T-LEVELS | Institute for Apprenticeships & Technical Education

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: Specimen assessment materials
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Assignment 2

Standard operating procedures

Contents

1 Introduction: glucose testing using the [insert name of device] meter

1.1. Purpose and clinical relevance

The glucose meter is approved for use by healthcare professionals to monitor the glucose (blood sugar) levels of patients with diabetes. In the clinical setting, glucose meters can lead to improved diabetic patient care by providing timely, accurate, cost effective glucose results and can contribute to greater patient involvement in the management of their diabetes. The meters are used by professional staff who work in the hospital. They are not accurate enough and therefore are not approved for the diagnosis of patients with diabetes. If diabetes is suspected, a venous sample should be sent to the laboratory for diagnosis.

1.2 Principle of method

Glucose in the patient's blood reacts with the chemicals on the test strips and an electric current is produced which is measured by the meter. This electric current is directly proportional to the concentration of glucose in the patient's blood. The method employed is:

Glucose strips: **[glucose dehydrogenase/glucose oxidase** (delete as appropriate or insert correct enzyme method found on glucose strip kit inset)**]**

1.3 Responsibility

- it is the responsibility of the pharmacy to maintain stocks of blood glucose test strips
- glucose control solutions can be collected from the pharmacy department when needed
- it is the responsibility of the user to ensure they understand and comply with this standard operating procedure (SOP) at all times and to uphold their competency in the use of this device

1.4 References

[Add title of user manual and strip insert]

1.5 Definitions

QC/iQC	quality control/internal quality control
EQA	external quality assessment
POCT	point of care testing

1.6 Implementation

1.6.1 Training

- all staff performing this procedure should be trained and have their competency recorded
- 2 years after initial training (and every 2 years thereafter), users will be required to complete the competency assessment. The user will be asked to perform a practical test and complete either the e-learning programme or the paper questionnaire to demonstrate competency to the cascade trainer. The paper competency assessment can be found on the hospital intranet. Once practical and theoretical competency has been demonstrated, then the completed record sheet should be either faxed or emailed to the POCT department for record keeping
- training records and competency records will be periodically checked by horizontal audit, carried out by a qualified auditor from the POCT department
- the POCT team are entitled to remove a meter from any member of staff who cannot demonstrate in date training/competency or who misuses the device

1.6.2 Staff affected by this document

All users of the glucose meter.

1.6.3 Publication and distribution

The document is held in paper record with the device, on the intranet and electronically on Q pulse, and can be accessed by all pathology staff.

Distribution: the document is distributed to all POCT staff electronically and is read and acknowledged electronically by those staff on the distribution list.

The latest version of this document is available to all clinical staff on the intranet site electronically.

2 Samples, reagents and equipment

2.1 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.

2.2 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

2.3 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

2.4 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.

2.5 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.

3 Method

3.1 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

3.2 Analysis of patient samples

3.2.1 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.

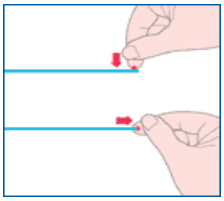
A single use lancing device is used to draw blood and the hand should be placed facing the ground to allow blood to flow. The finger should not be squeezed on the pad which has been punctured as this will lead to dilution of the blood sample and erroneous results. If there is an insufficient quantity 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.

3.2.2 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.

3.2.3 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

3.3 Internal quality control (iQC) procedures

Quality control (QC) solutions are only stable for [state number of days] days from opening. QC bottles must be discarded once the expiration date has passed.

Do not use QC material which has expired; fresh QC can be obtained free of charge from pharmacy stores.

1. your hands should be clean before performing this test
2. wear gloves
3. remove the test strip from its package and insert into the strip port with the [insert result indicator, for example, 3 black lines]. The meter will turn on automatically. The time, month and day will appear along with the lot number for the box of test strips
4. invert the low quality control bottle several times to mix the contents
5. release the cap and apply the low solution to the test area of the strip. Continue to touch the solution to the strip until the countdown starts
6. the result will be displayed in the window. The result should be checked against the acceptable ranges **and recorded in the QC record book kept with the meter.** If the QC result is outside the acceptable range, the meter should be recalibrated using the calibration stick inside the box of strips (if appropriate) and the test repeated. If it still fails, then test a new box of strips with fresh QC. If the QC continues to fail when using fresh QC, then the POCT department should be contacted

   Important: under no circumstances use a meter that fails the QC checks. The POCT department will issue a new meter.
7. the meter should be turned off and the strip discarded in a sharps bin
8. the test should be repeated with the high iQC and the results checked (as for low QC) and recorded as appropriate. **The QC check must be performed once a week regardless of how often the meter is used**

4 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

4.1 Reporting limits/reference intervals/critical values

Analyte measuring range

The measurable range is the range of values which the system is capable of reporting.

Analyte	Units	Accurate measuring range	Measurable range
Glucose	mmol/L	[range]	[range]
Ketone	mmol/L	[range]	[range]

The accurate measuring range is the range across which the meter provides results which the POCT team consider are accurate enough to action. Glucose results that are >20.0mmol/L should be checked with a venous laboratory result as they can be unreliable.

4.2 Limitations of the examination

Particular care should be taken with patients who are extremely unwell, particularly if they are:

- severely dehydrated
- severely hypotensive or in shock
- in a hyperglycaemic hyperosmolar state, for example, diabetic ketoacidosis (DKA)

Important: in these cases, the glucose meter should be used with care and it may be appropriate to send a venous sample to the laboratory for glucose analysis. Use of the meter in these situations can be dangerous and may lead to the generation of erroneous results.

Only trained personnel are permitted to use the device and access is restricted to those that have been trained and passed competency to ensure compliance with the manufacturer's, MHRA and UKAS standards.

