STANDARD OPERATING PROCEDURE SOP/POCT/57/3

Title: Abbott AFINION 2 Analyser for HbA1c Effective date: 28/07/2023

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Summary of Significant Changes at this Revision

- Change the qpulse reference number of the external documents from MAN/7 to EXT/POCT/5
- Cleaning of the analyser to be recorded on the quality control log in the column provided

Purpose and Scope

The Abbott AFINION 2 is a portable analyser used for quantitative *in vitro* determination of HbA1c in whole blood.
This standard operating procedure (SOP) explains the protocol for monitoring blood HbA1c concentrations. This relates to the users' responsibility in monitoring HbA1c and ensuring the quality of results, in addition to how the analyser is used. These procedures must be followed to protect the interests of staff and the welfare of the patient.

Items Required

Abbott AFINION 2 analyser
Afinion Test cartridges for HbA1c (includes sampling device)
Afinion HbA1c Quality Control Kit
Afinion Cleaning Kit
Standard blood collection equipment

Definitions and Abbreviations

QC	Quality Control
EQA	External Quality Assurance
IFCC	International Federation of Clinical Chemistry
cITm	Cobas IT Middleware
HbA1c	glycated haemoglobin, haemoglobin A1c
min	minute
ID	identifier
Max	maximum
SOP	standard operating procedure
Hb	haemoglobin
NEQAS	National External Quality Assurance Scheme

Grade / Qualifications

All grades of healthcare staff who successfully completed the required competency

Competencies Required
Current Version of: FM/POCT/COMP/4

Risk Assessment:
Current Version of: QMS/RA/POCT/8

Safety Precautions for This Procedure:
Refer to Risk assessment RA/POCT/8 found on the POCT intranet page

Contents

1. Clinical Relevance/Purpose and Limitations of the Examination

Clinical Relevance/purpose

Abbott Afinion™ HbA1c is an in vitro diagnostic test for quantitative determination of glycated haemoglobin (haemoglobin A1c, HbA1c) in human whole blood. The measure of HbA1c is used as a marker of long-term metabolic control in patients with diabetes mellitus. This test can be used as an aid in the diagnosis of diabetes and as an aid in identifying patients who may be at risk for developing diabetes.

Limitations of the test

• Any cause of shortened erythrocyte life span will reduce exposure of erythrocytes to glucose, resulting in a decrease in HbA1c values, regardless of the method used. Caution should be used when interpreting the HbA1c results from patients with conditions such as haemolytic anaemia or other haemolytic diseases, homozygous sickle cell trait, pregnancy, blood loss, polycythaemia, iron deficiency etc.

• This test should not be used to diagnose:

- Diabetes during pregnancy
- Patients with an elevated fetal haemoglobin (HbF >97 mmol/mol) such as hereditary persistence of fetal haemoglobin (HPFH)
- Patients with a haemoglobinopathy but normal red cell turnover (e.g. sickle cell trait)
- Patients that have received a blood transfusion within the past 3 weeks
- Patients that have received cancer chemotherapy within the past 3 weeks

• In cases of rapidly evolving type 1 diabetes the increase of HbA1c values might be delayed compared to the acute increase in glucose concentrations. In these conditions diabetes mellitus must be diagnosed based on plasma glucose concentration and/ or the typical clinical symptoms.

• Diluted samples cannot be used with Abbott Afinion™ HbA1c.

• Coagulated or haemolysed samples cannot be used with Abbott Afinion™ HbA1c.

• If the sample has a haemoglobin value below 60 g/L or above 200 g/L, no test result will be reported and an information code will be displayed.

2. References and Definitions:

REFERENCES

Quality Control Log Abbott Afinion 2 – FM/POCT/43
Abbott Afinion Operator's Guide – EXT/POCT/4
Abbott Afinion Stock Control Sheet – FM/POCT/60
Abbott Afinion Cartridge Kit insert – EXT/POCT/5
Abbott Afinion iQC Kit Insert – EXT/POCT/5
Abbott Afinion Safety Data Sheet – EX/POCT/5
Afinion Competency Sheet – FM/POCT/COMP/4
Validation and Change Control Documentation – VAL/POCT/14
Abbott Afinion Risk assessment - RA/POCT/8

Definitions

QC Quality Control
EQA External Quality Assurance
IFCC International Federation of Clinical Chemistry
cITm Cobas IT Middleware
HbA1c glycated haemoglobin, haemoglobin A1c
min minute
ID identifier
Max maximum
SOP standard operating procedure
Hb haemoglobin
NEQAS National External Quality Assurance Scheme

