Active	**Near patient blood glucose measurement using the Roche Advantage glucose meter**		Version: 1.05
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Related Documents	
Hazard Data Sheets	N/A
Risk Assessments	N/A
Others	EQA scheme glucose meters – SOP Abbott Medisense Optium glucose meter – SOP Medical Device Alert – MDA/2007/058

The Royal Liverpool and Broadgreen University Hospitals NHS Trust

Significant changes from previous version:

- Upgrade of the meter from the Advantage II to the Advantage III
- See section describing criteria for confiscation of meters at the end of the SOP.
- Staff will be required to attend Clinical Biochemistry to make exchanges or collect spares.
- IT IS THE WARD RESPONSIBILITY TO ENSURE THE MOST RECENT VERSION OF THE SOP IS IN USE. THIS CAN BE OBTAINED FROM THE CLINICAL BIOCHEMISTRY DEPARTMENT LINK ON THE INTRANET PAGE.
- When full, QC logbooks should be returned to the lab and exchanged for a new one.

Clinical Indications

The Diabetes Control and Complications Trial (DCCT) confirmed the significant benefits of self-monitoring of blood glucose when practiced as part of a larger intensive strategy to tightly control glucose concentrations. The device used to monitor blood glucose must be reliable, accurate, fast, easy and convenient to use. The glucose meters used by patients and hospital workers are for monitoring, **not diagnosis**. These meters should only be used by staff who have been trained and are aware of the contra-indications to their use. Patients who are undergoing peritoneal dialysis using icodextrin should have their glucose levels monitored with the Abbott Medisense Optium glucose meter (see appropriate SOP).

- It is important to remember that ALL equipment of this nature could give erroneous results unless used in the appropriate manner.
- It is not only important to carry out quality control checks BUT TAKE ACTION on these when outside operational limits (page 4).
- Correct sample collection is vital, particularly where patients are receiving intravenous fluids (page 2).

- Treat the patient NOT the results especially where patients may be treated under vigorous glycaemic control protocols and the result appears to be unexpectedly high or low (page 9).

Principles of Method

The Roche Advantage method for measuring blood glucose is based on novel enzyme technology and microelectronics. When whole blood is applied to the sensor electrode (strip), electrons are produced by the conversion of glucose to gluconolactone. The electrons are transferred through a mediator, potassium ferricyanide. The resulting current of electrons is proportional to the glucose level in the blood. This dynamic process is monitored by the sensor and is translated into accurate glucose readings.

Specimen Required

Whole blood from capillary, venous or arterial samples may be used.

Collection Procedure

Wash the patient's hands, rinse and dry thoroughly. Blood should not be collected from a patient if the area cannot not be cleaned thoroughly with water first. **Do not** use alcohol-based solutions or swabs or apply analgesic creams. Prick the underside of the patient's finger using an automatic lancet device, not the central pad, and gently massage the finger to obtain a hanging drop of blood. The hanging drop of blood should be applied at the side of the target area of the electrode until the yellow area is covered. Apply a piece of sterile cotton wool with gentle pressure to the patient's finger until the bleeding stops then discard the cotton wool into a clinical waste bag. The used lancet should be disposed of in a sharps disposal bin.

Blood glucose meters should not be used for patients who have peripheral circulatory failure for example in severe dehydration, hyperglycaemic hyperosmolar state with or without ketosis, hypotension, shock, peripheral vascular disease, severe vomiting and diarrhoea. Glucose meters are also contra-indicated for patients who cannot recognize or respond to thirst sensations and in patients who have sustained uncontrolled diabetes.

Interferences

See page 17 in the operator's guide and the chart inside the workstation lid.

Haematocrit:	Low haematocrit <20%	May cause higher results
	High haematocrit >65%	May cause lower results
	Venous blood	Will give approx. 10% higher result

Other Common Drugs:	Paracetamol	May cause lower results at levels > 80 mg/l (0.53mmol/L)
	Iodoacetate	
	Xylose absorption test	
	Immunoglobulin preparation "Octagam"	
	"extraneal" dialysis fluid for CAPD contains icodextrin*	

*Patients who are undergoing peritoneal dialysis using icodextrin should have their glucose levels monitored with the Abbott Medisense Optium glucose meter (see appropriate SOP).

