9.2.4. From the Patient Test screen, press QC.
9.2.5. Scan or manually enter the strip lot number. If manually entered, press the Accept key.
9.2.6. Scan or manually enter the QC lot number. If manually entered, press the Accept key.
9.2.7. The Insert Test Strip Screen should now be open. Take a single test strip out of the vial and insert the gold end into the meter with the NOVA label facing up.
9.2.8. Mix the appropriate control solution completely by gentle inversion.
9.2.9. Discard the first drop of control solution from the bottle to avoid contamination.
9.2.10. **NOTE: Always hold the meter level or at a slightly downward angle so the control solution does not travel from the outside of the test strip into the meter.**
9.2.11. Touch a drop from the bottle onto the tip end of the test strip. When enough control solution has been drawn into the strip an audible beep is made by the meter.
9.2.12. The test strip must fill completely upon touching the QC droplet. **Do not add a second QC drop to the test strip.** Discard the test strip and repeat the test using a new test strip if necessary.
9.2.13. Results will appear in 6 seconds. To accept results press “**Accept**”
9.2.14. Remove the strip manually or use the ejector button on the back of the meter to eject the strip directly into a biohazard container.
9.2.15. If QC fails, document the reason on the meter by selecting a comment and save. Repeat quality control testing to ensure adequate solution was added to the strip. Check the strip and QC expiration dates. Ensure the QC was mixed well.
a. Canned phrases on the meter for reasons for the QC failure:
- Ran wrong level
- Will Repeat QC
- Error Suspected

9.2.16. If the QC repeat fails, obtain another set of quality control solutions and repeat testing.

9.2.17. All results, quality control and patient, will upload into Telcor upon placing the meter into the appropriate docking station.
9.2.18. If QC fails with the new QC vials, call the POC department at 685-6610.

9.3. Quality Control Review **(Point of Care Department)**
9.3.1. A monthly summary of the performance of quality control is prepared by POC staff and reviewed by the division director.
9.3.2. All quality control errors are reviewed.
9.3.3. Follow up corrective action for QC failures is performed and documented.
9.3.4. All quality controls exceeding 3SD are excluded from the data summary.
9.3.5. See Telcor for a detailed error summary.

10. TEST PROCEDURE:
10.1. Before starting, check expirations dates, ensure daily QC was performed and you have performed your annual QC.
10.2. Login
10.2.1. From the Home Screen, press "Login".
10.2.2. Scan or manually enter Operator ID. If manually entered, press the Accept key.
10.2.3. From the Patient Test screen, press the Accept key.
10.2.4. If there is a "Lock Icon" next to the "Glu", the meter is in Control lock out. You must perform both QC levels before patient testing is permitted.
10.2.5. Scan or manually enter the strip lot number. If manually entered press the Accept key.
10.3. Patient Testing
10.3.1. Enter Patient ID (CSN #) by scanning the patient barcode or by manual entry. Do Not Use a Non-identifying number such as 99999999. If it is an emergency on a patient without a valid CSN number, please use 91111111 as the patient ID.
10.3.2. NOTE**:** To scan the patient ID, press the Scan key on the touch screen.
10.3.3. Once the Patient's ID has been entered, press the Accept key. If invalid patient appears ensure the CSN was correctly entered and select the downtime override button.
10.3.4. Choose the sample type on the meter:
a. Capillary
b. Venous
c. Arterial
d. Heel Stick (this choice will appear where applicable)
10.3.5. The Insert Strip screen displays. Insert a test strip as shown on the meter screen. Make sure you insert the strip with the gold edge toward the meter and the NOVA label on top
10.3.6. *** The meter must be held level ***
10.3.7. Holding hand downward, massage finger with thumb toward tip to stimulate blood flow. After proper cleaning of the finger, use the Safety Lancet to puncture the finger. Squeeze the finger above the second knuckle to form a drop of blood. Do not "milk" the finger. Wipe away the first drop of blood and use the second drop for testing. Discard Lancet after use in a sharps container; do not reuse.
10.3.8. The Apply Sample screen should be displaying. When the second blood drop appears, touch the end of the test strip to the blood drop until the well of the test strip is full and the meter beeps.
10.3.9. **WARNING:** The test strip must fill completely upon touching the blood droplet. If the test strip does not fill completely, do not touch the test strip to the blood droplet a second time. Discard the test strip and repeat the test with a new strip.
10.3.10. The test results will appear in 6 seconds. **NOTE:** Do not remove the test strip while the countdown is in progress.
10.3.11. Review the result and accept the result, press the Accept key.
10.3.12. If an error is suspected, reject the result and repeat testing. To reject the result press the Reject button and document the reason for rejection on the meter. If rejected, repeat testing using the above steps.