The meters should be used for monitoring blood glucose in patients with diabetes and not for diagnostic purposes; for this purpose, a laboratory result must be sought.

The glucose meter and glucose strips are designed for the analysis of fresh whole blood. Serum or plasma samples must not be used.

Haematocrit range is [insert range] for glucose measurements. Care should be taken when using the meters to test patients with a high or low haematocrit and if there is any doubt regarding the results, then a venous sample should be sent to the lab.

The test strips have been evaluated with neonatal blood. As a matter of good clinical practice, caution is advised in the interpretation of neonatal glucose values below 2.8mmol/L.

The glucose meter gives ‘plasma calibrated’ results to reduce the discrepancy in results usually seen between whole blood POCT devices and results reported by the pathology laboratory. Some discrepancy may be observed from the true result in patients with a low haematocrit (possibility of falsely elevated result) or high haematocrit (possibility of falsely reduced result).

5 Responsibilities

5.1 Operator

- only trained users are permitted to use the devices and any user found to be using the device without in date competency will have the meter removed
- it is the user's responsibility to complete the competency assessment every 2 years and return the paperwork to the POCT department for record keeping
- all users have a responsibility for ensuring that patient results are recorded accurately and completely
- all users have a responsibility for ensuring that the device is looked after and kept in good working order. Quality control (QC) must be performed and recorded as per this standard operating procedure (SOP)
- the operator must ensure that they use the results generated in accordance with any specific clinical guidance issued by their organisation
- cascade trainers are responsible for cascading any training on to new users and ensuring users of the device are competent
- cascade trainers are responsible for liaising with the POCT team regarding general issues and non-compliance

5.2 POCT team

- managing the block contract
- liaising with pharmacy regarding consumable supplies
- acceptance testing stocks of reagents before general issue
- maintaining up to date records of equipment
- maintaining up to date records of trained staff
- acting upon any MHRA alerts which may affect these meters
- providing regular training sessions for cascade trainers
- ensuring the documentation which supports the testing is regularly reviewed and updated, also making sure that this information is accessible and available
- informing users of any changes which may affect reporting/results
- issuing newly trained users with meters which have been acceptance tested
- auditing the service to ensure quality procedures are upheld

5.3 Clinical team leaders

- ensuring that reliable staff members are nominated to be cascade trainers
- ensuring all clinical staff use the meters appropriately
- ensuring any concerns are reported back to the POCT team
- ensuring all guidance is followed

5.4 Performance criteria

A method comparison has been performed, comparing results from these meters with the laboratory method; the conclusions from this comparison are available on the asset register or by contacting the POCT team.

5.5 Hazards and safety precautions

- all blood samples have the potential to contain blood borne viruses and therefore gloves should be worn whilst handling open samples or QC, or when bleeding patients. Any contaminated sharps and strips must be disposed of in a sharps bin. Small blood or QC spillages in clinic areas should be dealt with according to local protocols laid down within that area
- the meters should be cleaned with an alcohol wipe if they become contaminated with blood or QC material. If any chemical has come in contact with the skin, wash off with water

5.6 Service provision

- the POCT team offer this service routinely Monday to Friday during normal laboratory/clinic hours. The POCT team are responsible for in house training of cascade trainers
- issue of new devices and replacement devices is done by the POCT team. Any device which is broken through neglect will not be replaced under the block contract and the user may be liable for the cost of the replacement
- the user is responsible for ensuring the correct operation of the meter, recording QC results and carrying out corrective actions as appropriate. They are also responsible for analysing patient samples according to the SOP
- all users must have training and this training must be in date
- users are also responsible for ensuring that the equipment is kept free of infection risk and is in good working order. Any problems which cannot be dealt with by the user should be reported to the POCT department or their cascade trainer as soon as possible

6 Uncertainty

The factors listed below are in place to minimise uncertainty and control this procedure:

	Factors	What control measures are in place	Evidence
Physical	Sample collection	Samples collected by trained nursing staff as detailed in section 1.6.1	Training records
	Volume	Very small sample volume required Finger prick test	Not applicable
Reagents/ components	Lot no. of consumables	Lot no. of strip recorded in QC recording books as detailed in section 2.4	Paper record books on wards
	Storage	Strips and QC solutions stored at room temperature once opened The receipt and distribution of these is controlled by the pharmacy dept	Section 2 of this SOP
	Expiry	Expiry date of strips and QC solutions should be checked as outlined in section 2.4	Not applicable
Procedure	Training	POCT staff train cascade trainers to standard as laid out in device specific training instruction	Training records
		Biennial competency checks of users	Competency records
		POCT staff/cascade trainers must be signed off as competent to perform this procedure	Competency records
Instrumentation	Failure	Devices provided free of charge with pharmacy contract for strips Replacement of faulty devices is carried out by the POCT team – contract covers this	Section 5 of this SOP
System or processes	Documentation	Documentation reviewed as stated in this SOP	Section 1.2 of this SOP
Analyst	Human error	Used by trained staff only	Training records
Measurement data	Internal QC data	Commercial assayed QC used CV data used as measure of uncertainty	Recorded in paper record files and saved as detailed below
	External QA results	Quarterly EQA scheme participation and results reported at POCT committee meetings and pathology Quality meetings Devices replaced if EQA issues arise	Data saved on electronic spreadsheet Minutes of meetings

Further information on uncertainty values can be found on the asset register in the POCT department and is available on request.

Document information

The T Level Technical Qualification is a qualification approved and managed by the Institute for Apprenticeships and Technical Education.

Owner: Head of Assessment Design

Change History Record

Version	Description of change	Approval	Date of Issue
v1.0	Post approval, updated for publication.		January 2021
v1.1	NCFE rebrand		September 2021