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Nova StatStrip Glucometer

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. To describe how to perform point of care (POC) glucose testing with the Nova StatStrip glucometer and to provide quality monitoring and troubleshooting directions for non-laboratory personnel and phlebotomy personnel.

B. This document is only applicable to areas that are approved for testing under one of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) certificates.

II. PRINCIPLE AND CLINICAL SIGNIFICANCE:

A. The Nova StatStrip Glucose Meter is intended for *in vitro* diagnostic use by health care professionals at the point of care for quantitative determination of glucose in whole blood. These glucose results, along with clinical symptoms, aide in the treatment of the patient. The meter is not to be used in establishing the diagnosis of diabetes. It is only to be used to screen patients and monitor progress of treatment. Results that meet established criteria must be acted upon according to established policies. If the glucose result is inconsistent with the patient's clinical picture, a confirmatory glucose test should be performed in the main laboratory.

B. The Nova StatStrip Glucose Monitoring System is composed of a hand held analyzer and a multi-well test strip for the quantitative measurement of glucose in whole blood by enzyme amperometric technology. When 1.2 µL sample mixes with enzymes on the test strip, an electrode measures the amount of current that is produced and quantifies how much glucose is present. The result is displayed in 6 seconds. The meters are plasma-calibrated for ease in comparing to laboratory glucose levels.

III. SPECIMEN COLLECTION AND HANDLING:

Always follow established procedures for Standard Precautions/Hand Hygiene when drawing and handling a blood specimen. Hands must be washed or disinfected with antiseptic soap or an alcohol-based hand rub as outlined in the Laboratory Infection Control policy before and after gloves are used. Gloves must be worn when performing patient testing and changed between patients.

A. Patient Preparation

1. The collection site should be warmed prior to collection for neonatal heel-stick capillary samples. See the capillary section below.
2. Warming of the collection site is not required for finger stick capillary, arterial, and venous samples.

B. Patient Identification

1. Patients must be identified at the bedside using two identifiers (Joint Commission). Where applicable, scan the barcode on the patient's wristband to obtain the contact serial number (CSN).
2. In areas where patients do not have wristbands or where the wristband is not readily accessible (e.g., OR, Cath Lab), the patient CSN will be entered manually using the keypad. During the final verification/timeout process, these areas must validate any patient label used for obtaining the patient ID number as well as verify that the correct patient demographics appear on the meter before proceeding with the test.
3. If a glucose needs to be tested before a CSN is assigned, if the wristband is damaged or missing, or if a non-patient needs an emergency glucose test (see the Point of Care Testing Policy), the operator should:
    a. Note: POC testing should only be performed on patients with an appropriate written or electronic order from an authorized person.
        i. Use the provisional barcode or dummy ID (i.e. 999999999) number provided by site-specific POC department staff in place of the patient ID number
        ii. Free text the patient name as a comment in the meter.
        iii. Complete the Point of Care Testing Result Edit form (see attachment).
        iv. Submit the form to the site-specific Point of Care department to upload the result into the electronic health record.
        v. The operator is responsible to make sure any damaged or missing wristband is replaced as soon as possible.

C. Specimen Labeling

1. Glucose testing should be performed at the patient's bedside. If the venous or arterial specimen is taken to another location for patient testing, the specimen must be labeled with patient name and ID number.

D. Specimen Types

1. Whole blood from capillary, arterial, venous, neonatal heel-stick, or neonatal arterial draw sites are the only approved specimen types. Neonatal venous and cord blood samples are not acceptable.
    a. Capillary: Stimulate the finger (or heel for babies) by massaging the area to increase capillary flow. Use an alcohol pad to clean the sampling area and allow it to dry. Never contaminate the area by introducing any drying material. Capillary samples must be tested immediately.
        i. When performing a capillary heel stick glucose on a neonate, caution should be exercised to promote adequate blood flow to the heel. Operators should consider unswaddling the neonate, massaging and/or warming the heel prior to specimen collection.
    b. Venous: See the Venipuncture Technique procedure for more information. Only specimens collected in containers that have lithium heparin are acceptable. EDTA or sodium fluoride anticoagulants should not be used. Fresh whole blood samples collected into a syringe from venous sources should be mixed well and tested immediately.
        i. Note: Expel the first few drops of blood from the syringe onto a piece of gauze to eliminate air bubbles before dosing the strip.
    c. Arterial: Caution should be taken to properly clear arterial lines before blood is collected (using the same approved anticoagulants as required for venous draws). Fresh whole blood samples collected into a syringe from arterial sources should be mixed well and tested immediately.
        i. Arterial puncture complication verification checks should be documented in the patient's chart (i.e. presence of collateral blood flow, collection site, Modified Allen's test, etc.)
        ii. Note: Expel the first few drops of blood from the syringe onto a piece of gauze to eliminate air bubbles before dosing the strip.

