

Afinion AS100

Quality Control HbA1c Test



Frequency

Two (2) levels of Afinion HbA1c QC must be run upon receipt of stock (for each lot number) and/or monthly basis respectively.

Materials Required

1. 2 x HbA1c Test Cartridges
2. HbA1c Controls, Level 1 and Level 2
3. Afinion HbA1c QRG document



Preparing QC Materials

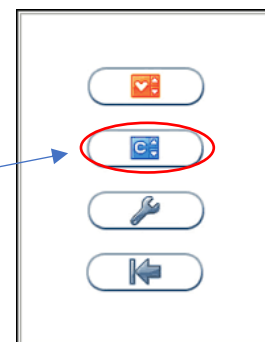
Allow 45 minutes for Controls to reach room temperature before use.

Allow 15 minutes for the Test Cartridges to reach room temperature before use.

Unopened control vials are stable until the expiry date indicated when stored refrigerated (2-8°C). Opened control vials are stable for **60 days** when stored refrigerated (2-8°C). *Note: record the date of opening on the vial label before returning to the fridge for future use.*

Procedure

1. Turn the Analyzer on, then scan or enter your Operator ID.
2. Mix the control material thoroughly by shaking the vial for 30 seconds. Inspect the control vial to ensure the control solution is homogenous.
3. Open the test cartridge pouch and remove the cartridge. Use the cartridge within 10 minutes after opening
4. Proceed to the Afinion HbA1c Testing Procedure document in your PoCT manual
Please Note: when running Quality Control samples use the Control Mode icon instead of the Patient Test mode icon.
5. Clean the outside of the control vial neck, replace the cap and immediately return vial to the refrigerator after use.
6. Record Control result on the Alere Afinion AS100 Maintenance Log sheet.



QC Failures and Corrective Actions

If one or more of the HbA1c Controls fails to give expected results:

1. Check that the HbA1c cartridges or controls are not expired.
2. Ensure the control vials have not been in use for more than 60 days.
3. Ensure cartridges and controls have been stored correctly.
4. Repeat testing using new control materials, ensuring control vials are well mixed and the testing procedure is carefully followed.
5. If this repeat testing fails, **DO NOT PERFORM ANY PATIENT TESTING** until the issue is resolved. Refer to the Troubleshooting Escalation Pathway.
6. Document any error codes etc in the Log Issues section of the Maintenance Log Sheet.