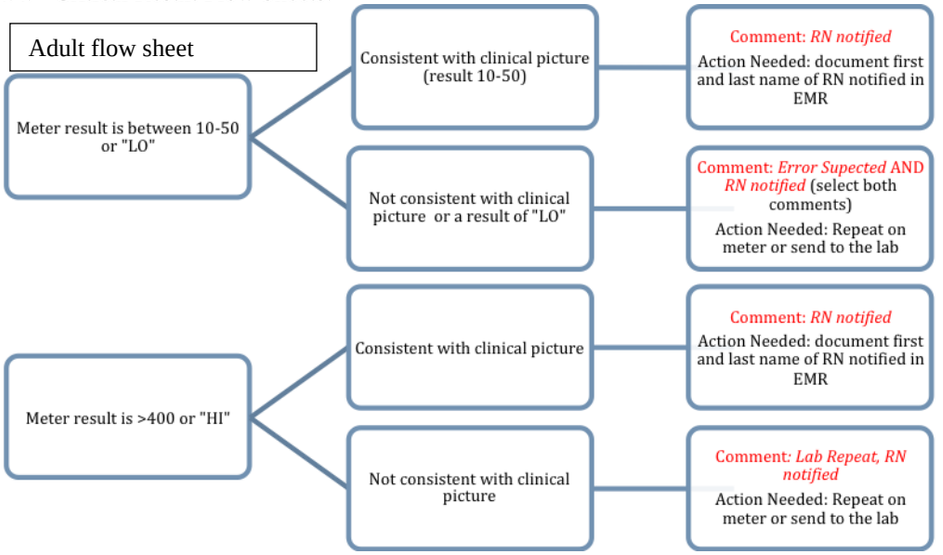
10.4. Critical Results / Confirmatory Results: See OneSource/Laboratory Guide to Services or OSU nursing policy
10.4.1. Critical results, also known as "critical values," are test results that fall significantly outside the normal range and may represent life-threatening values, even if from routine tests.
10.4.2. All critical results must be called and the call documented in the glucose meter. ***Per laboratory regulations, all critical results must be tracked in the glucose meter software.***
a. Add a comment using the meter software.
b. Press the Comment key.
c. Select one or more appropriate comment
10.4.2.c.1. There are comments pre-entered into the meter for your selection. The operator can choose appropriate comments on critical values including:

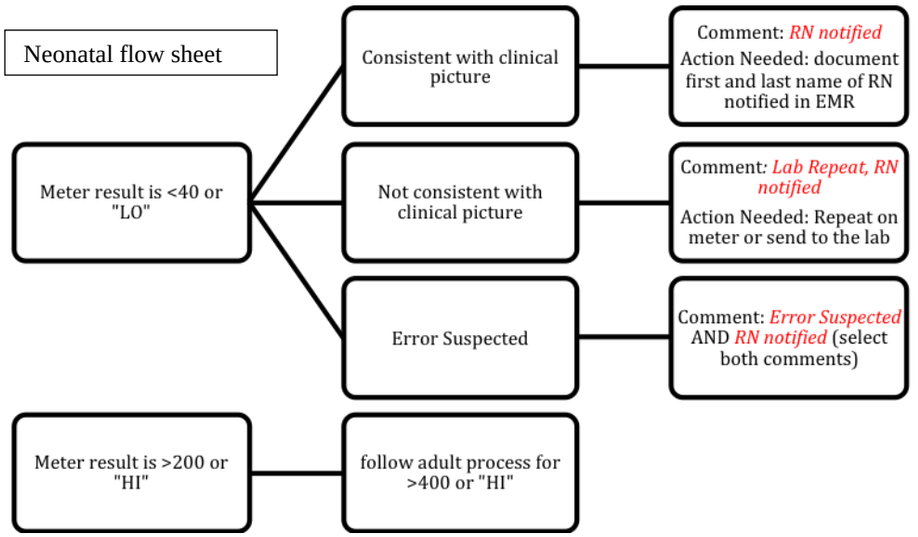
- Notified RNread back – The RN in charge of the patient has been notified of the abnormal POC glucose result
- Error Suspect/Repeat – The POC glucose result is unexpected and will be repeated
- Notified MDread back – The MD in charge of the patient has been notified of the abnormal POC glucose result
- Test on Newborn – The POC glucose was performed on a baby
- Lab Draw to Verify – The POC glucose result needs verified by a lab order/draw
- RNonly-OrderPresent – The POC glucose result is critically high or low on a repeated basis; therefore once the initial result has been called (to an RN or MD) the subsequent results can be documented with this comment

d. Select the **accept key a SECOND** time to accept the comment and the result.
e. Per CAP, in the POC setting, the identity of the testing individual and person notified need not be recorded when the individual performing the test is the same person who treats the patient.
f. When the OSU testing personnel is the RN taking care of the patient, notification information does not need to be documented in IHIS.

10.4.3. Confirmatory Results are needed when a glucose result is beyond the limits of the meter
a. If a patient test result is higher or lower than expected, reject the result on the glucometer. Repeat testing on the glucometer to confirm previous result. Consult a healthcare professional, order and send the specimen to the main laboratory.

10.4.4. Critical Result Flow Sheets:





10.5. After Each Test:
- 10.5.1. Clean the meter
  - a. Immediately after use clean the meter using a Super Sani-Cloth Plus wipe. For C Diff patients a Sani bleach cloth is acceptable.
  - b. Remove one wipe from the container and wring out any excess fluid.
  - c. Wipe down the external surfaces of the meter three times.
  - d. Wipe the meter dry.
  - e. Avoid getting fluid inside the meter strip port.
- 10.5.2. All data is stored in Telcor (POC Middleware)
- 10.5.3. Dock the meter in an appropriate docking station. The results will transfer to the patient's medical record.

11. CALCULATIONS: None

12. INTERPRETATION AND REPORTING OF RESULTS

12.1. Record the patient's result in the medical record via Telcor.
12.2. In the event of a downtime the meter will hold the results until normal operations resume. Once the downtime is over the meter will transmit held data when docked.
12.3. Refer to master listing chart for reference intervals. See OneSource/Clinical Labs/Test Catalog
12.4. Refer to master listing for Analytical measurement range (technical range). See OneSource/Clinical Labs/Test Catalog
12.5. Refer to master listing chart for reportable range (CRR). See OneSource/Clinical Labs/Test Catalog
12.6. Refer to Critical Result/Critical Value policy for critical values. See OneSource/Clinical Labs/Test Catalog
12.7. It is recommended that the meter remain in the docking (download) station at all times when not in use to allow result download and updates (to include admissions, discharges and transfers) to be sent to the meter. If the meter is not docked for an extended time (approx 8 hours), the battery may be depleted and a docking session will be required to recharge the battery.
12.8. Upon initial critical result, a specimen can be sent to the main lab for confirmation. Review clinical picture, nursing protocols and consult physician if necessary.
12.9. Improper collection and/or handling of blood specimens can cause pre-analytical error. Possible sources of error include: incorrect heparin type, the speed at which the collection device is filled, improper sample mixing, improper sample storage, clotted samples and delays in analysis.

13. LIMITATION OF PROCEDURE:

13.1. Caution should be exercised when testing capillary whole blood due to potential pre-analytical variability in capillary specimen collection.
13.2. A capillary whole blood specimen relies upon an adequate non-compromised capillary blood flow. The healthcare provider must be aware that a capillary whole blood specimen glucose result may not always be the same as an arterial or a venous whole blood glucose result, especially when the patient's condition is rapidly changing.
13.3. The Nova StatStrip meter is not intended for use with neonate cord blood samples.

13.4. Test results may be inaccurate when test strips are stored outside of the storage and handling conditions.
13.5. Do not use serum or plasma with the Nova Stat Strip meter.
13.6. The Nova StatStrip meter is not intended for screening or diagnosis of diabetes mellitus.
13.7. If a comment needs to be appended to a result, the accept button must be pressed twice before the meter is docked or the comment will not save.
13.8. If needed lithium heparin collection devices should be used for arterial and venous specimens.
13.9. Fluoride, EDTA, Sodium, and Ammonium blood collection devices should not be used.
13.10. The Stat Strip® glucose meter exhibits **no interference** from the following substances up to the following concentrations:

Tested Interfering Substances	Tested Concentration Level
Acetaminophen	**10.0 mg/dL**
Ascorbic acid	**10.0 mg/dL**
Bilirubin	**15.0 mg/dL**
Cholesterol	**500.0 mg/dL**
Creatinine	**6.0 mg/dL**
Dopamine	**10.0 mg/dL**
Ephedrine	**0.9 mg/dL**
D(+) Galactose	**350.0 mg/dL**
Hematocrit	**20-65 %**
Ibuprofen	**48.0 mg/dL**
L-Dopa	**100.0 mg/dL**
D(+) Maltose Monohydrate	**240.0 mg/dL**
D(+) Maltotetraose	**240.0 mg/dL**
D(+) Maltotetriose	**240.0 mg/dL**
Methyl-Dopa	**1.0 mg/dL**
Oxygen	**All concentrations**
Salicylate	**30.0 mg/dL**
Tetracycline	**30.0 mg/dL**
Tolazamide	**15.0 mg/dL**
Tolbutamide	**45.0 mg/dL**
Triglycerides	**750.0 mg/dL**
Uric acid	**20.0mg/dL**

14. REFERENCES:

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15. RELATED DOCUMENTS

15.1. Refer to QPulse System or Document Detail Report for related Laboratory Policies, Procedures, and Master Forms.