E. Specimen Collection

1. Gloves must be worn when performing patient testing and changed between patients. Only use single-use device (lancet) for capillary (fingerstick/baby's heel) collection. Verify that the puncture site is warm and not swollen.
    a. Verify that specimen collection devices are labeled with an expiration date than that they are not expired.
    b. Holding the hand downward, massage the finger toward the tip to stimulate blood flow. Heel warmers may be used to stimulate blood flow on the heel of babies.

c. Prepare the puncture site by thoroughly cleaning with an alcohol pad. Allow a few seconds to air dry.
d. Twist and pull off the lancet tip.
e. Firmly press the lancet against the fingertip (or heel for babies). The lancet will project and protract immediately.
f. Dispose of the lancet into a sharps container.
g. Use gauze to wipe away the first drop of blood.
h. Squeeze the finger (or heel for babies) gently and slowly (do not milk) and apply steady pressure along entire length of finger (or heel).
i. With an adequate drop of blood on the fingertip (or heel for babies), dose the test strip immediately and all at once.

F. Specimen Handling, Transportation, and Processing
1. Venous and arterial samples collected in syringes and capillary samples must be tested immediately.
2. Blood glucose determinations using lithium heparin preserved venous or arterial blood should be performed within 30 minutes of specimen collection to avoid glycolysis, and samples must be mixed thoroughly prior to testing.
3. If a syringe sample must be taken from the bedside to perform testing, the sample must be labeled with the patient's name and ID.
4. Storing samples on ice is not recommended.

G. Specimen Acceptability Criteria
1. Capillary fingerstick, venous whole blood, arterial whole blood, neonatal arterial whole blood, and neonatal heel stick
2. Lithium heparin anticoagulant for venipuncture or arterial collections

H. Specimen Rejection Criteria
1. Specimens collected using EDTA, sodium fluoride, and ammonium anticoagulants should not be used.
2. Capillary specimens collected from areas that lack good circulation (i.e. peripheral vascular disease, shock, dehydration, severe hypotension, or hyperosmolar-hyperglycemia).
3. Capillary specimens collected from sites are swollen or calloused.
4. Capillary specimens that are collected from sites other than a heel (babies) or finger.
5. Evidence of clotting
6. Unlabeled specimen not tested at the bedside
7. Specimens on ice

IV. REAGENTS:

A. Nova StatStrip Test Strips

1. Availability: Each box contains two vials of 50 test strips.
    a. Dearborn: Material Management
    b. Farmington Hills: Laboratory - Specimen Processing Area
    c. Grosse Pointe: Laboratory
    d. Royal Oak: Inventory Control/Kanban
    e. Taylor: Material Management
    f. Trenton: Material Management
    g. Troy: Central Supply
    h. Wayne: Material Management
2. Ingredients: Each strip contains enzyme glucose oxidase (*Aspergillus* sp.) greater than or equal to 1.0 IU. Additional ingredients (mediator, buffer, etc.) greater than or equal to 20 µg. The test strip vial contains molecular sieve desiccant.
3. Storage: Store test strips at room temperature, below 30ºC (86ºF) and between 10-90% relative humidity. Do not refrigerate or freeze the test strips.
4. Handling: Remove one test strip at a time and replace the cap immediately. Keep vial tightly closed. Never transfer test strips from one vial to another.
5. Expiration: Test strips expire 6 months after opening. Write both the open and expiration dates on the vial using a permanent marker. For ease of dating, document the expiration date at 6 months from the opening date. Use before the new expiration date and manufacturer's expiration date. See the Nova StatStrip Consumable Expiration Reference Guide.
6. Warnings: For *in vitro* use only. Adhere to standard precautions policy when handling reagents.

