T Level Technical Qualification in Healthcare Science

Occupational specialism assessment (OSA)

Assisting with Healthcare Science

Assignment 2 - Standard operating procedures

Assignment brief insert

v1.1: Additional sample material
21 November 2023
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Contents

1 Samples, reagents and equipment

1.1 Specimen requirements

The analyser has been validated for use with 2 types of whole blood samples:

- capillary finger prick
- venous sample collected into an EDTA container

Serum and plasma samples are not suitable for use.

The minimum sample volume required is [insert volume, for example, 0.6µL].

The device is used for several clinical functions:

- by community nurses to measure glucose of patients with diabetes in the community who are on insulin
- by community staff **to investigate whether further testing is required** for someone showing symptoms of diabetes who is not diagnosed as diabetic
- by community dentists to measure glucose of patients with diabetes in the community
- by hospital staff running outreach and outpatient clinics
- by diabetes research nurses
- by any community staff to investigate a potential diabetic related emergency

A capillary sample must be collected from a clean site; the patient's hands should be washed with warm water where possible or wiped with cotton wool soaked in warm water and then dried. Soap and alcohol wipes must not be used as they can lead to erroneous results.

1.2 Reagents and equipment

The glucose meters are acquired as part of a block contract and only the one issued by your hospital should be used. Internal quality control (iQC) and bimonthly external quality assessment (EQA) materials are also provided. The consumables are available at an extremely competitive price and the cost of the box of strips covers the provision of the full support service provided, including training, meters, record books and quality control (QC). The devices have been evaluated and approved for use by the POCT team based in pathology.

Important: no other glucose/ketone devices are approved for use by staff.

All reagents and control solutions are CE marked and are ordered and distributed by pharmacy stores.

Important: strips should only be ordered through pharmacy stores and not through any other method (such as using the patient's own prescription) as this will lead to the hospital paying a higher price or the wrong strips being purchased.

- the glucose meter approved for use is the [insert name of device]

[insert picture of the device here]

- [insert name or type of strips] strips are available from pharmacy stores by using the electronic ordering system

[insert picture of the box of strips here]

The [insert name or type] **glucose** test strips contain the following reagents:

- [insert name or type]
- [insert name or type]
- [insert name or type]
- [insert name or type]

These should be stored between [insert temperature range] ºC.

Important: meters and strips should not be left in areas of extreme temperatures overnight.

- iQC solutions are available from pharmacy stores by using the electronic ordering system. These are free of charge and need to be replenished [insert number] days after opening or by the expiry date on the bottle, whichever comes first
- meters (including replacement meters), QC record books and transport bags are available from the POCT team based in pathology
- lancets are available from supplies/NHS supply chain. The lancets recommended for use are the single use [insert name or type]. Please do not use the patient's own lancing device as it can lead to a potential infection risk for the healthcare worker

1.3 Calibrants

[Delete this section if the meter does not require calibration]

There is a calibrator stick in each new box of glucose strips. The calibrator for the glucose strips is white. The calibrator codes the meter to the lot number of strips which are being used, enabling more accurate results to be obtained. The calibrator stick must be used:

- when a meter is being used for the first time
- when a new box of strips is opened
- if the user is concerned about the accuracy of the results. The calibrator stick should be inserted and the test repeated

1.4 Internal quality control materials

The internal quality control (iQC) material which is used on the glucose meter is called [insert name of meter].

There is a low and a high level solution which are used to check that the meter is performing as expected at the critical decision points.

Glucose iQC solutions ingredients:

Low: glucose	[name or type]	w/v
Non-reactive ingredients	[name or type]	w/v
High: glucose	[name or type]	w/v
Non-reactive ingredients	[name or type]	w/v

Any unused solution after the expiration date should be discarded. Solutions can be stored between [x] and [x] ºC. The solutions should be allowed to reach room temperature before they are tested.

The iQC material should be kept along with the glucose meter at all times. The low and high control solutions should be analysed, checked against the acceptable ranges (which can be found [state location, for example, on the kit insert within the strip box]) and recorded in the quality control record book weekly for glucose strips.

1.5 External quality assessment

Many of the meters are registered in a UKAS registered external quality assessment (EQA) scheme. The laboratory is responsible for the receipt, distribution and the electronic recording of these results. The interpretation of the EQA results is the laboratory's responsibility and erroneous results must be investigated. Trained users of each meter are responsible for analysing the EQA samples in a timely manner, in the same way as they would a patient sample, and returning the results to the POCT department.

All users have a responsibility for ensuring that they analyse the EQA samples and return the results as soon as possible after they receive them.

