

Internal (ABBOTT) and External Quality Controls EQAS

Crib Sheet for the Afinion AS and

ABBOTT AF2 Shropshire NHS Health Check Devices

Please note – Both devices use the same quality control procedures.

Table of Contents

1. Quality Control Schedule, Machine Preparation and Cassette Panel use.

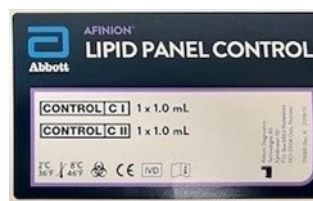
Afinion 2



Afinion™ AS100 Analyzer



2. Receiving, storing and use of the Quality Controls
3. Undertaking and recording Internal ABBOTT HbA1c and Lipid Quality Control.



4. Undertaking and recording External RIQAS Lipid and HBA1C Single Sample Control.



5. Trouble shooting / Error Codes / Quick Reference Guides and Online Manual

1. Quality Control Schedule / Machine Preparation / Cassette Panel use

- If you are the nominated person trained by Abbotts Alere to Undertake Quality Controls on the Afinion devices used either for NHS Health Checks or SMI Health Checks – you will be undertaking the following control schedule.
- Internal Abbot Controls are completed Monthly.
- External RIQAS controls are completed monthly.
- BOTH must be completed the first week of each month.

Machine and QC Preparation

To ensure accurate QC results and prevent error codes.

We recommend.

If running controls from a cold machine start – please start up and leave the machine on for 1 hour prior to undertaking the control.

If the machine has been undertaking human sampling prior to QC – please restart the machine prior to undertaking the control.

Ensure the machines software is up to date. **AS100 7.05 – AF2 21.14** – If software is not up to date please contact mike.parry@shropshire.gov.uk or nathan.thomas@shropshire.gov.uk

Cassette Panels

Testing Panels - All testing panels that are ordered should be placed immediately in a fridge upon arrival.

Lipids

- Must be out of the fridge for at least 15 minutes to warm up before they can be used.
- Must be used within 10 minutes of opening the package and must be put into the machine **within 1 minute** of taking a sample.
- The panels must be left out of the fridge once removed and must be used with **14 days** (please mark this date on the box)

HBA1C

- Out of the fridge for at least 15 minutes to warm up before they can be used.
- Use within 10 minutes of opening the package and must be put into the machine **within 2-3 minutes** of taking a sample.
- Panels must be left out of the fridge, can be left out and used within **90 days** (please mark this date on the box)

2. Receiving, Storing and Use of the Quality Controls

Quality Control samples are delivered on a monthly and bimonthly basis for both Internal (ABBOTT) Controls and RIQAS External one single blood sample control.

Please store all QC samples in a fridge immediately upon arrival until ready to use.

Samples will need to be brought to room temperature before use – please refer to the internal supplied instructions with each sample type.

To reduce the risk of errors, undertake the controls within the specified retention period and recommendation for each sample type.

Typically

Internal ABBOTT controls will be delivered bimonthly in the first week of the month.

Internal ABBOTT **HBA1C** Controls should be brought to room temperature for 45 minutes and used within the hour.

Internal ABBOTT **LIPID** Controls can be used directly from the Fridge.

And

External RIQAS Single Blood Sample control will be delivered the first week of each month.

You should receive an email from Randox letting you know the sample is on the way and the submission deadline date. The single sample is used for both the HBA1C and Cholesterol control test.

The External RIQAS Single Blood sample can be used after coming to room temperature for at least 45 minutes.

Storage and Retention

Internal ABBOT controls can be kept in the fridge and used within the expiry date until opened.

External RIQAS Controls should only be retained for single use and disposed of immediately after use. This will prevent left over samples building up in the fridge.

External RIQAS **BLOOD** sample controls **MUST** be stored immediately in a fridge.

Use

Internal ABBOT controls (HBA1C and LIPID) can be used monthly and returned to the fridge for 60 days once opened - please mark day of first use and expected 60-day expiry date on the box.

External RIQAS Blood sample control **MUST** be used and reported to the online platform within 9 days of receipt.

IMPORTANT –

Handle all samples as you would Patient sampling.

Internal ABBOT controls can be returned to the fridge for later use.

Once you have run the monthly external RIQAS control – please dispose of immediately and DO NOT return to the fridge.

3. Undertaking and recording Internal HBA1C and LIPID control

Please Note – Undertake Internal Controls using BLUE C Control Icon

Internal HBA1C

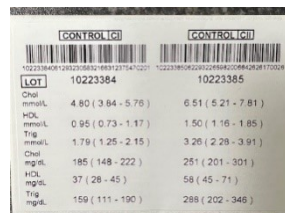
- Delivered Bimonthly in 2 boxes. Inside are two small bottles marked C1 and C2



- Please follow the instructions which come with the controls on storage and mixing prior to running a test.
- Undertake Control using two HBA1C cassettes with the same LOT number.
- Ensure that the test results are within the expected range indicated on the QC package insert.
- Record result in the logbook.
- For practices with more than one device, there is enough QC sample for all devices during the QC period.