B. Nova StatStrip Quality Control, L1 (Low) and L3 (High)

1. Availability: Each level is packaged separately. Each vial of control solution contains 4 mL.
    a. Dearborn: Central Supply
    b. Farmington Hills: Laboratory - Specimen Processing Area
    c. Grosse Pointe: Laboratory
    d. Royal Oak: Inventory Control/Kanban
    e. Taylor: Central Supply
    f. Trenton: Central Supply
    g. Troy: Central Supply
    h. Wayne: Central Supply

2. Ingredients: Buffered aqueous solution containing D-Glucose, preservative, FD&C dye, viscosity-adjusting agent and other non-reactive agents.
3. Storage: Store controls at room temperature, 15-30°C (59-86°F). Do not refrigerate or freeze.
4. Handling: Keep the vials tightly closed when not in use.
5. Expiration: Controls expire 3 months after opening. Upon opening, document the new 3-month discard date on the vial using a permanent marker. Use before the new expiration date and manufacturer's expiration date printed on the vial. See the Nova StatStrip Consumable Expiration Reference Guide.
6. Warnings: For *in vitro* diagnostic use only. Adhere to the standard precautions policy when handling reagents. Do not take internally. If swallowed, seek immediate medical attention.

C. Nova StatStrip Linearity Kit
    1. Each kit contains five numbered vials (Levels 1-5). Each vial contains 4 mL of solution.
    2. Ingredients: Buffered aqueous solution containing D-Glucose, preservative, FD&C dye, viscosity-adjusting agent and other non-reactive agents.
    3. Storage: Store controls at room temperature, 15-30°C (59-86°F). Do not refrigerate or freeze.
    4. Handling: Keep tightly closed when not in use.
    5. Expiration: Linearity solutions expire 3 months after opening. Upon opening, document the open date and new 3-month expiration date on the box or vial. Use before the new expiration date and manufacturer's expiration date.
    6. Warnings: For *in vitro* diagnostic use only. Adhere to the standard precautions policy when handling reagents. Do not take internally. If swallowed, seek immediate medical attention.

V. EQUIPMENT/SUPPLIES:

A. Nova StatStrip Meter
    1. WARNING: Do not point the laser scanner towards the eyes or look directly at the laser light.

B. Recharge/Docking Station

C. Rechargeable Battery

D. Carrying Case (Optional)

E. Specimen Collection Supplies (e.g., alcohol pads, lancet, gauze, syringe, tourniquet, blood collection tubes)

F. Hospital-Approved Disinfectant or Bleach Wipes

VI. CALIBRATION/CALIBRATION

VERIFICATION:

A. The meter does not require calibration by the operator.

B. Calibration verification is the process of assaying reference standards or calibration materials in the same manner as patient samples, to confirm that the calibration of the analyzer has remained stable throughout the reportable range.

C. Five different levels of linearity solutions with known concentration of glucose are tested prior to assigning a new meter for patient testing or for troubleshooting.

1. No preparation is required for the linearity materials.
2. From the “Patient Test” screen, press “Menu”.
3. Choose "Linearity" and follow the prompts on the meter, or follow the corresponding steps described in the Quality Control section below.
4. Acceptable results fall within ±8% or ±6 mg/dL from the mean printed on each vial.
5. If a linearity result is outside the acceptable range, follow the steps below.
    a. Check the expiration date on the linearity box or vial to make sure they are not expired or contaminated.
    b. Check the expiration date on the test strip vial.
    c. Repeat the test while following the instructions carefully, using a well-mixed sample.
    d. Retest using a new vial of test strips, as the strips may have been compromised.

VII. MAINTENANCE:

A. Cleaning and Disinfection

1. Clean and disinfect the meter after every patient use. See the Nova StatStrip Cleaning and Disinfection Reference Guide attachment.
    a. Note: Cleaning is not the same as disinfecting. Cleaning is intended to remove protein, visible blood, bodily fluids, and soils from the external surfaces. Disinfecting kills or prevents the growth of disease carrying microorganisms.
    b. Note: If the carrying case is brought into the patient's room, the carrying case should be cleaned after removal from the room.
2. Gloves should be worn during meter cleaning and disinfecting.
3. The meter should be cleaned prior to disinfecting it.
4. Clean the meter using a fresh hospital-approved disinfectant or bleach wipe to wipe the external surface of the meter thoroughly. Discard the wipe.
5. Disinfect the meter using a fresh hospital-approved disinfectant or bleach wipe to thoroughly wipe the surface of the meter (top, bottom, left, and right sides) a minimum of 3 times horizontally followed by 3 times vertically while avoiding the

barcode scanner and electrical connector. Gently wipe the surface area of the test strip port, making sure no fluid enters the port.

a. Do not immerse the meter or hold it under running water. Do not spray or soak the meter with a disinfectant solution.