Endogenous substances:	Uric acid	No effect at levels up to 0.6 mmol/l
	Ascorbic acid	No effect at levels up to 690 µmol/l
	Bilirubin	No effect at levels up to 342 µmol/l
	Triglycerides	No effect at levels up to 57 mmol/l

Galactose	No effect at levels up to 0.56mmol/l
Maltose	No effect at levels up to 0.47mmol/l
Oxygen	No effect at levels up to 45kPa

Instrumentation
The instrument used is the Roche Advantage system.

Equipment
Automatic lancing device
Sterile cotton wool

Reagents
Roche Advantage II accessories can be obtained from:

Royal Liverpool Site

Roche Advantage II Electrodes	-	Pharmacy Dept (RLUH)
Replacement meters	-	Clinical Biochemistry
Technical queries	-	Clinical Biochemistry
Log Books	-	Clinical Biochemistry
Assessment diabetic patients	-	Diabetic Nurse Specialists
External Quality Assurance	-	Clinical Biochemistry
Training sessions	-	Clinical Biochemistry

Broadgreen/CTC Site

Roche Advantage II Electrodes	-	Pharmacy Dept (BGH)
Replacement meters	-	Clinical Biochemistry
Technical queries	-	Clinical Biochemistry
Log Books	-	Clinical Biochemistry
Assessment diabetic patients	-	Diabetic Nurse Specialists
External Quality Assurance	-	Clinical Biochemistry
Training sessions	-	Clinical Biochemistry

Staff will be required to go to the Clinical Biochemistry laboratory if a meter requires repair, to collect spares or to exchange a quality control record book. The old quality control record book can be stored in the laboratory OR kept in a secure location on the ward.

Standards
A calibrator is supplied with each box of electrodes, and the meter is calibrated with each new box of strips.

See page 7 of the operator guide.

In order to obtain an accurate blood glucose reading the meter must be calibrated every time a new pack of electrodes is opened. A calibrator chip (code key) is included in each pack of electrodes and this has the calibrator code printed on it. After calibration is complete, the code key must be kept in the back of the meter. Only one pack of electrodes should be open at any one time. Always ensure that the number printed on the back of the code key corresponds with the number printed on the package of electrodes.

1. Discard any code keys from previously opened boxes of electrodes and any previously used kit inserts.

2. Place the meter on a clean, flat dry surface with the display window facing upward.

3. Open a new box of electrodes and locate the code key in the newly opened box.

4. Insert the code key into the back of the meter, code facing outwards. Gently push the code key in until it stops.

5. Calibration is now complete.

Quality Control

The meter should be checked daily with both levels of quality control solutions, when a new box of electrodes is opened, if the meter is dropped or the battery changed and also if an unexpected high or low result is obtained prior to repeating the test. In low usage areas the meter should be checked weekly or prior to performing a patient blood glucose test. The control material is stored at room temperature in the workstation and is stable for 3 months after opening.
This can be obtained from the Pharmacy Dept (RLUH or BGH).

Performing a quality control test on a Roche Advantage glucose meter
See also the back of the quality control record book or pages 8,9 and 10 of the operator guide.

1. Gently shake the quality control solution and insert an electrode into the meter, ready for use.

2. Allow solution to be drawn into the yellow target area of the electrode (do not permit dropper tip to touch electrode or to draw quality control material back into the vial).

3. The meter will start automatically and count down for 25 seconds, displaying the sequence of squares

4. The quality control result will be shown.

5. Record this result in the blue and white quality control logbook with date, time, electrode and quality control lot number and the operator signature.

6. Check to see if QC result is within the range stated on the electrode pack. Repeat the QC test with the blue top bottle.

It is important a senior member of the ward staff eg. Sister or matron, reviews the QC results regularly and takes the appropriate action if the results are not within the limits.