3. Actions and Methods:

3.1. Principle and Method of the Procedure Used for the Examination

Abbott Afinion 2 analyser is a portable analyser used for quantitative *in vitro* determination of HbA1c in whole blood.
The test principle for the measurement of HbA1c using this analyser is by boronate affinity assay.
Afinion Test Cartridge contains all the necessary reagents for determination of HbA1c concentration.
Sample material is obtained using sampling device (integrated with cartridge) and the test cartridge is placed in the analyser.
Blood sample is automatically diluted and mixed with liquid in order to release haemoglobin from erythrocytes. Haemoglobin then precipitates. Sample mixture is transferred to blue boronic acid conjugate, which binds with glycated haemoglobin. This mixture is then soaked through filter membrane and all precipitated haemoglobin (glycated and non-glycated) remains on the membrane, excess conjugate is removed with washing reagent.
Analyser evaluates the precipitate on the membrane by measuring reflectance and evaluating colour intensities of glycated haemoglobin (blue colour) and total haemoglobin (red). Ratio between the colour intensities is proportional to percentage of HbA1c in the sample. Analyser displays HbA1c concentration at the end of the assay in mmol/mol (HbA1c values are aligned to IFCC reference method).

3.2. Specimen Requirements and Means of Identification

Whole blood specimen is required for HbA1c analysis and sample may be obtained by either finger prick (capillary blood) or venepuncture (venous blood).

If venous blood is used the following anticoagulants are suitable: EDTA, lithium heparin, sodium citrate and fluoride/oxalate.

Capillary on the sampling device (refer to figure 3) holds 1.5 µl of whole blood and this is minimum volume required for the test.

Capillary blood samples cannot be stored and are discarded into appropriate waste once analysis has taken place. Venous blood samples with anticoagulants can be stored in the fridge (2-8^{0}C) for 10 days or at room temperature (18-30 ^{0}C) for 8 hours. Venous blood samples should not be stored frozen.

All samples will be identified by patient identification written on the tube to include a minimum of 3 of the following: full name, hospital number, NHS number, date of birth, address.

4. Patient Preparation

When collecting capillary blood sample make sure that the finger is clean, warm and dry. Allow for a good drop of blood to form before sampling.

4.1. Environmental and Safety Controls

Risk assessment: QMS/RA/POCT/8 – if performing the finger prick gloves must be worn, dispose of lancet in sharps bin. Reagents are sealed inside the cartridge - if leakage occurs wear gloves, use paper towel to absorb the spilled fluids and clean the surfaces with Clinell wipes – dispose of these into correct waste bin. Dispose of cartridges into a yellow burn bin.

5. Required Reagents, Quality Controls, Calibrators and Equipment Preparation

5.1. Reagents

Single Afinion test cartridge (Ref 1116795) contains all necessary reagents for one test and is supplied ready to use (Figure 3).

Boxes of cartridges need to be acceptance tested before use with patient samples, this can be done by running two levels of quality control on two cartridges from:

- Any new lot number of cartridges ahead of going into use.
- A new batch (each delivery) of cartridges regardless of lot number ahead of going into use.

When either a new lot arrives or when a delivery arrives (of same lot to previous) iQC should be run on cartridges from these on the next Friday, this will count as your weekly iQC check. Please write on the stock sheet that the batch or lot was accepted into use, with the date and time and by whom.

5.2. Quality Control

Afinion HbA1c Control kit (Ref 1116793) contains two controls:

- 1 x 0.5 mL Afinion HbA1c Control C I – supplied as stabilised liquid preparation
- 1 x 0.5 mL Afinion HbA1c Control C II – supplied as stabilised liquid preparation

Controls should be handled and disposed of as potentially biohazardous materials. Gloves should be worn at all times when handling control material. Controls contain sodium azide as preservative.

Storage

Control vials should be stored refrigerated at 2-8^{0}C – avoid exposure to direct sunlight and temperatures above 25^{0}C.

Unopened control is stable until expiry date indicated on the vial when stored refrigerated.

Opened control vials are stable for 60 days when stored refrigerated – note the date of opening on the vial. Store vials refrigerated, tightly capped and in an upright position when not in use.

Frequency

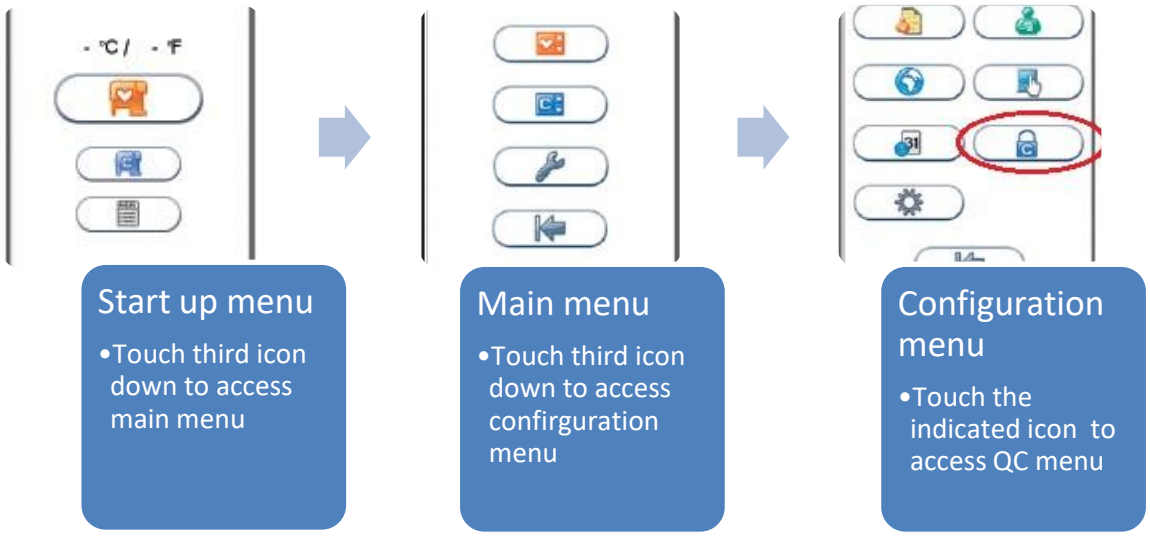
It is required to run both controls at a set time interval to ensure satisfactory performance of the analyser. Controls will need to be run every 168 hours from last satisfactory control (approx. every 7 days). Analyser automatically locks out when this time has lapsed and it will not be possible to run patient samples until controls are run and the result is satisfactory.