6. Be aware of the contact time of the disinfectant wipe used. The contact time refers to the length of time the surface of the device should remain wet. Verify that the meter is completely dry before returning it to the dock.
7. Dispose of wipes and gloves after cleaning and disinfecting the meter.
8. Follow the established procedure for hand hygiene.

B. Battery Maintenance

1. When the meter is not in use, place it in the docking station. This keeps the battery fully charged. Meter also receives full updates from the server every time it is placed in the docking station. Make sure the meter is seated properly in the docking station.
2. The light on the right side of the dock is green when the meter battery is fully charged or amber while the battery is charging.
3. There is a slot to store and charge a spare battery. The light next to the spare battery will be lit if it is seated properly. The light near the spare battery is green when fully charged and amber when charging.
4. The lithium polymer battery life is 6-8 hours when in use, or approximately 40 tests. An auto-sleep feature conserves power when the meter is not in use.
5. Batteries must be replaced when the battery expiration date is reached.
6. The meter will display a “Battery Low” alert. Charge the meter or replace the battery.
    a. To change a battery, push down on the cover latch to release the cover. Remove the cover.
    b. Remove the low battery and replace with a fully charged battery by inserting from the bottom first, gold contact to gold contact. Replace the battery cover.
    c. Place the low battery in the spare battery slot on the docking station.
    d. If more than 20 seconds elapse before replacing the battery, the date and time will be lost. Dock the meter and allow it to upload the date and time before using.
7. Always check for battery light illumination on the docking station.
8. The light in the middle of the dock flashes green when data is transferring.

C. Emergency Shut-Down

1. Remove the battery from the meter to instantly power down the device.
2. Unplug the docking station from the wall outlet to instantly power down the docking station.

VIII. QUALITY CONTROL (QC):

The Nova StatStrip Glucose Control Solutions have known glucose values that are used to confirm that the meter and test strips are working correctly. There are two controls, low and high. The two levels must be run once every 24 hours or the meter will lock out for patient testing. When the 24 hour period has been exceeded, “Glu” appears with a lock symbol next to it with the message “L1, 3 Glu QC Required. Press QC for QC Testing.”

Additional control testing is indicated when a control fails, if the meter is dropped, if a problem is identified with test strip or QC storage conditions, if there is a concern about the accuracy of the glucose meter, and when results contradict the patient’s clinical symptoms (e.g., the results are higher or lower than expected even after repeat patient testing).

A. Quality Control Procedure:
    1. Check expiration dates of test strips and QC solutions.
    2. No preparation is required for the QC materials.
    3. Log into the meter as described in the Procedure section.
    4. From the “Patient Test” screen, press “QC”.
    5. The “Enter Strip Lot” screen appears. Scan the strip bar code then press “Accept”.
    6. The “Enter QC Lot” screen appears. Scan the QC bar code then press “Accept”.
    7. The “Insert Strip” screen appears.
    8. Gently mix the QC material.
    9. Insert a test strip into the meter.
    10. Discard the first drop of control solution from the bottle to avoid contamination.
    11. Apply the sample. Hold strip to sample until 6 second countdown is displayed. The meter will beep when enough sample is applied.
    12. Recap the QC solution.
    13. The “QC Result” screen displays “Pass” (blue) or “Fail” (red).
    14. If the result passes, press “Accept”.
    15. If the result fails, press “Comment” and choose the appropriate comment from the choices displayed or press “Chart” to free text a comment. Press “Accept” to finalize the result. The instrument will be locked out from patient testing until QC has passed. See the Quality Control Failure Procedure section below for more information.
    16. Remove the test strip manually or eject the strip by pushing the lever on the back of the meter while holding directly over a trash receptacle (QC does not contain biohazardous materials).

