POCT - Analysis of Blood Glucose by Nova StatStrip Glucometer

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5.0	29/11/2024

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Distribution List	Operators of Nova StatStrip glucometer

1. PURPOSE AND SCOPE

This document defines the procedures for performing Point-of-Care (POC) whole blood glucose measurement using Nova StatStrip glucometer.

2. POLICY

All Point-of-Care Testing (POCT) procedures must comply with the requirements of Hospital Authority (HA) Point-of-Care Testing Policy. Refer to the latest HA POCT Policy for details.

Any breach of HA POCT Policy will be reported to the NTEC POCT Coordinating Committee. The non-conforming POCT operator / site might be forbidden to perform POCT until compliance is restored.

3. TESTING PERSONNEL

1. According to the Hospital Authority Point-of-Care Testing Policy, the POC blood glucose testing is classified as Complexity Level I testing.
2. Hospital staff, including supporting staff, can perform the blood glucose testing after appropriate training.
3. All POCT BGA operators must be trained and assessed (certified) before performing blood glucose testing procedures.
4. All POCT BGA operators must attend either classroom-based or web-based training courses organized by the NTEC POCT Coordinating Committee every 3 years in accordance with the HA POCT Policy.
5. Certified BGA operators must pass the following two assessments:

    a) POCT BGA MCQ test at i-Learn on hospital's website; and
    b) Internal quality control (IQC) skill tests assessed by BGA link nurses.

6. Updated list of certified BGA operators and training/assessment records shall be kept by individual POCT sites.

4. CLINICAL SIGNIFICANCE

The point-of-care whole blood glucose (haemoglucostix) is used for the monitoring of carbohydrate metabolism disturbances including diabetes mellitus, and idiopathic hypoglycaemia, and of pancreatic islet cell carcinoma. It is not aimed for the diagnosis of diabetes mellitus and hypoglycaemia.

5. PRINCIPLE OF METHOD

The test strip is designed with an electrode that measures glucose levels. Glucose (sugar) in the blood sample reacts with enzyme reagent on the test strip. This process generates electric current. The amount of electric current produced depends on the concentration of glucose presents in the blood (amperometric measurement).

6. SPECIMEN

6.1. Sample Type:

1. Capillary finger stick, venous whole blood, arterial whole blood, neonate arterial whole blood, or neonate heel stick specimens.
2. It is not intended for use with neonate cord blood specimens.
3. Use only whole blood. Do not use serum or plasma.

6.2. Handling Condition

NOTE:
Samples used for POC testing must be handled in the same manner as other biological fluids. Every sample may be infectious and staff should observe universal precautions when collecting POCT samples. Equipment or consumables identified as "single use" must not be re-used. Lancets or syringe needles must be disposed into sharp boxes. Used sample devices and test strips should be discarded according to hospital's infection control policy.

1. Apply fresh whole blood whenever possible.
2. Make sure the puncture site is clean and dry before obtaining a blood sample. Avoid excessive squeezing of the puncture site.
3. Accuracy of measurement relies upon an adequate, non-compromised capillary blood flow.
4. Only fresh whole blood or whole blood collected in lithium heparin collection devices should be used for arterial and venous specimens.
5. Fluoride, EDTA, Sodium, and Ammonium blood collection devices should NOT be used.

7. REAGENTS

NOTE:
All testing materials (e.g. reagent, cartridges, strips) have to be approved by the NTEC POCT Coordinating committee prior to use in patient testing. In PWH, only glucose strips are allowed for NOVA StatStrip glucometer analysis. Please seek advice from the NTEC POCT Coordinating committee if the use of other strips is required.

1. Nova StatStrip Glucose Test Strip:

   Store test strips at room temperature below 30^0C. Test strips should be stored only in tightly closed original vial. Strips have to be used within 6 months after first opening. Mark the date of discard after uncapping a new test strip vial.

2. Nova StatStrip Glucose Control Solutions (Level 1 & 3):

   Store at 15 – 30^0C. Control solution has to be used within 3 months after first opening. Mark the date of discard after unsealing a new control solution.

8. CALIBRATION

No calibration is required. The measurement is traceable to NIST Standard Reference Material.

9. QUALITY ASSURANCE (QA)

9.1 Internal Quality Control (IQC):

1. Perform two levels of Nova StatStrip Glucose Control at least once daily for all actively-in-use glucometers. For non-daily-use glucometers, two levels of IQC are required before patient testing.
2. Repeat IQC testing if:

   a) IQC results is out of acceptable range
   b) A new bottle/pack of test strips is being used
   c) The glucometer has been dropped
   d) Accuracy of blood glucose result is questioned
   e) Batteries of glucometer has been changed

3. Check the discard/expiry date of the IQC materials before use.
4. Press "**Login**" in Nova StatStrip handset welcome screen. Scan operator's 331 code to unlock the meter.
5. Press "**QC**" to start IQC testing.
6. Scan strip lot number on the strip vial.
7. Scan lot number on the control solution bottle.
8. Insert one test strip into the test strip slot. Place it horizontally or slightly downward to prevent control solution from entering the slot.
9. Gently mix the control solution, discard the first drop and wipe the bottle tip.