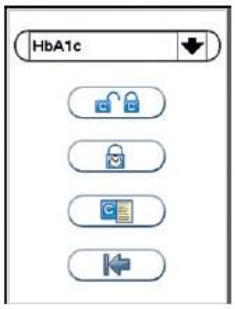
On how to run control samples please refer to section **8.3.**

5.3. Installing a new lot number of iQC

It will be necessary to manually enter new iQC lot numbers into the analyser's database to ensure controls are within the correct limits.
Control Data is encoded into a barcode and contains the following: lot number, control type, control level, expiry date and acceptable control range. Barcode can be found on Afinion Control Kit Package Insert.

To enter new lot into database refer to flowchart below:





In configuration menu touch  to access database settings – now it is possible to view, add or delete stored control settings.

Touch add button  end enter Control Data from Kit insert – either scan in a barcode or manually enter the long number which is located directly underneath the barcode.
Data for both controls are required to be installed into the analyser. Repeat the same procedure for the next control.

To go back to the previous screen press  .

5.4. Calibrators

Abbott Afinion HbA1c does not require calibration. Analyser is originally calibrated during manufacturing against reference system.

Test specific calibration data are established for each lot of test cartridges and stored in the barcode label (see Figure 3). Barcode is read by integrated camera when cartridge is placed inside the analyser and calibration data for the lot are transferred to the instrument and used for calculating results (See Abbott Afinion cartridge kit insert EXT/POCT/5)

5.5. Equipment

Abbott Afinion 2 analyser (Figure 1) is a portable analyser used for quantitative *in vitro* determination of HbA1c in whole blood.

Analyser self-tests during start up to ensure it is operating as per established specifications. This test validates hardware and software integrity, test cartridge transport system, liquid transport system and camera vision system. If the test fails at any point, red LED will flash and information code will be displayed on the touch screen.
When analyser stays switched on for longer period of time, it will automatically restart once a day to ensure self-test is done – this procedure does not interrupt analysis of the test cartridge.

Touch screen (Figure 1) allows operation of the instrument and only fingertips should be used – **do not use pens or other sharp instruments.**

Screen saver will turn on after 3 minutes when touch screen is not in use – to reactivate, touch the screen.

The lid (Figure 1) opens automatically when required, but needs closing manually – **do not attempt to open the lid manually.**

LED signals (red and green)

- Red – indicates analyser is busy
- Flashing red – information code is displayed
- Green – analyser ready for use
- Flashing green – analysis completed

Sound signals – short beep indicates completion of analysis. Two beeps mean information code is displayed.