B. Quality Control Failure Procedure
    1. Verify strips and controls are not past expiration dates.

2. Confirm proper temperature and humidity storage for strips and QC.
3. Confirm that the strip vial was not left open.
4. Confirm that the proper procedure was followed.
5. Repeat with a new strip.
6. Repeat with new QC solution.
7. If QC still fails, label the meter clearly with “Do not use for patient testing”.
8. Follow the site-specific instructions below for assistance:
    a. Dearborn: Return the meter to the main laboratory. Complete the Glucometer Exchange form attachment. Take a loaner instrument for immediate use until a functioning meter is returned.
    b. Farmington Hills: Call the POC Lead MT at 947-521-7167.
    c. Grosse Pointe: Call Point of Care at 313-473-1831 or the Laboratory at 313-473-1637.
    d. Royal Oak: Exchange the meter with a loaner meter in 3C Phlebotomy. Complete the Glucometer Exchange form attachment. Or call Ancillary Testing at 248-898-8012.
    e. Taylor: Return the meter to the main laboratory. Complete the Glucometer Exchange form attachment. Take a loaner instrument for immediate use until a functioning meter is returned.
    f. Trenton: Return the meter to the main laboratory. Complete the Glucometer Exchange form attachment. Take a loaner instrument for immediate use until a functioning meter is returned.
    g. Troy: Call Decentralized Testing at 248-964-8009.
    h. Wayne: Return the meter to the main laboratory. Complete the Glucometer Exchange form attachment. Take a loaner instrument for immediate use until a functioning meter is returned.

IX. PROCEDURE:

A. Upon removal from the docking station, the "Welcome" screen will be displayed. If the meter was not docked and is in an energy saving mode, touch the display screen to wake up the meter.

B. Press "Login".

C. When prompted to “Enter Operator ID”, hold the meter approximately 2 to 6 inches from the barcode on the employee badge.

D. While holding the scanner parallel over the barcode, press “Scan”.

E. The “Patient Test” screen appears with operator name (abbreviated) in the upper right corner. Press “Accept” to continue unless a lock symbol appears next to "Glu" with the message “QC lockout. L1, L3 QC Required. Press QC for QC Testing.” See the Quality Control section for details about running QC.

F. The “Enter Strip Lot” screen appears. Scan the barcode on the strip vial and press “Accept”.

G. The “Patient ID” screen appears. While holding the bottom of the meter 2-6 inches from the barcode on the wristband, press “Scan”. Manually enter the patient ID using the keypad if a barcode is not available.

H. Verify that the patient ID number and name are correct and press “Accept”.

    1. If no Admission Discharge Transfer (ADT) information has been sent to the meter for a patient, the ID will appear with the message “… is not a valid Patient ID. Try again.” Verify the patient information is correct before proceeding. If the number is correct, press “Downtime Override” on the screen to continue without ADT. If incorrect, press “Back” to return to the “Enter Patient ID” screen and re-enter the ID correctly.

I. The “Insert Strip” screen appears. Insert the gold end of a test strip into the strip port on the meter. Make sure the Nova label is facing upward.

J. The “Apply Sample” screen appears. Obtain the blood sample, following the Specimen Collection and Handling instructions above.

K. Hold the meter level to avoid damage from blood getting into the strip port. Touch the end of the test strip to the blood drop. Verify that the drop is large enough to fill the strip all at once. The test strip fills by capillary action.

    1. The operator may need to tap the screen to wake it up before applying the sample. The touch screen of the meter goes into a sleep mode after 90 seconds, if the sample is not applied.
    2. Do not apply blood to the top of the strip.
    3. If the strip does not fill completely, do not touch the strip to the blood droplet a second time. Discard the test strip and repeat the test with a new strip.

L. When enough blood has been drawn in, the “Testing Sample” screen appears and a 6 second analysis countdown begins.

M. The “Patient Result” screen appears with the glucose level.

    1. Results within the normal range appear in blue and results outside the normal range appear in red.
    2. Critical results will display with a message “Critical Low” or “Critical High”. See the Critical Values section for more information.

N. A comment is required to indicate the specimen source (i.e. capillary, arterial, venous, neonatal heel-stick, or neonatal arterial). Touch desired comment(s) from the list. Press “Accept”.

    1. Testing personnel may additionally free text a comment (press “Chart” for the comment to appear in the electronic health record).

