

CLIA statement

This is a CLIA-waived test. A CLIA Certificate of Waiver is needed to perform testing in waived labs. If the laboratory modifies the test instructions, including quality control, the test will no longer meet the requirements for waived categorization. A modified test is regarded as highly complex and is subject to all applicable CLIA requirements.

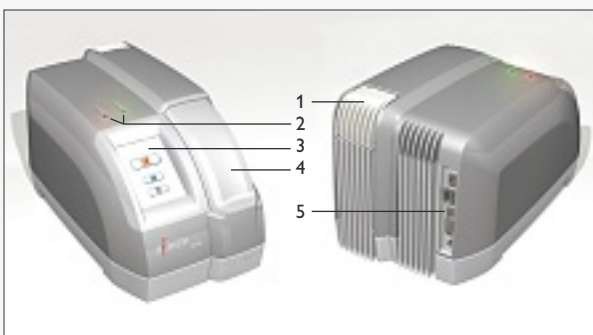
Important!

- Read the entire Afinion™ HbA1c Quick Guide before testing patient samples or controls.
- See the Afinion™ AS100 Analyzer User Manual for more information about the operation of the Analyzer and Test Cartridge.
- See the Afinion™ HbA1c Package Insert for more information about the HbA1c assay.
- Use quality control materials to confirm that the Analyzer and test kit are working properly.

1 GETTING STARTED

Take time to familiarize yourself with the Analyzer and the test kit.

Afinion™ AS100 Analyzer

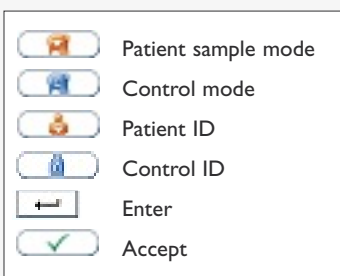


- 1 ON/OFF button
- 2 Light emitting diodes
- 3 Touch screen
- 4 The lid
- 5 Connectors

Cleaning the Analyzer

Clean the Analyzer every 30 days. Follow the procedure in the User Manual. See section "Cleaning and Maintenance".

Important touch buttons



Important information codes

Code	Cause
103	Hemoglobin below 6.0 g/dL
104	Hemoglobin above 20.0 g/dL
105	HbA1c below 4.0%
106	HbA1c above 15.0%
202	Excess sample on the sampling device exterior
204	- Hemolyzed or coagulated sample - Analyzer failure

Afinion™ HbA1c Test Cartridge



2 PREPARE FOR TESTING

- Switch the Analyzer on.
- Allow 15 minutes for the Test Cartridge to reach operating temperature (64-86°F) before use.
- Open the pouch just before use. Hold the Test Cartridge by the handle.
- Label the Test Cartridge with sample ID. Use the ID area.
- Analyze Afinion™ HbA1c Control before analyzing patient samples.



3 PROCEDURE FOR COLLECTING THE SAMPLE

Sampling from a control vial

Follow the procedure described below.

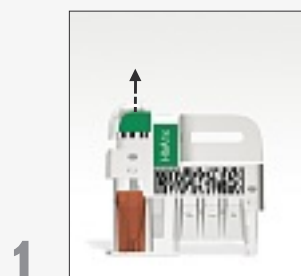
See page 4 for control testing recommendations.

Sampling from finger

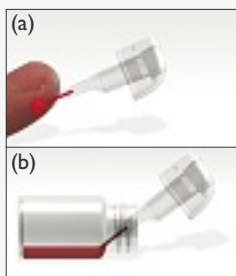
- Always use gloves.
- Cleanse the finger using alcohol. Allow the area to air dry.
- Use a lancet and firmly prick the finger (a). Properly dispose the lancet.
- Allow a good drop of blood to form before sampling (b).
- Apply direct pressure to the wound site with a clean gauze pad.



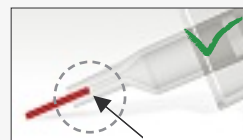
Specimen collection using the Afinion™ HbA1c Test Cartridge



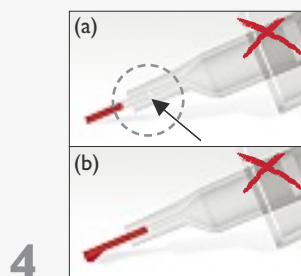
1 Pull up the sampling device.



2 Touch the surface of the blood drop (a) or control (b).



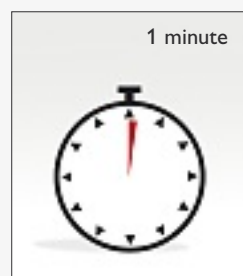
3 Fill the capillary to the end. It is not possible to overfill.



4 Avoid air bubbles and incomplete filling (a). Avoid sample on the outside of the capillary (b). Do not wipe off.



5 Insert the sampling device immediately.




6 Within 1 minute place the Test Cartridge in the Analyzer.

4 RUNNING SAMPLES ON THE ANALYZER

1



Patient sample:
Touch  for patient samples.

Control:
Touch  for controls.

2



The lid opens automatically.
Insert the Test Cartridge.
The barcode should face left.


3



Close the lid manually.

4



Patient sample:
Touch  for patient samples.

Control:
Touch  for controls.

Enter ID during processing.

Touch  to confirm.

5



Record the result when it appears
on the screen.

Touch  to accept.

6



The lid opens automatically.
Remove and discard the cartridge.

Close the lid manually.

Information codes

Important information codes are listed on page 1. Consult the Analyzer User Manual for information codes not listed on page 1. Follow the actions listed in the User Manual to correct the error.

Verification of test results

Consult the HbA1c Package Insert. See section "Test result reporting".

Verification of Control results

Compare the results with the values listed on the front of the Afinion™ HbA1c Control Package Insert.

Technical Support?

Call 1-877-4-Afinion or 1-877-423-4646. This is a toll free number. Available for use only in the United States of America. US Technical Support can also be reached by E-mail. Send your request to: techsupport@us.axis-shield.com



CONTROL TESTING

Read the entire Afinion™ HbA1c Control Package Insert before use.

How often do I have to run controls?

In CLIA waived labs, it is recommended analyzing controls:

- With each new shipment of HbA1c kits.
- With each new lot of HbA1c kits.
- At least every 30 days.
- When training new users.
- Anytime an unexpected test result is obtained.

How should I use the Afinion™ HbA1c controls?

- Allow the control to reach room temperature before use. This takes about 30 minutes.
- Mix the control well by thoroughly shaking the vial for 30 seconds.
- Inspect the vial to ensure that the control solution is homogenous.
- Analyze the control using the procedures described on page 2 (Specimen collection) and page 3 (Running samples on the Analyzer).
- Compare the test results with the values listed on the front page of the Afinion™ HbA1c Control Package Insert.

What do I do if Afinion™ HbA1c Control results are not within the acceptable range?

- Do not analyze any patient samples.
- Check the control vial label to make sure it is not expired.
- Ensure that the control has not been used for more than 60 days.
- Verify that the controls and test cartridges have been stored correctly.
- Verify that there is no visual sign of bacterial or fungal growth in the control vial.

Correct any procedural error. Re-test the control.

If the control values are still not within acceptable range, repeat the test using a new vial of control. If the control results are still not acceptable, call Afinion™ Technical Support.

Technical Support?

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