10. Squeeze the vial to produce another drop of control solution for testing. A hanging drop is preferred. It may also be dispensed on a clean non-absorbent surface.
11. Touch the end of test strip to the control solution droplet. Measurement starts and test result will display on the screen after 6 seconds. Do not remove test strip during countdown.
12. Eject the test strip after countdown. Wipe the tip of control solution bottle before recapping.
13. Control test result and IQC ranges will be displayed with "**PASS**" or "**FAIL**". Confirm "**PASS**" result by pressing "**Accept**".
14. Repeat Steps 3 – 14 for the other level of control solution.
15. If the IQC results are outside the acceptable limits:

    a) Check whether correct testing strips and IQC materials have been used. Look for any signs of deterioration (expired / uncapped bottles).
    b) Repeat IQC testing.
    c) Contact BioAsia if the problem persists.

9.2 External Quality Assurance (EQA):

1. Participation in an EQA scheme is highly recommended by the HA POCT Committee.
2. EQA program for NTEC POC glucose testing is provided by Department of Chemical Pathology, Prince of Wales Hospital.
3. EQA program cycle begins in July every year and ends in June of following year.
4. Two levels of EQA samples are distributed to enrolled POCT sites monthly.
5. Participants perform glucose analysis as patient samples and report the results via NTEC POCG EQAPS website.
6. EQA performance reports are released in the EQAPS websites. Those who have unsatisfactory performance in EQAP would receive a pair of fresh EQA material for repeat.
7. Glucometers could not pass the repeat test should be withdrawn from service. Contact BioAsia for repairment or replacement.
8. EQA results and performance reports should be recorded and kept for at least three years.
9. Corrective actions for all nonconformance of EQA shall be documented and kept for at least three years.

10. PATIENT TESTING PROCEDURE

10.1 Procedure for Patient Sample Analysis:

1. Touch Nova StatStrip handset screen to turn on the handset. Press "**Login**".
2. Scan operator's 331 code to unlock the glucometer.
3. Press "**Accept**" to proceed patient testing.
4. Scan Strip lot number on the strip vial.
5. Scan patient wristband 2D barcode as Patient ID.

6. Insert one test strip into the test strip slot.
7. Obtain a round drop of blood from patient's finger with lancet. If the blood drop smears or runs, repeat sampling.
8. Touch the end of test strip, facing downward, to the drop of blood. Measurement will start automatically. Do not remove test strip during countdown.
9. Eject the test strip after countdown. Patient test result will be displayed on the screen.
10. Press "**Accept**". The accepted result will be uploaded to POCT server automatically if the handset is Wi-Fi connected.
11. Alternatively, place the handset into the Docking/Charging Station for result upload and battery charging. See Figure 1 below for details.
12. Patient results can be reviewed in Clinical Management System (CMS) after uploading.
13. Each POCT site should maintain at least one Docking/Charging Station connected to MNI port. It serves as a backup in the event of Wi-Fi network failure.

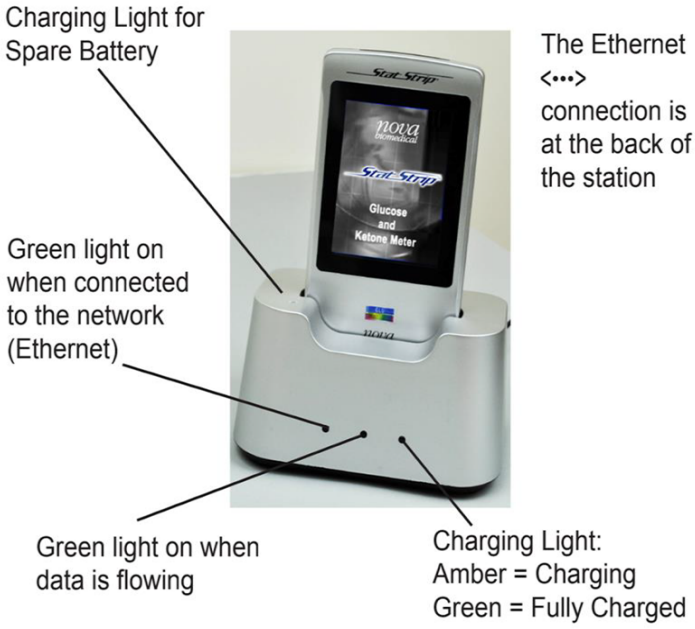

Figure1. Nova StatStrip Docking / Charging Station

10.2 Procedure for Reviewing Results in Nova StatStrip Glucometer:

1. Each Nova StatStrip glucometer can store up to 1,000 patient test results.
2. In case data upload is interrupted, patient results can be recalled in the glucometer as followings:

a) After login the glucometer, press "**Review**" and "**Review Result**" screen displays.
b) Results can be sorted by pressing **ID**, **Time/Date** or **Type**.
c) Scroll through the sorted results and select the one to be reviewed.
d) Press "**View**" and details of the selected result will be displayed.