O. To accept the final result and comment(s), press “Accept”.

P. To reject a result, press “Reject” and then a mandatory comment must be entered. Choose from the list or free text an explanation (press “Chart”) if necessary. “Accept” the comment. Press “Reject” again to prevent the result from uploading to the electronic health record.

Q. Remove the test strip manually or eject the strip by pushing the lever on the back of the meter while holding directly over a biohazard container.

R. Clean and disinfect the meter after every patient test. See the Maintenance section for more information.

S. Log off the glucose meter by placing the meter in the dock or from the “Patient Test” screen, press “Logout”. The “View Operator” screen appears. Press “Logout”.

X. RESULT REPORTING:

A. The meter communicates wirelessly to send results. The meter must be docked to receive operator updates and patient demographics. When idle, two icons will be seen in the upper right corner that displays the signal strength and whether or not the meter has established a network connection. All valid patient glucose results will transfer to the patient’s electronic health record through the TELCOR QML Data Management System.

XI. REPORTABLE RANGE:

A. 10-600 mg/dL

B. Results below 10 mg/dL will read “LO” and results above 600 mg/dL will read “HI”. Retesting is recommended to verify all questionable results using a new test strip and confirming proper technique or send a glucose sample to the lab if the result does not correlate with the patient’s clinical presentation.

XII. EXPECTED VALUES:

A. The glucometer will display normal results in blue. Abnormal results display in red on the meter.

1. Random: 70-139 mg/dL
2. Fasting: 70-99 mg/dL

XIII. CRITICAL VALUES:

A. The glucometer will display critical results in red accompanied by two upward facing arrows for critically high results or two downward facing arrows for critically low results.

1. 0 - 23 Months: <45 mg/dL and >180 mg/dL
2. 24 Months - 16 Years: <50 mg/dL and >300 mg/dL
3. ≥17 Years: <50 mg/dL and >500 mg/dL

B. Follow the institutional policy for critical result reporting and documentation.

C. Critical values may be confirmed by repeating the test on the meter or sending a glucose sample to the main laboratory, per the operator's discretion. If the critical value will be confirmed on the meter, follow the steps to reject a result as described under the Procedure section.

XIV. SYSTEM DOWNTIME:

A. If a glucometer is unable to download patient information (e.g., Wi-Fi downtime, Hospital

Information System downtime, Point of Care software downtime, etc.), continue to scan barcodes to enter operator and patient identification into the meter. Proceed with testing.

B. Results may be obtained from the meter. See the Result Review section.

C. When the system becomes available, patient results will be automatically transmitted to the electronic health record.

XV. RESULT REVIEW:

A. To review the results in the meter, login to the meter, as outlined in the Procedure section.

B. Press "Review".

C. The “Review Results” screen appears. If desired, sort the results by pressing “ID”, “Time/Date”, or “Type”.

D. Press “Page Down” or “Page Up” to scroll through the sorted results.

E. Touch the desired result on the display screen and press “View”.

F. Press “Previous” to see the previous result or “Next” to view the next result.

XVI. LIMITATIONS:

A. In situations where the patient is edematous, or where there is decreased peripheral blood flow or peripheral vascular disease caused by severe hypotension, shock, hyperosmolar-hyperglycemia (with or without ketosis), and severe dehydration, fingerstick glucose testing may not be appropriate and may not reflect the true physiological state.

B. 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 venous whole blood glucose result, especially when the patient's condition is rapidly changing. If a capillary whole blood glucose 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 glucometer or a specimen may be sent to the main laboratory for testing.

C. Glucose results may be affected if excessive water loss or dehydration occurs.

D. The StatStrip Nova meter exhibits no interference in blood specimens with hematocrits from 20% to 65% or with varying oxygen content.

E. Improper storage and handling of the test strips may render inaccurate results.

F. Humidity below 10% or above 90% may cause inaccurate results.

G. Using expired test strips may cause inaccurate results.

H. Venous and capillary blood may differ in glucose concentration by as much as 70 mg/dL, depending on the time of that collection after food intake.

I. Not for use with serum or plasma.

J. The glucose meter cannot be used with neonatal venous samples.

K. EDTA, sodium fluoride, citrate, and oxalate blood collection tubes should not be used as preservatives for specimens.

L. Blood collected in a heparinized syringe may cause dilution errors due to the amount of heparin in the syringe and whether it is filled to capacity with blood.