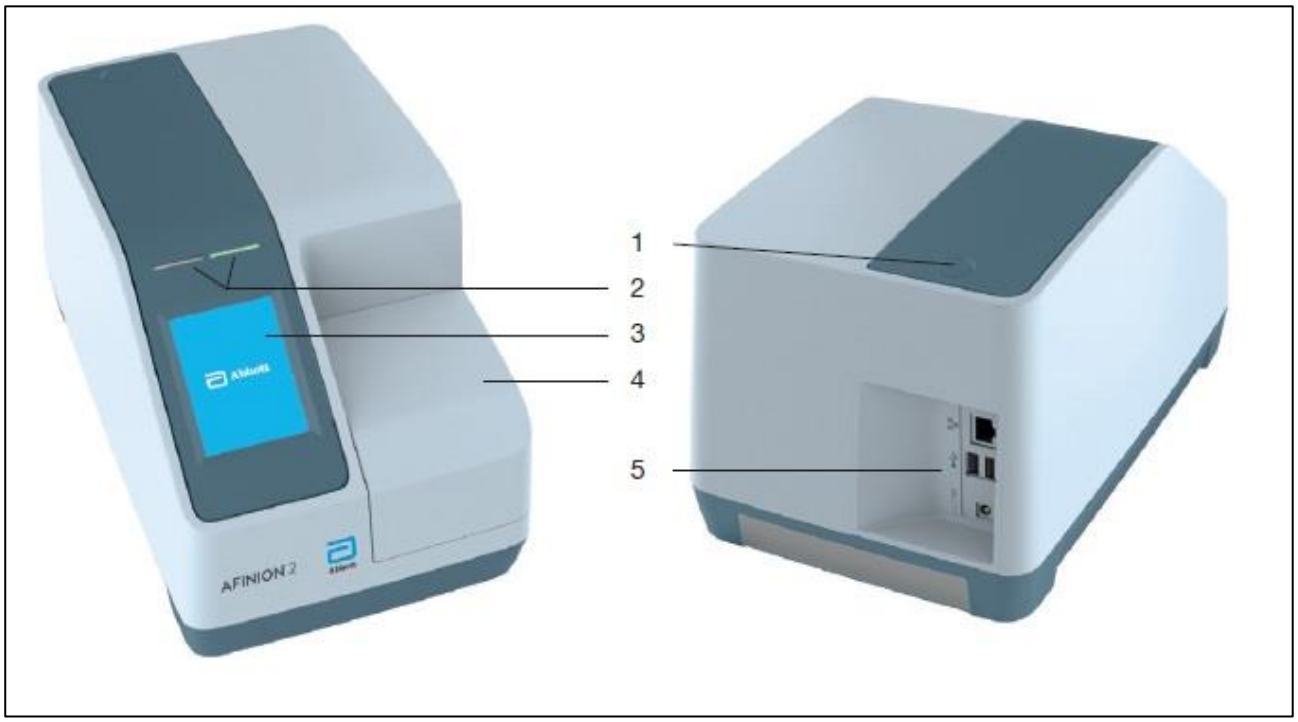


Figure 1. Main exterior parts of Abbott Afinion Analyser.

1) ON/OFF button –used to turn power on and off to the analyser
2) Red and green LEDs – indicate whether analyser is busy or not
3) Touch screen – allows communication with and operation of the analyser through touch buttons and messages
4) Lid (closed position) – covers and protects the cartridge chamber
5) Connectors – used for connecting to mains power supply

<u>How to switch analyser ON/OFF</u>

Switch analyser on by pressing ON/OFF button (Figure 1) – start up and self-test is initiated.

Figure 2. Start-up menu

- LED on top of analyser will flash red to indicate analyser is busy (Figure 1)
- Analyser is ready to use when LED on top of analyser turns green (Figure 1) and start up menu is displayed (Figure 2)
- To switch the analyser off press ON/OFF button, wait for the touch screen to switch off. It is now safe to unplug the analyser from the main power supply if it needs to be moved.
- When analyser is moved off site and exposed to outdoor conditions, please allow 15 min for the analyser's temperature to equilibrate before switching analyser on.

6. Monthly Maintenance

There are two procedures to be carried out for the monthly maintenance which are detailed out below.
Afinion analyser cleaning kit (Ref: 1116784) should be used for cleaning the chamber – cleaning kit is a pack of cleaning swabs. Please note the analyser must be unplugged before cleaning. Please take care not to drip off any liquid from the swab into the analyser (this can affect the optics).

6.1. Cartridge chamber cleaning:

- To be performed regularly every 30 days and every time when materials or liquids are spilled inside the chamber
- Touch  to open the lid
- Unplug the power supply
- Wet cleaning swab with 3 drops of water or a mild detergent – do not soak the swab
- Remove spills and particles from the cartridge using the moistened swab, to disinfect the chamber the surface should be exposed to disinfectant for 10 minutes
- Wipe off any residual liquid with a new, dry swab
- Close the lid and at this point you can carry on with the step below or alternatively plug in the power supply and switch analyser on

6.2. Cleaning the exterior

- To be performed regularly every 30 days and when it is necessary (spillage, stains, disinfecting the surface when taking analyser off site etc.)
- Switch off analyser and unplug the power supply when shutdown is complete
- Clean outside of the analyser and touch display with clean, lint free and non-abrasive cloth/tissue/wipe moistened with water or mild detergent
- Allow to air dry
- Plug the power supply and switch on the analyser

Once maintenance has been done, please record it on Abbott Afinion quality control log (QMS/FM/POCT/43).

7. Afinion Test Cartridge

Test cartridge for HbA1c analysis (Ref 1116795) is supplied in a kit which contains 15 test cartridges packaged separately in foil pouches with a desiccant bag.

Test cartridges are stable until the expiry date only when stored refrigerated (2-8^{0}C) in sealed foil pouches.

Test cartridges can be stored in unopened foil pouches at room temperature (15-25^{0}C) and are then stable for 90 days – note the date of removal from the refrigerator on the cartridge box.

Test cartridge must reach an operating temperature of 18-30^{0}C before use – once removed from the fridge allow 15 minutes for the cartridge to reach desired temperature.