11. RESULT REPORTING

1. Results should be reported in mmol/L and to one decimal place.
2. The measurement range of Nova StatStrip is 0.6 – 33.3 mmol/L.
3. Results that fall below the lower limit of measurement range are reported as "**< 0.6 mmol/L**".
4. Results that exceed the upper limit of measurement range are reported as "**> 33.3 mmol/L**"
5. A repeat sample should be sent to laboratory for confirmation if the POC glucose is < 3.0 or > 20 mmol/L

12. REFERENCE RANGE

Not applicable.

13. LIMITATIONS OF THE PROCEDURE

1. Extreme haematocrit level (>70%) may falsely lower blood glucose measured.
2. Severe hypertriglyceridemia with high triglyceride level may falsely lower blood glucose measured.
3. In condition of poor capillary perfusion such as hypotensive, glucose measured at finger tips would be lower than venous or arterial samples.
4. Edematous patients / drip arm may cause falsely low blood glucose measured due to dilution effect.
5. Glucose-containing food residue on fingers may affect glucose measurement.

14. MAINTENANCE

1. Avoiding the barcode scanner and electrical connector, clean the exterior of the glucometer with alcohol pad.
2. Do not spray any liquid directly onto the glucometer.
3. Caution should be taken to prevent fluid from contacting test strip slot and electrical connector areas.

4. To check Wi-Fi connection status of NOVA handset:

Network connection status is displayed as follows:	
	Meter has established a connection and is communication with the device manager.
	Meter has not established communication with the device manager.

Radio status is displayed as follows:	
	Radio is ON and connected to the WAP with the strongest signal strength.
	Radio is ON and connected to the WAP with approximately 3/4 signal strength.
	Radio is ON and connected to the WAP with approximately 1/2 signal strength.
	Radio is ON and connected to the WAP with approximately 1/4 signal strength.
	Radio is ON with no signal, or no connection to the AP. In this state, the meter may be in the process of attempting association with the local Wireless Access Point (WAP).
	Radio is OFF or no connection to WAP.

15. TECHNICAL SUPPORT

1. Contact Bio-Asia at 2787 0906 for technical support during office hour.
2. Create Work Request via PWH EAM Self service platform.
3. If Nova StatStrip glucometer breaks down during non-office hours, use your back-up Nova StatStrip glucometer available in the ward.
4. If the Nova StatStrip glucometer is borrowed from other ward for emergency use, perform docking in the ward where the glucometer is originally owned. Otherwise, results might not be able to upload to CMS.
5. In urgent situation, for example, no back-up Nova StatStrip glucometer is available, on-loan Nova StatStrip glucometer can be borrowed from the laboratory during non-office hours using loan form. Patient results done by laboratory glucometer can only be uploaded to CMS via laboratory docking station after returning the on-loan unit.

   Note: Patient results can be reviewed in Nova StatStrip glucometer during the downtime of result uploading (refer to ***Section 10.2 "Procedure for Reviewing Results in Nova StatStrip Glucometer"*** *for details).*

16. REFERENCE

1. StatStrip Glucose and ß-Ketone Hospital Meter Instructions for Use Manual, 2018 (Ref 53736)
2. Package insert of StatStrip Glucose Hospital Meter Test Strips, 2020 (Ref 44214)
3. Package insert of StatStrip and ß-Ketone Control solution, 2019 (Ref 46947)
4. Practical Tips on Capillary Blood Glucose & QC Testing, NTEC Diabetes Nursing Service Sub-Committee, 2020
5. Nova StatStrip Glucose Meter Training presentation, BioAsia, Oct 2020

Amendment History

Version	Effective Date	Amendment
2.0	09/03/2023	1. In Section 6.2, note for specimen handling was added. 2. In Section 9.2, handling of unsatisfactory QC performance was added. 3. In Section 12, reference ranges were added.
3.0	29/04/2023	1. Amendments in Section 2 Policy. 2. Amendments in Section 6.2 Handling Condition. 3. Amendments in Section 7 Reagents. 4. Amendments in Section 9.2 External Quality Assurance (EQA). 5. Amendments in Section 15 Technical support.
4.0	29/04/2024	1. Amendments in Section 10.1 Procedure for Patient Sample Analysis. 2. Amendments in Section 14 Maintenance.
5.0	29/11/2024	1. Amendments in Section 15 Technical support.