7. If result is NOT within range CHECK:

a) Advantage meter	i)	correctly calibrated for batch of electrodes in use
	ii)	any error messages
b) Electrodes	i)	expiry date
	ii)	electrodes are not bent or damaged
c) QC solution	i)	no bubbles present
	ii)	empty/nearly empty bottle
	iii)	bottle has not been open more than 3 months

8. Repeat QC test and record results as before.

9. If the result is now within range, continue with the second QC test or patient blood glucose as appropriate.

10. If result is still outside stated range, do not use the meter and ensure no other operators can use it and contact the laboratory for further guidance. Inform the sister or charge nurse on duty the QC results were not satisfactory.

The external quality assurance material is supplied bi-monthly from WEQAS, distributed by the laboratory and the results compiled by the laboratory. The sample should be treated as a patient sample and the result obtained returned to the laboratory as soon as possible. Each ward will be informed of their performance; the laboratory will contact poor performers and wards not returning results.

When the Quality Control Log Book is full, it can be returned to the Clinical Biochemistry laboratory and exchanged for a new one. Alternatively the log book can be stored on the ward.

Method

See also the images at the back of the QC log book or page 12 and 13 of the operator's guide.

1. Wash and dry hands

2. Wash patient's hands and rinse and dry thoroughly, do not use alcohol-based solutions or swabs or apply analgesic creams.

3. Remove one electrode from the pack of electrodes and immediately replace the lid.

4. Insert the Advantage II Electrode into the meter, the metal contact bars should face upwards.

5. The meter will automatically display the code for that batch of electrodes followed by an image of an electrode at the bottom right of the screen, above which will be an image of a drop of blood.

6. Verify that the calibration code displayed matches the code printed on the pack of electrodes and recalibrate if necessary.

7. Prick the underside of the patient's finger away from the thumb using a sterile automatic lancing device and collect a hanging drop of blood in to the side of the electrode at the yellow target area. The blood will naturally be drawn into the electrode.

8. If some of the yellow target area remains exposed, further blood can be added within 15 seconds.

9. The display on the meter will start automatically and count down for 25 seconds, displaying a sequence of squares around the screen.

10. The blood glucose result will be shown in the window.

11. Apply a piece of sterile cotton wool with pressure to the patient's finger until the bleeding stops and then discard cotton wool into a clinical waste bag.

12. Discard the lancing device into a sharps box.

13. Remove the electrode from the meter and discard into a clinical waste bag.

14. Any accidental blood contamination of equipment or surfaces must be wiped immediately using damp tissue and then an alcohol impregnated wipe if necessary.

15. Restock workstation if required.

Calculations
N/A

Reporting of Results
All results are displayed in mmol/l. The results must be documented directly in patient's case notes or the blood glucose monitoring record sheet with the nurse's name, title and the time of the test and the appropriate action taken if any.

Turnaround Time
All samples should be analyzed immediately.

Assay Characteristics
Linearity 0.5 to 33.3mmol/L

Precision, liquid QC:	3.0 mmol/l	= 3.8 CV %
	17.2 mmol/l	= 1.6 CV %
Patient samples	1.4 mmol/L	= 4.1 CV %
	22.7 mmol/L	= 3.4 CV %

A high or low result should be confirmed on a venous sample analysed in the laboratory.

Reference Range
Whole blood glucose concentrations can be 10 to 15% lower than the corresponding plasma glucose depending on the haematocrit of the sample. These devices are intended to be used only for monitoring glucose concentration, not diagnosis and therefore a reference range is not applicable.

Additional Information
Changing battery for the Roche Advantage meter
See also page 16 of the operator guide

One round 3V alkaline battery is required to power the meter. This will last approximately 1000 tests, depending on whether the meter has been immediately switched off after use.

1. Remove the old battery from the back of the meter by sliding out the battery cover

2. Replace the battery noting carefully the positive contacts should be uppermost.

3. Replace the sliding cover and wait 5 seconds before switching on the meter for use.

Cleaning the Roche Advantage meter
See also page 15 of the operators guide.