Open the cartridge just before use – once foil pouch is opened the test cartridge needs to be used within 10 minutes after opening. Avoid exposure to direct sunlight and **avoid** touching optical area at all times (refer to figure 3) – **use designated handle to hold the cartridge.**

Test cartridge is single use only – once used it is to be discarded into biohazard waste.

Do not use test cartridge when:

- It has passed the expiry date
- It has not been stored as per recommendations
- If foil pouch, desiccant bag or the test cartridge itself is damaged

How to open the foil pouch

Open the foil pouch by using the tear strip as indicated. Grip the handle (refer to figure 3) and remove the test cartridge from the pouch. Discard desiccant bag and foil pouch in suitable waste container.

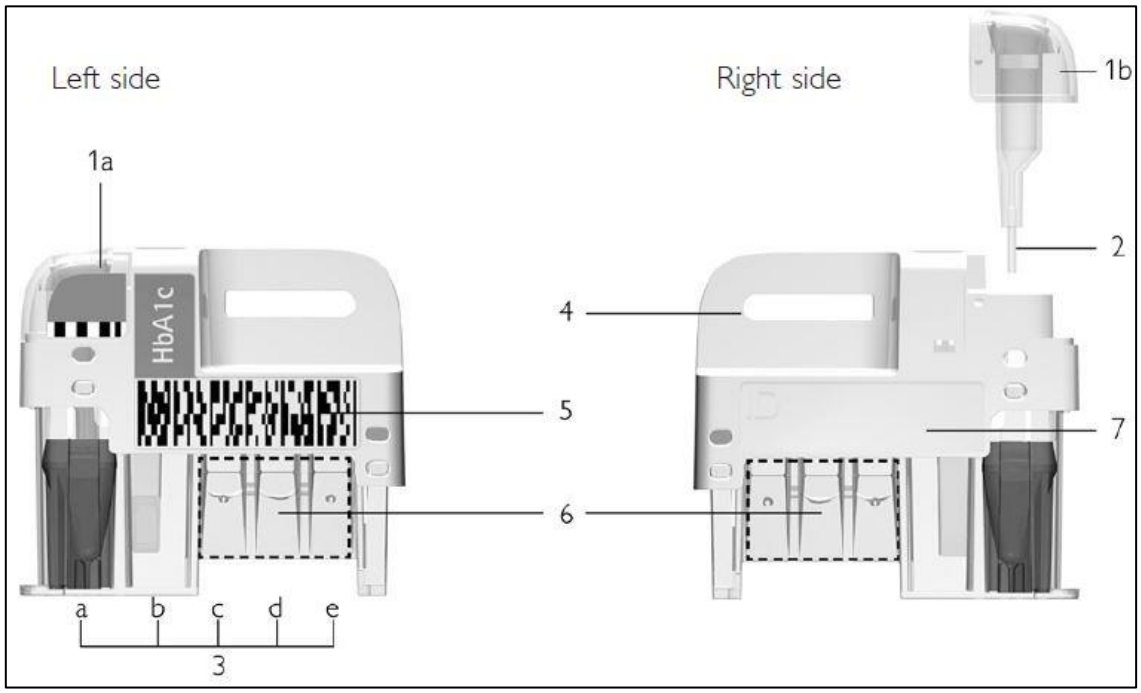
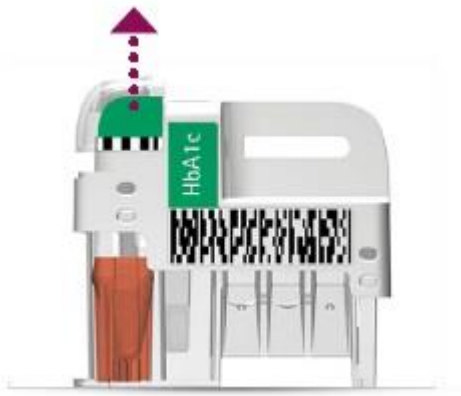


Figure 3. Test cartridge and its components

1. Sampling device used for collection of patient sample or control
    a. Closed position
    b. Lifted position
2. Capillary used to fill with sample material (1.5µL)
3. Reaction wells – contain reagents required for one test:
    a. Conjugate
    b. Membrane tube
    c. Washing solution
    d. Reconstitution reagent
    e. Empty
4. Handle to ensure correct finger grip
5. Barcode label – contains assay- and lot-specific information for the analyser
6. Optical reading area – area for transmission measurement
7. ID area – space for written or labelled sample identification

8. Instructions for the Performance of the Examination

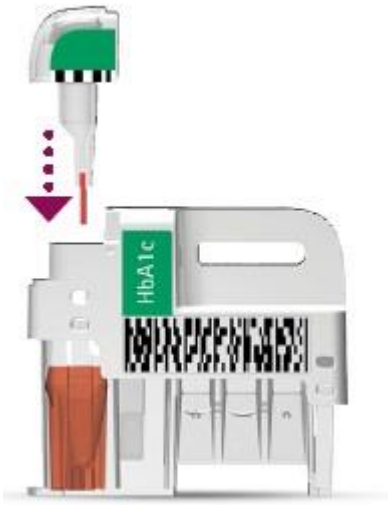
8.1. Filling capillary



a. Remove sampling device by pulling it straight up from test cartridge – take extra care to not touch the optical reading area

b. Bring the tip of capillary just beneath the surface of patient sample or control material – capillary fills automatically to the end and it is not possible to overfill it, avoid filling with bubbles and excess sample on the outside of capillary. **Do not wipe off the capillary.**

Gloves should be worn at all times when handling patient or control sample – take extra care when using lancets or needles to obtain the specimen to avoid sharps injury. Sharps should be discarded into appropriate biohazardous waste container.

