Use of the Roche Accu-Chek Performa

for

Glucose Analysis

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Changes from last version of this document

First entry

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1 Purpose and Principle

The Roche Accu-Chek Performa system is intended for diagnostic use in the quantitative determination of blood glucose levels in venous, capillary, arterial and neonatal whole blood samples. It can be used by any healthcare professional to monitor glucose levels in any clinical setting providing they have completed the required training. The test strip is impregnated with a modified glucose dehydrogenase enzyme which converts glucose into gluconolactone. This reaction creates an electrical current which the meter converts to a blood glucose result. The sample and environmental conditions are also evaluated using a small AC current

2 Patient Preparation & Sample Requirements

- Patient hands MUST be cleaned prior to lancing. DO NOT use alcohol-based products as this interferes with the strip function.
  - 0.6uL of fresh capillary, venous or arterial blood
  - Heparin (sodium/lithium) anticoagulated venous samples can also be used
  - All human blood samples must be treated as potentially BIO-HAZARDOUS.
  - Approved Personal Protective Equipment (PPE) including lab coats, gloves and eye-protection must be worn when handling open blood samples or derivatives thereof.

	When performed according to the protocol detailed in this SOP, and in conjunction with adherence to Trust Policies and Good Laboratory Practice, the handling of patient samples represents minimal risk to staff.

Exposure to Bio-Hazardous Material

In the event of a needle stick injury or accidental blood splashes to eyes or mouth:

- If skin has been punctured encourage bleeding by gently squeezing. Wash with soap and running warm water then dry and dress the wound.
- Splashes to the eyes: irrigate eyes thoroughly with eye wash / saline.
- Splashes to the mouth: gargle with drinking water (avoid swallowing)

Contact the Occupational Health Department / Emergency Department for guidance and report all adverse incidents to your line manager / complete a DATIX form.

Disposal of Patient Samples

Ensure compliance with the Laboratory Medicine Policy for the Retention, Storage and Disposal of Laboratory Samples.

3 Tasks, Responsibilities and Authorisations

- These procedures must only be carried out by staff who have received documented training on the use of the Performa analyser. Training is documented in Cobas Infinity
- All tasks should be performed under supervision of trained, competent colleague until staff member has passed competency and feels competent to perform tasks alone.

Tasks	Responsible	Authorised
Patient testing	Clinical staff who have received POCT training as above	Trained member of POCT staff or certified POCT link trainer
Maintenance tasks	POCT staff who have received training	Trained member of POCT staff

4 Equipment

- Roche Performa meter
- Single use finger prick lancets
- For issues and support contact:

• Community POCT	• 01904 725294 (ext 772 5294)
• York POCT	• 772 5890

- Please provide the following information:
- Serial number of the meter
- Location of the meter
- Name of the meter owner
- Description of the error

5 Chemicals and Reagents

- Roche Performa meter
- Single use finger prick lancets
- For issues and support contact:

Community POCT	01904 725294 (ext 772 5294)
York POCT	772 5890
Scarborough POCT	771 2659

Please provide the following information:

- Serial number of the meter
- Location of the meter
- Name of the meter owner
- Description of the error

6 Risk Assessment (Environmental and Safety Controls)

Staff carrying out this procedure should have read and understood the Local Rules or Health and Safety Manual applicable to their site which should be followed at all times during the procedure.

- All human samples must be treated as potentially BIO-HAZARDOUS.
- Approved Personal Protective Equipment (PPE) including laboratory coats, disposable gloves must be worn. Eye protection should also be considered and must be worn when directed within the procedure.

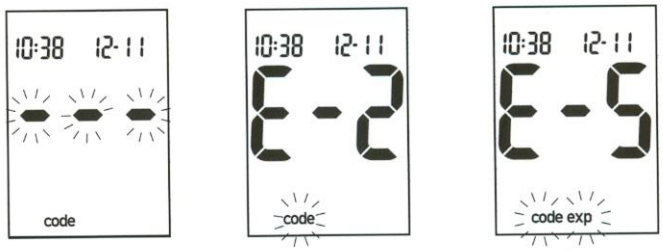
For full risk assessment see PC/RA/YS-13

This SOP and the associated risk assessment(s) have considered all hazards and necessary precautions required to control any risks identified. Where appropriate this is detailed in the COSHH assessment and Risk Assessment. Any risk; where possible is mitigated and or monitored with health surveillance to ensure health and safety for all those affected by this procedure

7 Calibration

The test method is referenced to the hexokinase method and is traceable to the NIST standard.

A Calibration must be carried out before you use a new meter and every time you open a new box of test strips and when the error codes below are displayed.



- Make sure the meter is turned off.
- Turn the meter over so that you are looking at the back.
- Remove the old code key from the right-hand side of the meter and discard.
- Insert the new code key until snaps into place.

- Turn on the meter. A 3-digit code number will appear. This code must always match the code number on the 'key code' and the 'CODE' printed on the side of the container of test strips.
- Ensure that the clock in the meter has been set to the correct time and date. To do this press and hold the on/off button until **set up** flashes. Using the arrow keys you can then select the correct hour, followed by the on/off button again. Repeat procedure for minutes & date and press on/off to confirm.

8 Quality Control

- Internal Quality Control (QC): Two levels of QC solution must be performed once a week and in addition on every day the meter is used to analyse a patient blood sample.