2 Method

2.1 Maintenance

There is no regular maintenance required for this meter but the user has a responsibility for ensuring the following:

- the meter is kept in a clean, infection-free condition – mild detergent/soap and water or 70% isopropyl alcohol can be used to clean the exterior of the meter
- replacement batteries can be sought from the POCT team
- the meter should be stored and transported in the appropriate carry case – these are provided by the POCT team with the issue of the meter
- **important:** the meter should not be placed in extreme cold or hot temperatures overnight or for any significant length of time
- users will be liable for the cost of a replacement if the meter is broken through neglect

2.2 Analysis of patient samples

2.2.1 Examination procedure-sample collection

Patient samples

Only trained operators are authorised to use the device. Training from a named cascade trainer or the POCT team should be sought if access is needed.

The glucose measurement is performed at the point of care (next to the patient) and the results are input directly into the patient notes. As there is no request form or sample sent to the laboratory, all pre-examination checks must be performed by the operator. In order to ensure patient safety and conform with UKAS requirements, the following procedure must be adhered to:

- check in the meter quality control (QC) record book that the meter has had a valid QC performed within the last 7 days and that the strip lot to be used matches that in the QC record book
- if there is not a valid QC record from the previous 7 days, then this should be performed before the patient test and recorded in the record book
- ensure patient notes are available
- verbally check with the patient their ID against the notes. A minimum of 3 points of ID are required and should include name and date of birth
- obtain permission from the patient to perform the test
- ensure the date is input along with the result in the patient notes
- ask the patient whether or not they are fasting

Important: the user should ask the patient to verify their name and date of birth and gain permission to perform the test. If an incorrect patient is bled, then the result should still be reported (not rejected) for **that** patient in **their** notes.

Sample collection

The patient should be asked if they have a preference for which finger is used. Ideally, one of the last 3 digits should be used. Avoid using the thumb and forefinger as this can lead to some discomfort afterwards.

The finger should be cleaned with a cotton wool ball and warm water and dried. Isopropanol (alcohol) wipes must not be used as these can interfere with the test results.

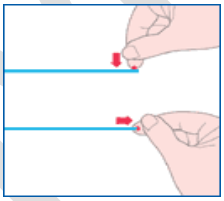
A single use lancing device is used to draw blood and the hand should be placed facing the ground to allow blood to flow. The finger should not be squeezed on the pad which has been punctured as this will lead to dilution of the blood sample and erroneous results. If there is an insufficient quantity of blood, then the patient's hand should be squeezed gently from the palm towards the tip of the finger. Avoid 'milking' the puncture site as this can lead to falsely low results being generated. The meters only require a pinprick of blood.

Used sharps should be disposed of in the sharps bin.

Gloves should be worn by the user.

2.2.2 Examination procedure-sample analysis (patient, EDTA or EQA sample)

- remove the test strip from its package and insert into the strip port with the 3 black lines. The meter will turn on automatically [state relevant additional information, for example, the time, month and day will appear along with the lot number for the box of test strips]. Check that the lot number matches the number on the test strip box and that the date and time displayed are correct
- following the steps above in **sample collection**, a blood sample should be obtained and immediately applied to the test strip
- the blood drop should be touched to [state location, for example, the white area on the end of the strip]



- continue to touch the blood to the end of the strip until the meter starts the test
- the result should then be displayed

Abnormal results

Glucose

The meter displays the results in mmol/L and will display results between [state the values in mmol/L].

Important: patients with **type 1 diabetes** should have their ketones checked if a glucose result of >15.0mmol/L is reported.

2.2.3 Post-examination procedures

- report the displayed result in the patient notes under today's date – there should be a record of who has performed this test as well

- the type of sample must be recorded to distinguish that the result is from a POCT meter and not a laboratory result which is reported as plasma glucose
- it is the responsibility of the operator to ensure that the result reported is a valid result and lies within the reporting limits of the meter
- the result is stored in the meter's memory but as there is no facility for storage of patient details, it is unsafe to recall results from the meter at a later date – the meter should be turned off and the strip disposed of in the patient's sharps bin or a sharps bin at the site of testing

3 Results

Patient results generated from the devices are shown on the display and are stored in the memory of the meter. However, it is unsafe to recall results from the memory as there is no function to record the patient details needed to correctly/safely identify which patient the results belong to. The results must be transcribed into the patient's notes immediately after the test in a way which identifies it as a **POCT glucose result** (as opposed to a lab generated result).

If the patient's results appear to be inconsistent with the physical symptoms, there may be a problem with the test strip or sampling technique. Rule out common errors in technique and repeat the test using a new test strip before making any changes to the diabetes medication plans. If, for any reason, the accuracy of the result is in doubt, do not make any changes to the patient's clinical management based on the test result alone.

Document information

The T Level Technical Qualification is a qualification approved and managed by the Institute for Apprenticeships and Technical Education. NCFE is currently authorised by the Institute to develop and deliver the T Level Technical Qualification in Healthcare Science.

Owner: Head of Assessment Design

Change History Record

Version	Description of change	Approval	Date of issue
v1.0	Additional sample material		01 September 2023
v1.1	Sample added as a watermark	November 2023	21 November 2023