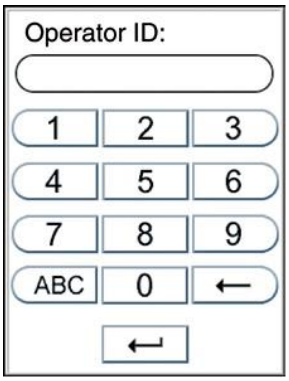


c. Replace the sampling device into test cartridge immediately by pushing it back in its original position.

d. Analysis of test cartridge should start within 2-3 minutes – if stored too long before analysis the sample may dry or coagulate and analyser will display an information code – it will be necessary to use new cartridge and obtain fresh specimen.

e. Do not use test cartridge that has been accidentally dropped on the floor or bench after sample collection.

8.2. Entering Operator ID



Operator ID is required to be entered before processing. Both letters and numbers can be entered (max 16 characters). Operator ID is displayed with the results and it is stored in results record.

To enter ID by letters, touch ABC button.

Touch ↵ to confirm and return to previous screen.

To log out press .

8.3. Analysing Quality Control Sample

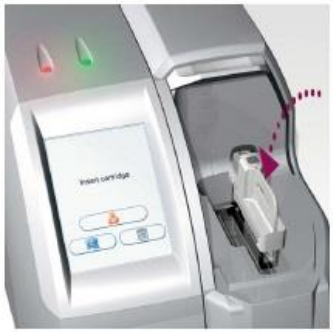
Please note that controls are potentially biohazardous materials – gloves should be worn at all times when control material is handled.

a. Remove control material from the fridge and allow to reach room temperature (15-25^{0}C) before use (takes about 45 minutes). Discard the vial if there is evidence of microbial or fungal contamination and use fresh control material.

b. Control material should be mixed prior to use by vigorously shaking the vial for about 30s.

c. Refer to procedure 3.6.1 (b) on how to fill capillary with control material.

d. When cartridge is ready press the blue icon on the main screen in order to analyse control sample – the lid will automatically open (slides out towards the operator).



e. Insert the cartridge into chamber with barcode facing left.

f. Close the lid manually by gently pushing it in to start analysing – analysis starts automatically and takes about 3.5 minutes.

g. While analysis takes place press the blue icon on the screen and enter control ID - this is the lot number of the control material used. Lot number can be found on the control kit insert and on the side of control vial.

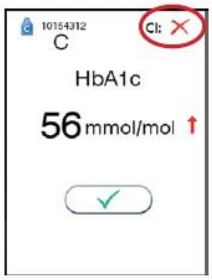
h. Enter ID by numbers, touch ABC in order to enter letters. Touch ↵ to confirm – this action takes you back to previous screen. Entered ID will appear on the screen in the upper left corner. Blue button remains in the same place and corrections can be made if necessary.

i. Result of the control is checked against acceptable range for corresponding lot number:

Passed QC screen

Green tick ✓ will be displayed indicating that result is within acceptable range

Failed QC screen



Red arrow alerts that QC is above ↑ or below ↓ acceptable range.

Red cross ✗ will be displayed.

Patient testing is disabled, failed QC to be corrected.

j. Record result in the Quality Control log, then press ✓ to accept. Results are stored in the analyser memory by date and time.

k. Proceed from step a. for the second level of iQC ensuring the blue icon is pressed before running the next level.

l. Email the Internal Quality Control results to POCT email address: ruh-tr.biochempoc@nhs.net. Please include the following: IQC results, lot number of both controls used and lot number of cartridges used.

m. The QC results will then be entered onto cITm in the Biochemistry Lab.

n. Laboratory staff: please refer to SOP/IT/IT/43 Cobas IT middleware, section 5.5 for instructions on how to record results in cITm manually.

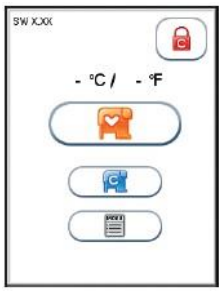
<u>QC lockout</u>

Set at 168 hours (from last satisfactory QC), after this interval the assay will be locked and not available for patient testing. Controls must be run and be successful to reset the interval and to unlock patient testing.

QC within interval

Green padlock in upper right corner of the touch screen indicates that both controls are within required interval. Patient testing is enabled.

QC interval expired



Red padlock in upper right corner of the touch screen indicates that control interval is expired. Patient testing is disabled.

Yellow padlock appears in the upper right corner of the touch screen as a warning when all controls are within interval, but there is ≤ 10% of the interval remaining before it expires. Patient testing is enabled.

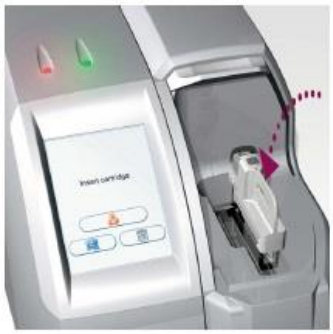
It is possible to check when QC interval will expire – touch the padlock and the screen will show QC lockout status. Remaining time will be displayed next to the control (C I and C II) in the following format DD:HH:MM (DD-days, HH- hours, MM-minutes).

9. Analysing patient sample

Please note that gloves should be worn at all times when performing this procedure.

a. Refer to procedure 3.6.1 on how to fill capillary with sample - analysis of test cartridge should start within 2-3 minutes – if stored too long before analysis the sample may dry or coagulate and analyser will display an information code – it will be necessary to use new cartridge and obtain fresh specimen.

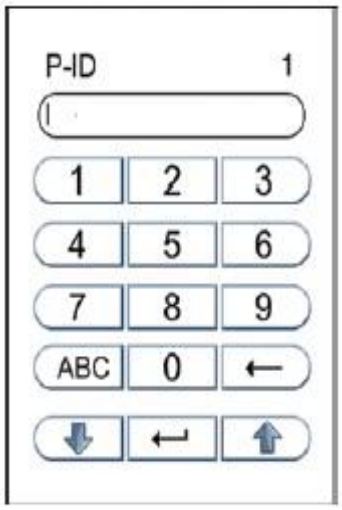
b. When cartridge is ready press the orange icon  on the main screen to analyse patient sample – the lid will automatically open (slides out towards the operator).



c. Insert the cartridge into chamber with barcode facing left.

d. Close the lid manually by gently pushing it in to start analysing – analysis starts automatically and takes about 3.5 minutes.

e. While analysis takes place press the orange icon  on the screen to enter patient demographics.



f. On the next screen enter patient's MRN/NHS number (either manually or using barcode scanner).

- It is possible to enter up to 4 identifiers – press down arrow  to access the next field – enter patient's surname*.
- If MRN or NHS numbers are not available, then enter patient's name and date of birth.
- Use  button to enter letters. Touch up arrow  to move back to previous field (it is possible to make corrections at this point).

Entering the ID does not interrupt the analysis.

- Touch  to confirm and return to previous screen – entered patient ID will appear on the screen. Patient ID can also be entered once analysis complete.

*** Only first entered patient identifier will be visible in results record. Other ID's are stored in the memory – these are only visible when the data is transferred to USB flash drive.**

g. Result (in mmol/mol) will be displayed on the screen together with entered patient ID.

h. Press ✓ to accept. The lid opens automatically.

i. Remove and discard the cartridge into biohazardous waste. Close the lid manually by gently pushing it in. Analyser goes back to start up menu screen and green LED will lit up to indicate analyser is ready to use again.

Result will NOT be displayed on the screen if:

- The operator failed to enter patient ID – use orange button to enter relevant IDs and accept to display result.
- The result is outside the measuring range – send venous sample to lab for HbA1c.
- The sample was to small – repeat the finger prick and re-analyse

An information code will be displayed (refer to Manufacturer's manual for full list).

10. Procedure for Recording of Results

❖ Record in the patient notes:

- The result
- Your signature
- Time and date of measurement
- The analyser the result was measured (Afinion 2)

❖ Record results manually in Diamond for a permanent electronic record.

❖ Results will also be stored on the analyser temporarily (500 samples).

N.B If no result is available for reporting this **MUST** be recorded in the patient notes.

11. Potential Sources of Variation and Measurement Uncertainty of Measured Values

Traceability

Abbott Afinion™ HbA1c is traceable to the IFCC Reference Method for Measurement HbA1c (EXT/POCT/5)

Validation & Change Control

Potential sources of variation impact on uncertainty within a method. The variables that impact on the examination procedure have been considered in the document VAL/POCT/14

MoU

Refer to comparison data under properties in VAL/POCT/14 for Measurement Uncertainty calculation for HbA1c measured on the Afinion 2 analyser.

12. Performance characteristics and interferences

12.1. Specificity

Abbott Afinion measures total glycated haemoglobin and reports HbA1c value. No significant interference (<7%) was observed for samples with Hb variants and derivatives up to certain concentration levels.
For full list please refer to Abbott Afinion Cartridge Kit Insert (QMS/EXT/POCT/5)

12.2. Linearity and measuring range

The measuring range for HbA1c is 20-140 mmol/mol and the assay is linear throughout this range.