How to measure quality control

1. Insert a test strip into the meter (the meter should automatically turn on)
2. The code number displayed MUST match the code number on the pot of test strips.
3. Pick up the first control to measure (there is Level 1 and Level 2, they can be run in any order)
4. Mix the bottle gently, remove the cap and wipe the tip of the bottle. Squeeze the bottle gently until a drop forms on the tip and touch this to the front edge of the test strip. Replace the cap on the bottle.
5. A result will appear on the display along with a control bottle symbol and a flashing 'L-'at the top of the screen. Press the right-hand arrow button once for level one 'L1' and twice for level two 'L2'. Press the button on the top right-hand side of the meter (power button) to confirm and to commit the result to the meters memory.

6. 'OK' and the result flash alternately on the display if the result has passed.
7. 'ERR' will appear if the result has failed. CHECK:
    - The QC material is in date and well mixed.
    - Retry if with new QC material.
    - Retry using a new pot of strips.
    - Contact the point of care team as detailed in section 3 if it fails again and quarantine the meter.
8. The QC MUST be recorded in the QC logbook for the meter, ensuring the lot numbers are recorded and the entry is signed.

9 External Quality Assurance (EQA)

External Quality Assurance (EQA): All meters are enrolled in the WEQAS EQA scheme. Every 3 months POCT will distribute EQA samples with instruction letters to each of the Community Hub Admin Teams. The admin teams will, in turn, distribute the EQA to each member of staff assigned the use of a Performa meter, please follow the instructions set out in the accompanying letter and return EQA results **promptly.**

EQA reports are monitored by the POCT coordinator and discussed at the POCT committee meetings.

10 Procedural Steps

Analysing Patient Capillary Samples

1. The test may be requested verbally by qualified members of staff, clinicians or via documented protocols. Please document the source.
2. Protective gloves must be always worn.
3. Take the workstation and glucose meter to the patients' bed side.
4. Positively identify your patient (name, DOB and NHS number)
5. Explain the procedure to gain verbal consent.
6. Ask patient which finger they would like the sample taken from. If they show no preference please use the middle, ring or small finger.
7. Clean the patients' hands or finger prior to testing. DO NOT USE ALCOHOL WIPES OR GEL.
9. Insert the test strip into the bottom of the Performa meter as far as it will go, with the lettering facing upwards. The code number displayed MUST match the code number on the pot of test strips. A drop symbol will appear on the display to show it is ready for the blood sample. Remember to close the pot of strips.

8. With the single use lancet, puncture the chosen finger on the side of the pad no lower than the nail bed. Draw a small drop of blood for use on the test strip. If no blood is visible milk the finger from the heel on the hand downwards.
9. Give the patient a clean swab for the puncture site when test is complete.
10. The result is available after 5 seconds. Please ensure the result is documented in the patients records and escalated if required.
11. All waste materials should be disposed of in accordance with local guidelines.

11 Reporting of Results

Results outside the range (<4.0->16 mmol/L) for patients in secondary care should be escalated immediately to medical staff in charge of the patient. In community results outside the patients agreed target range (recorded on the patient's insulin prescription chart) should be escalated to the case manager /GP.

All results are obtained in mmol/L. The meter can analyze glucose levels between 0.6mmol/L and 33.3mmol/L. Results less than 0.6mmol/L display **LO** at results screen. Results above 33.3mmol/L display **HI** at results screen. Results should be documented in the patients' notes.

12 Reference Intervals

- Fasting glucose: 2.5- 6.0mmol/L (taken from the WHO guidelines).
- Critical Alert: < 4.0mmol/L, > 16.0mmol/L. Please escalate your patient immediately. (Limits set by diabetes specialist team).
- Hypoglycaemia: < 4.0 mmol/L. Patient should be treated as per the Hypoglycaemia protocol and retested following treatment (protocol written by diabetes specialist team and available on the Trust Intranet).

13 Performance Characteristics

Precision and Detection Limits

- Inter batch precision.

	Low	Medium	High
Roche Mean	2.03	11.19	19.09
SD	0.14	0.36	0.49
CV	6.98	3.24	2.55
York mean (n=20)	2.47		16.48
SD	0.17		0.56
CV	6.80		3.4

- Intra batch precision

	Low	High
Roche Mean	2.75	17.30
SD	0.07	0.14
CV	2.57	0.82
York Mean(n=20)	2.47	16.7
SD	0.08	0.33
CV	3.0	2.0

- Assay detection limit.

The lowest value displayed is 0.6mmol/L. The measurement range is 0.6-33.3 mmol/L

14 Known Limitations

Common interfering substances known to cause over estimation of POC blood glucose are:

- Intravenous administration of **N-acetylcysteine**. Do not use Accu-Check meters during intravenous infusion of N-acetylcysteine.
- Blood Galactose in excess of 0.83 mmol/L
- Triglycerides in excess of 20.3 mmol/L
- Intravenous administration of ascorbic acid which results in blood concentrations in excess of 0.17 mmol/L

The meter should not be used with capillary samples on patients with compromised peripheral circulation as the results will not reflect the true physiological blood glucose level. This may apply in the following conditions:

- Severe dehydration
- Diabetic ketoacidosis
- Severe hypotension
- Severe shock

In these occasions you may use venous or arterial blood on the meter.

The meter should only be used on patients with a haematocrit between 10% and 65%.

The system is approved for use with neonatal blood but caution is advised in the interpretation of glucose values below 2.8mmol/L.

15 Related Forms/Templates and Documents

- Risk Assessment PC/RA/YS-13
- Operator Manual PC/ED/YS-5

16 References

- Accu-Chek Performa operator's manual
- Accu-Chek Performa test strip insert.
- Method evaluation stored in Q-Pulse under file name PC-EVA-ROCHE
- MSDS safety sheets can be found on the Roche web site www.cobas-roche.co.uk