Performa Blood Glucose Meter

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AUTHOR	D O'Neill
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CONTENTS

1.0 PURPOSE AND SCOPE

To outline the procedures for the use of Roche Performa Blood Glucose Meters used for Point of Care Testing (PoCT).

2.0 RESPONSIBILITY

The PoCT team is responsible for the maintenance of the blood glucose meters in use* in the Northern Devon Healthcare Trust (including District Nurses), some Devon Partnership Trust meters and a few other Community based meters. The PoCT team in collaboration with the manufacturer and occasionally the Trusts' Diabetes Specialist Nurses ensure provision of training. Pharmacy/PoCT supplies the test strips and the PoCT team holds a stock of meters, batteries, workstations, control solutions, QC log books and ward manuals.

*N.B. This applies to meters supplied by or adopted by the NDHT.

Ward/Location managers
Are responsible for ensuring meters are used in accordance with Trust Policies and are consequently fit for purpose.

Where meters are found to be or suspected of being faulty they are responsible for removing them from service and ensuring that the PoCT team are informed so the appropriate remedial action can be taken.

Meter Users
Complying with Board ratified policies and procedures.

Participation in medical device education and training, and ensuring individual training matrix and Personal Development Portfolios are updated.

Acceptance of individual or team responsibility and accountability for maintaining a safe environment and only operate devices for which the user is competent and this competence can be demonstrated.

Adhering to incident reporting procedures.

3.0 REFERENCES

MHRA DB2010(02) Management and Use of IVD Point of Care Test Devices.
BS EN ISO 22870:2006 Point of care testing- Requirements for quality and competence.

4.0 DOCUMENTATION

Manual Standard Operating Procedure: Number POC-SOP-18.
Related documents, POC-EXT-33 and POC-EXT-35.

5.0 ACTIONS AND METHODS

5.1 Principle of test

Glucose Dehydrogenase, in the presence of the coenzyme (PQQ), on the test strip converts the glucose in the blood sample to gluconolactone the reaction is monitored amperometrically.

5.2 Sample Requirements

A drop of fresh whole venous, capillary or arterial blood. Blood that has been collected into tubes containing heparin or EDTA can be used but fluoride tubes are not suitable.

5.3 Personnel applicable

All members of staff with appropriate training i.e having completed the relevant competency or manufacturer/PoCT team training.

5.4 Internal Quality Control

Quality Control checks should be run in accordance with the Trust's Glucose Meter Quality Assurance Policy.
The manufacturer supplies two levels of QC for use with the meter (Roche product code 05078164001). Once opened it has a 3 month shelf life hence on first opening the printed expiry must be crossed out and the date three months hence must be written onto the bottles.

5.5 External Quality Assurance

Each month every location using glucose meters is sent a result sheet for each meter and an EQA sample this must be tested and the results returned by the return date printed on the sheet. A report will be sent to each location showing the performance of the meter/s. Poor performance and non returns will be followed up as appropriate.

5.6 Running a Quality Control

1. Check that the test strips have not exceeded the expiry date.
2. Check the two Accu-Chek Performa Glucose Control Solutions are within date.
3. Check that the meter serial number matches the one in the QC log book.
4. Switch the meter on and hold the button down for a few seconds until the display shows all bars/characters. Make sure there are no

missing bars/characters as this is an indication that the meter has been damaged and will need to be replaced.

5. Once turned on the screen will display a flashing test strip symbol.
6. Remove a test strip and recap the test strip pot, insert the strip (yellow window face up) in to the meter test strip slot.
7. Make sure the code number on the meter display matches the code number on the test strip container.
8. When the display on the meter shows a drop gently mix the solution then uncap, invert and gently squeeze until a small drop appears.
9. Bring the drop to the **front edge** of the strip, making sure that the meter is level and not held with the test strip pointing upwards. Allow the drop to be drawn in until the yellow window is completely filled.
10. An hourglass will appear whilst the measurement is taking place.
11. Replace the QC bottle cap.
12. The result appears on the display, along with the control bottle symbol and flashing "L". **Do not** remove the test strip yet.
13. Press the right or left hand button until the display cycles to the appropriate level.
14. Press and release the on/off button to set the control level in the meter. "O.K." and the control result alternate on the display if the result is in range held on the code chip. Alternatively the range can be checked manually as it is printed on the test strip container label.
15. Record the result in the QC log book and remove the test strip.
16. Repeat the procedure for the Level 2 QC.
17. If the meter fails QC repeat the procedure ensuring all materials are in date and the QC is mixed. If the results are still outside limits repeat the procedure with fresh QC/test strips. If having tried the above the meter is still failing QC remove it from service and inform the local manager. The PoCT team must be contacted to arrange repair/replacement.

5.7 Running a Patient Sample

N.B. The following only covers the use of the meter and not the sample collection or clinical aspects, please refer to the relevant policies and procedures prior to undertaking the testing procedure.

1. Check that the test strips have not exceeded the expiry date, that the meter has been QC checked within the last week, **with the current test strips.**
2. Switch the meter on and hold the button down for a few seconds until the display shows all bars/characters. Make sure there are no missing bars/characters as this is an indication that the meter has been damaged and will need to be replaced.
3. Once turned on the screen will display a flashing test strip symbol.

4. Remove a test strip and recap the test strip pot, insert the strip (yellow window face up) in to the meter test strip slot.
5. Make sure the code number on the meter display matches the code number on the test strip container.
6. Obtain a drop of blood (following sample collection procedure) and bring the meter to the drop so that it meets the **front edge** of the strip, making sure that the meter is level and not held with the test strip pointing upwards. Allow the drop to be drawn in until the yellow window is completely filled.
7. When you see the hourglass flash, you have enough blood in the test strip. If you applied blood but do not see the flashing hourglass, you may reapply more, if applied within five seconds.
8. The result appears on the display.
9. Record the result and dispose of the test strip according to Trust policy.
10. Ensure the meter is clean when put away.

5.8 Changing the battery

It is important to note that when the battery is changed in the Performa Glucose Meter, the screen will flash "Set Up" at the top of the display. Press/hold down the on/off button for the meter to return to the normal display i.e. flashing test strip. If the display shows the wrong date/time please refer to the Operator's Manual to reset.

6.0 Interpretation

Reference range (fasting) 2.5 – 5.8 mmol/L

Fasting glucose levels are used in the diagnosis of diabetes mellitus (together with a glucose tolerance test if necessary).
Raised concentrations are also found in shock, phaechromocytoma, Cushing's syndrome, acromegaly, pancreatic disease, and in Wernicke's encephalopathy (Vit. B1 deficiency).
Decreased levels are most often seen in neonatal hypoglycaemia from various causes, with insulin excess e.g. over treated diabetics, pancreatic islet cell tumours, acute infections, poisons and glucogen storage disorders.

7.0 COSHH

Follow Universal Precautions when handling patient specimens as detailed by the Infection Control Manual. Handle all components and all patient samples as recommended for any potentially infectious human serum or blood specimen in the HHS Publication No. (CDC) 93-8395, Biosafety in Microbiological and Biomedical Laboratories, U.S. Government Printing Office; Washington, DC. Use supplied personal protective equipment. Wipe up spills promptly and decontaminate affected surfaces. Avoid generation of aerosols. Follow appropriate waste handling regulations applicable to your area.

See associated COSHH sheets for details of individual reagents.

http://physchem.ox.ac.uk/MSDS/

Contacts

Diabetes Specialist Nurses	2726
PoCT Team	3114