Internal LIPID

- Delivered Bimonthly, in 2 Boxes. Inside there are two small bottles marked C1 and C2



- Please follow the instructions which come with the controls on storage and mixing prior to running a test.
- Undertake Control using two LIPID cassettes with the same LOT number.
- Ensure the test is within the expected QC range indicated on the QC package insert.
- Record result in the Logbook
- for practices with more than one device, there is enough QC sample to for all devices during the QC period.

Quality Control Log - Sample of completion

Logbook Recording examples.

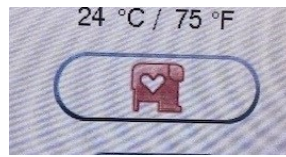
Internal ABBOTT Controls

Download from [here](#)

Months	July / August 24	Sample Lot no.	HBA1C CI	HBA1C CII
Practitioner	Alan Smith		10225042	10225272
Month	Date of Test	Target (Range) in mmol/mol	43 (37 – 50)	68 (60 – 77)
July	05/7/24	Sample Lot no.	LIPID CI	LIPID CII
August	05/8/24	Target (Range) in mmol/L	10223384	10223385
		TOT CHL	4.80 (3.84 – 5.76)	6.51 (5.21 – 7.81)
		HDL	0.95 (0.73 – 1.17)	1.50 (1.16 – 1.85)
Month 1	HBA1C	Cassette Lot	Result	Pass/fail
July	HBA1C CI	102234576	42	PASS
	HBA1C CII		68	PASS
	LIPID	Cassette Lot	Result	Pass/fail
August	LIPID CI	105432265	TOT 4.79 HDL 0.96	PASS
	LIPID CII		TOT 6.49 HDL 1.46	PASS
Month 2	HBA1C	Cassette Lot	Result	Pass/fail
August	HBA1C CI	10345689	44	PASS
	HBA1C CII		67	PASS
	LIPID	Cassette Lot	Result	Pass /Fail
	LIPID CI	102346753	TOT 4.78 HDL 0.97	PASS
	LIPID CII		TOT 6.51 HDL 1.51	PASS

4. Undertaking and Recording External RIQAS control

Please Note – Undertake External Controls using Patient RED ICON



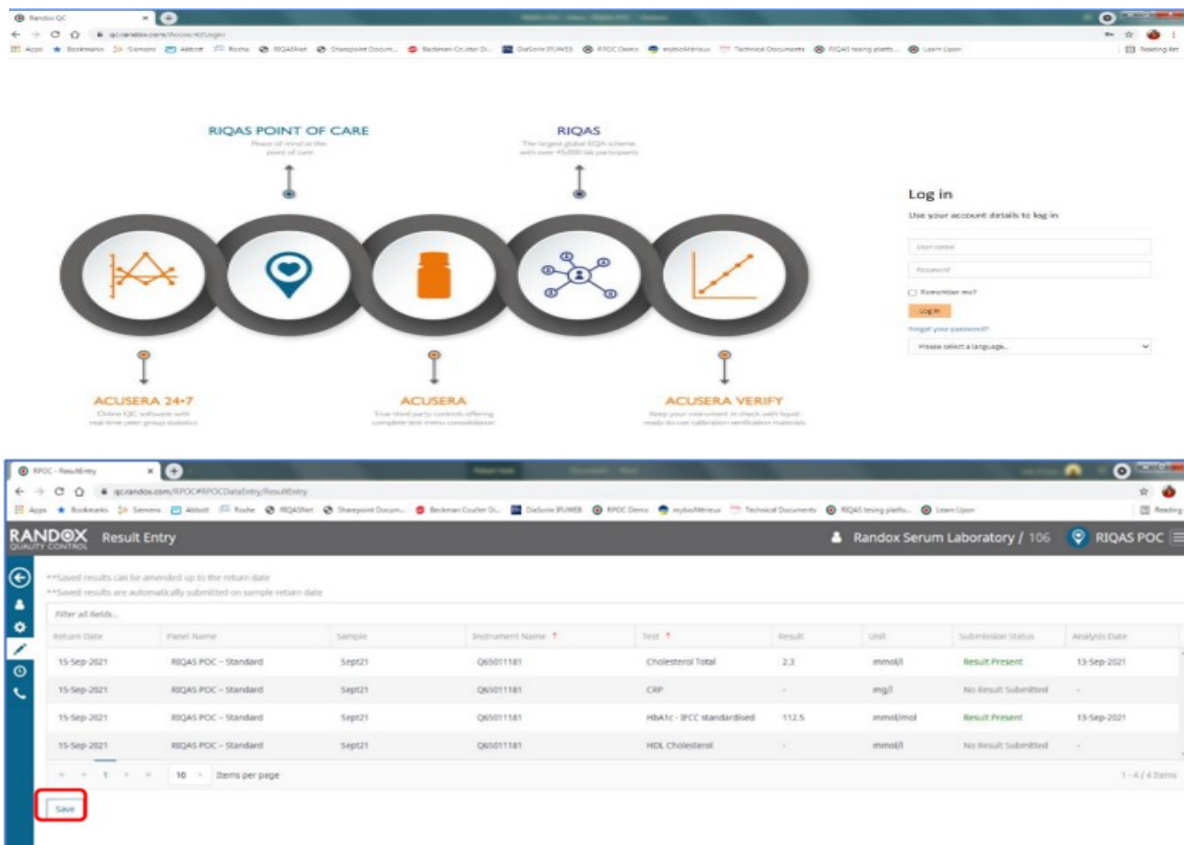
Single Blood Sample for HBA1C And LIPID Control (RIQAS)



IMPORTANT – Please use the SINGLE SAMPLE delivered to complete 1 test each of HBA1C and Cholesterol

- Please follow the instructions which come with the control on storage and mixing prior to running a test.
- Undertake 1 sample of **LIPID** and note Total Cholesterol and HDL.
- Undertake 1 sample of **HBA1C** and note result in mmol/l.
- For practices with more than one device, you will receive enough sample to process on all devices.
- Please record the results in the online platform. (Use Google Chrome for the online platform)

Results Submitted after the Submission Closing date will not be accepted.



The screenshot displays the Randox QC website interface. The top navigation bar includes 'Randox QC' and 'Randox Serum Laboratory / 106'. The main content area features a central graphic with five circular icons representing different services: 'ACUSERA 24x7', 'ACUSERA', and 'ACUSERA VERIFY'. To the right, there is a 'Log in' section with fields for 'User name', 'Password', and a 'Log in' button. Below the main content, a screenshot of the 'Randox Result Entry' system is shown, displaying a table of test results. The table has columns for 'Return Date', 'Panel Name', 'Sample', 'Instrument Name', 'Test', 'Result', 'Unit', 'Submission Status', and 'Analysis Date'. The data rows show results for 'RIQAS POC - Standard' tests performed on '15-Sep-2021' for 'Cholesterol Total', 'CRP', 'HbA1c - IFCC standardised', and 'HDL Cholesterol'. A 'Save' button is highlighted in a red box at the bottom left of the screenshot.

Return Date	Panel Name	Sample	Instrument Name	Test	Result	Unit	Submission Status	Analysis Date
15-Sep-2021	RIQAS POC - Standard	Sep21	Q6501181	Cholesterol Total	2.3	mmol/l	Result Present	13-Sep-2021
15-Sep-2021	RIQAS POC - Standard	Sep21	Q6501181	CRP	-	mg/l	No Result Submitted	-
15-Sep-2021	RIQAS POC - Standard	Sep21	Q6501181	HbA1c - IFCC standardised	112.5	mmol/mol	Result Present	13-Sep-2021
15-Sep-2021	RIQAS POC - Standard	Sep21	Q6501181	HDL Cholesterol	-	mmol/l	No Result Submitted	-

5. Trouble shooting / Error codes / Quick Reference Guides and Online Manuals

If you experience any issues with results or error codes, please write down all the information below,

- Machine Software Version
- Cartridge Type
- Cartridge Lot number (Outer lot = Kit lot no. and/or Inner lot = Cartridge lot no.)
- Cartridge storage
- Any shipping concern noted for the cartridges and/or controls?
- Environment/ Facility condition /Temperature/ Humidity?
- Any noted deviation when received by the customer or any deviation in the customer's facility?
- Sample type
- What was the appearance?
- Frequency of failed assays
- Control outer and inner Lot, if applicable
- What is the frequency of occurrence/number of assays failed?
- Was the test repeated? What was the outcome?
- Are the codes appearing across different tests/different lots?
- Do you have additional instruments with the same issue?

Please email to EME.TechSupport@abbott.com and contact mike.parry@shropshire.gov.uk and nathan.thomas@shropshire.gov.uk

For external quality controls

Contact Details for any errors, questions or queries with External control.

RIQAS POC team via:

- email on riqas_poc@randox.com
- telephone on 028 944 54399 between the hours of 0840 – 1720 GMT.

Quick reference guidance and online manuals.

Available by the links embedded below.

Afinion Manual for [AS100 Device](#)

Afinion (ABBOTT) Manual for [AF2 Device](#)

Quick Reference Guides Randox Point of Care External RIQAS controls.



RIQAS Point of Care
Scheme RQ9181.pdf



RPOC Instructions.pdf

Shropshire Council NHS Health Check professional resources page

<https://www.shropshire.gov.uk/public-health/healthy-shropshire/nhs-health-check/professional-resources/>