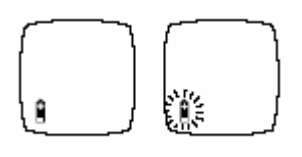
Cleaning of the insertion slot is not necessary because blood and test solution should not enter the meter. However, if the outside of the meter needs to be cleaned, use a moistened cloth or sponge with a mild detergent solution.

Display messages

See also pages 18 and 19 in the operator guide and the instructions at the back of the QC logbook.

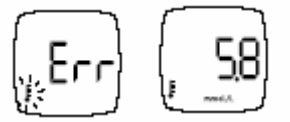
Various messages may appear in the meter display window. These messages are listed below along with an explanation of each message and the action required, if any.

General messages



ACTION – change battery, call Clinical Biochemistry for replacement

System check failure. Testing cannot take place. ACTION – phone Clinical Biochemistry



Operating temperature <14 or >40°C. The result may not be accurate.
ACTION – move to a cooler or warmer area. Wait 5 minutes then repeat the test.

Testing messages

Insufficient sample applied. ACTION – repeat the test with a new electrode

Faulty electrode or sample too small. ACTION – repeat the test with a new electrode

Calibration messages

The code key has not been inserted. ACTION – insert the code key at the back of the meter

The code key has been removed during use or is faulty. ACTION – replace the code key with one for the correct electrodes.

Test result messages

Result less than 0.56mmol/L. ACTION – send a venous sample to the lab and inform the medical staff

Result is greater than 33.3mmol/L. ACTION – send a venous sample to the lab and inform the medical staff

The result is very much >33.3mmol/L. ACTION - send a venous sample to the lab and inform the medical staff

References

1. Guidelines for the Implementation of Near Patient Testing. *The Association of Clinical Biochemists.* September 1993 ACB Administrative Office, 2 Carlton House Terrace, London SW1Y 5AF.

2. Marks, V. Essential considerations in the provision of near-patient testing facilities. *Ann Clin Biochem,* 1988: 25, 220-25.

3. Extra-Laboratory Use Of Blood Glucose Meters and Test Strips: Contraindications, Training and Advice To The Users. *MDA Safety Notice 1996*

4. Blood Glucose Measurements: The Need for Reliability of Results Produced in Extra-Laboratory Areas. *NHS Hazard Notice 1989*

5. Near Patient Testing: Welsh Scientific Advisory Committee (Welsh Office) 1995.

Clinical Interpretation

Recent studies have shown that the use of self-monitoring devices by diabetic patients to achieve a tighter control of their glycaemic status can help to reduce the onset of retinopathy, nephropathy and neuropathy. However these monitoring devices should only be used by staff who are adequately trained and this training should be documented. The use of blood glucose meters by staff who are untrained may lead to misleading results which may adversely affect patient treatment. A safety notice has been issued by the Medical Devices Agency (MDA/2003/011) and can be found, on their website (www.devices.mhra.gov.uk). All staff using blood glucose meters must be aware of this document.

Blood glucose results below 3 mmol/l or above 15 mmol/l should be reported to the patient's Doctor unless otherwise instructed by the medical team.

If the reading is unexpectedly High or Low, a quality control test should be performed to check the performance of the meter. If this is satisfactorily, the patient test should be repeated and if confirmed then the medical staff informed.

Criteria for the Confiscation of Meters

- If a meter has been found to be used inappropriately during an audit or spot check on the ward or as a result of the reporting of an adverse incident the meter(s) will be removed from that location immediately, pending investigation of the incident.
- If the frequency of ward quality control is inappropriate for the frequency of use or the meter(s) or the workstation is found broken and contaminated with used strips, the ward will be verbally notified that performance must be improved and given 1 week notice to comply before confiscation. This warning will be confirmed in writing and copied to the Ward Manager, Sister present at the time of the incident, Matron Risk Management, the Point of Care Testing Committee and the Director of Nursing.
- If the ward does not return results for the laboratory external assessment (EQA) scheme for 3 consecutive distributions, the use of the meter will be reviewed on the ward and appropriate action may include confiscation of the meter.