XVII. INTERFERING SUBSTANCES:

A. The Nova StatStrip exhibits no interference from the following list of drugs or physiological conditions commonly found in patients in intensive care settings with complex medical conditions and drug regiments up to the following concentration levels:

Interfering Substances	Concentration Level (mg/dL unless otherwise noted)
Acetaminophen	20.0
Acetoacetate	51.0
Acetone	69.7
Acyclovir	0.6
Albuterol	0.06
Amitriptyline	0.06
Amoxicillin	5
Ampicillin	0.8
Ascorbic Acid	22.5
Atropine	0.01
Beta-hydroxybutyrate	166.6
Bilirubin	29.3
Captopril	0.6
Carbamazepine	1
Cefaclor	35
Cholesterol	1000
Cimetidine	5
Citric Acid	384.3
Creatinine	6
Digoxin	0.3
Diltiazem	0.1
Dopamine	20
Enalapril	0.5
Ephedrine	1
Ethanol	399.9
Famotidine	0.042
Fluconazole	2

Fluoxetine Hydrochloride	2
Fructose	500
Furosemide	3
Galactose D(+)	500
Galactose-1-Phosphate	500
Gentamicin sulfate	12
Glycerol	500
Heparin	1.2
Hydrochlorothiazide	2
Hydrocortisone	20
Ibuprofen	48.0
Ketoprofen	6
Lactose	500
Lansoprazole	20
L-dopa	5
Levofloxacin	1.8
Lidocaine	0.7
Lisinopril	0.5
Maltose D(+)	500
Maltotetraose D(+)	240
Maltotetriose D(+)	240
Mannitol	6000
Mannose	500
Methy-dopa	1.0
Metoprolol Tartrate Salt	1.8
N-acetylcystein	81.6
Naproxen	40
Nifedipine	0.02
Norepinephrine	10
Nortriptyline Hydrochloride	0.02
Olanzapine	0.02
Pancuronium bromide	0.4
Penicillin	72
Phenytoin	2.5

Prednione	1
Propofol	3.2
Propranolol Hydrochloide	0.3
Ranitidine hydrochloride	1
Salicylate	120
Sodium Chloride Deviation from a normal sodium or chloride level	234
Sodium Nitroprusside dihydrate	0.05
Sorbitol	500
Sucrose	500
Sulfamethoxazole	1.5
Tetracycline	30
Theophylline	2
Toazamide	45
Tolbutamide	50
Triglyceride	1500
Uric Acid	23.5
Vancomycin hydrochloride hydrate	3
Verapamil Hydrochloride	0.1
Warfarin	1.2
Xylose	500
Hematocrit	20% and 70%
Oxygen	All concentrations
pH	6.6 and 8.0 (pH units)

XVIII. TROUBLESHOOTING:

A. Frozen Screen

1. If the meter freezes, reset it by removing the battery for 10 seconds and replacing it. See the Battery Maintenance procedure under the Maintenance section.

B. Meter Screen Alerts

1. Battery Low - Change the battery or place the meter onto the Docking Station.
2. Test Strip was Removed - The test strip was removed before testing was completed. The test has been canceled. Insert a new test strip.
3. Temperature Error - The meter is outside the range for testing: 15-40°C (59-104°F).

Move the meter to an area within the acceptable temperature range. Allow the meter to adjust to the temperature. Repeat the test.

4. Bad Sample - Insert a new strip and rerun the test.
5. Replace Strip - Occurs after insertion of strip or occurs during analysis. Insert another strip and repeat the test.
6. Flow Error - The specimen was incorrectly drawn into the test strip due to insufficient or incorrect sample application. Repeat the test with a new strip.
7. Transfer Failed - The wireless system is down or the connection to the server was broken.
8. Date/Time Lost - Respond to the on screen message, then dock the meter and allow it to upload the date/time settings.
9. If the meter locks, reset it by removing and replacing the battery. See the Battery Maintenance procedure under the Maintenance section.