References to assay performance details

Sensitivity: See Abbott Afinion cartridge kit insert QMS/EXT/POCT/5page 9
Specificity: See Abbott Afinion cartridge kit insert QMS/EXT/POCT/5page 10 & 11
Linearity: See Abbott Afinion cartridge kit insert QMS/EXT/POCT/5page 13
Accuracy and precision: See Abbott Afinion cartridge kit insert QMS/EXT/POCT/5 page 12 & 13

12.3. Interferences

- No significant interference (<7%) was observed for bilirubin (conjugated and unconjugated), glucose, lipids, rheumatoid factor, total protein and glycated albumin (for specified concentrations please refer to Abbott Afinion Cartridge Kit Insert (QMS/EXT/POCT/5).
- No significant interference (<7%) was observed for over-the-counter and prescription drugs including acetaminophen, ibuprofen, metformin. For full list and specific concentrations please refer to Abbott Afinion Cartridge Kit Insert (QMS/EXT/POCT/5)
- *In-vitro* haemolysis affects the assay at concentration of 14% or greater.
- Anticoagulants at concentrations used in blood collections tubes do not interfere with the assay.

External Quality Assessment Schemes

Laboratory is participating in UK NEQAS Glycated Haemoglobins scheme. Material used is fresh whole blood. Samples are received on a monthly basis (third week of each month).
For procedural information, refer to SOP/CH/MAN/7.

External Quality Assessment (EQA)

EQA samples differ from internal QCs in that the accuracy of the procedure is not known until after the results have been issued.
As the user does not know the HbA1c result at the time of analysis, and the results are assessed independently, it allows confidence that the performance of the analyser and operators is not varying over time.
Samples are issued from NEQAS on a monthly basis and will be distributed by the POCT team for analysis on the Afinion analyser.

The samples should be tested as a patient on receipt (refer to section 3.6.3):

- allow samples to reach room temperature
- Ensure they are well mixed this should be several inversions over at least a minute (avoid foam formation) before analysis.
- Samples should be mixed again immediately before analysis to ensure sample has not separated out.
- The results returned on the form provided to POCT and/or emailed to **ruh-tr.biochempoc@nhs.net** as soon as possible.
- If analysis cannot be performed immediately then the samples may be stored refrigerated for up to 24 hours.

For full procedure, please refer to SOP/CH/MAN/7 HbA1c NEQAS.

14. Reference Limits, Reportable intervals and Report Interpretation

Please note: local guidelines should be considered and adhered to when interpreting results.

Reference Limits

All patients should have an individual target, balancing long term risk of complications with quality of life and risk of hypoglycaemic events.

Expected values

Patients with HbA1c levels between 39 and 47 mmol/mol are identified as being at risk for developing diabetes.
The diagnostic cut-off is 48 mmol/mol.

Reportable Intervals, Reporting and Interpretation

The measuring range for HbA1c is 20-140 mmol/mol and the assay is linear throughout this range.

Results outside lower limit (<20 mmol/mol)

A result less than the lower limit will not display on the screen. Instead an information code **#105** will be displayed – this means HbA1c value is below measuring range.
Report the result as less than 20 mmol/mol HbA1c.

Results <20 mmol/mol are rare and may indicate that the sample contains substantial amounts of foetal haemoglobin or that the patient may have haemolytic anaemia.

Results outside upper limit (>140 mmol/mol)

A result greater than the upper limit will not display on the screen. Instead an information code **#106** will be displayed – this means HbA1c value is above measuring range.

Report the result as greater than 140 mmol/mol.

If any result appears questionable or if the clinical signs and symptoms appear inconsistent with the result, re-test the patient and / or confirm the result by sending a labelled EDTA sample to the Biochemistry Lab for confirmation.

15. Personnel Involved in Interpretation, Authorising, Reporting and Monitoring of Reports

Only trained staff can operate the Afinion 2 analyser and the paediatric specialist diabetes nurses should be authorising, interpreting and reporting the results they produce. The wider clinical paediatric diabetes team can also interpret the results produced and make decisions based on these results.

The POCT coordinator is responsible for supply of and performance monitoring of the EQA for the Afinion 2.

16. Troubleshooting

Result not displayed

If a result does not display this could be due to:

- The patient ID not being entered during the analysis time - enter an ID after analysis (refer to section 9 **e.** & **f**.).
- An insufficient sample **–** This **must** be recorded in the patient's notes – and recorded as an incident in Datix if appropriate.

- An inadequate blood sample was obtained by finger prick - This must be recorded in the patient's notes - record as an incident in Datix if appropriate. A venous sample should be collected into an EDTA tube (purple top), to be analysed on Abbott Afinion analyser (refer to section 8) or send to the laboratory for HBA1C analysis.

Error codes

See the user manual for the full list (EXT/POCT/4)

Information code **#105 =** Result below the measuring range – report as <20 mmol/moL

Information code **#106 =** Result above the measuring range – report as >140 mmol/mol

Copy number	Location held
1	Paediatric diabetes OP
2	Website