C. Follow the site-specific instructions below if troubleshooting steps are unsuccessful.

1. Dearborn: Return the meter to the main laboratory. Complete the Glucometer Exchange form attachment. Take a loaner instrument for immediate use until a functioning meter is returned.
2. Farmington Hills: Call the POC Lead MT at 947-521-7167.
3. Grosse Pointe: Call Point of Care at 313-473-1831 or the Laboratory at 313-473-1637.
4. Royal Oak: Call Ancillary Testing at 248-898-8012 or exchange the meter with a loaner meter in 3C Phlebotomy. Complete the Glucometer Exchange form attachment.
5. Taylor: Return the meter to the main laboratory. Complete the Glucometer Exchange form attachment. Take a loaner instrument for immediate use until a functioning meter is returned.
6. Trenton: Return the meter to the main laboratory. Complete the Glucometer Exchange form attachment. Take a loaner instrument for immediate use until a functioning meter is returned.
7. Troy: Call Decentralized Testing at 248-964-8009.
8. Wayne: Return the meter to the main laboratory. Complete the Glucometer Exchange form attachment. Take a loaner instrument for immediate use until a functioning meter is returned.

XIX. PERSONAL GLUCOSE MONITORING DEVICES:

A. The laboratory does not oversee or provide direction regarding the use of personal glucose monitoring devices. CLIA regulations related to laboratory testing apply when a specimen (blood) is removed from the patient for the purpose of providing information to diagnose, prevent, treat disease, or to assess a patient's health. CLIA and CAP regulations do not view

insulin pumps or continuous glucose monitoring devices as laboratory testing devices that are regulated under CLIA directives since the device probes are inserted in the interstitial fluid for continuous monitoring and a specimen never leaves the patient's body. Such devices are governed by the FDA and TJC.

B. The laboratory does not perform, review, or approve validation or comparison studies on personal glucose monitoring devices.

C. Refer to the policies below for more information:

    1. Perioperative Insulin Pump Guidelines (Age: 18+ years)
    2. Insulin Pump, Self-Management By The Adult Patient

D. Continuous glucose monitor devices have not been approved by the FDA for inpatient use (American Diabetes Association).

XX. REFERENCES:

A. Point of Care Testing Approval Process

B. The Joint Commission. (2022) Standard NPSG.01.01.01 EP 1 in The Joint Commission. Comprehensive accreditation manual. Hospital edition. Oak Brook, IL: The Joint Commission.

C. Instructions for Use Manual. StatStrip Glucose Hospital Meter Nova Biomedical, Waltham, MA 02454-9141 copyright 1/9/2019

D. Nova StatStrip Glucose Test Strips package insert, LPN 55873H 01/2020 Nova Biomedical, Waltham, MA 02454-9141

E. Skin Puncture Techniques

F. Quick Safety 59: Safe patient use of insulin pumps and CGM devices during hospitalization | The Joint Commission

G. ElSayed, Nuha A. et. al., (1/2023) Diabetes Care in the Hospital: Standards of Care in Diabetes-2023. American Diabetes Association. 16. Diabetes Care in the Hospital: Standards of Care in Diabetes—2023 | Diabetes Care | American Diabetes Association (diabetesjournals.org)

Attachments

Glucometer Exchange.pdf

Nova StatStrip Calibration Verification and AMR.pdf

Nova StatStrip Cleaning and Disinfection Reference Guide.pdf

Nova StatStrip Consumable Expiration Reference Guide.pdf

Nova StatStrip New Lot Number Validation.pdf

Nova StatStrip Training and Competency Assessment.pdf

Nova StatStrip Training Guide.pdf

Point of Care Testing Result Edit.pdf

Approval Signatures

Step Description	Approver	Date
CLIA Medical Directors	Muhammad Arshad: Chief, Pathology	1/8/2024
CLIA Medical Directors	Jeremy Powers: Chief, Pathology	1/3/2024
CLIA Medical Directors	John Pui: Chief, Pathology	12/26/2023
CLIA Medical Directors	Vaishali Pansare: Chief, Pathology	12/26/2023
CLIA Medical Directors	Ryan Johnson: OUWB Clinical Faculty	12/19/2023
Policy and Forms Steering Committee Approval (if needed)	Jessica Czinder: Mgr, Division Laboratory	12/19/2023
CP System Medical Director	Ann Marie Blenc: System Med Dir, Hematopath	12/19/2023
	Caitlin Schein: Staff Physician	11/30/2023
Technical Director	Nga Yeung Tang: Tech Dir, Clin Chemistry, Path	11/28/2023
POC Best Practices	Jessica Czinder: Mgr, Division Laboratory	11/28/2023
	Jessica Czinder: Mgr, Division Laboratory	11/28/2023

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne