

CLIA Statement

Afinion™ HbA1c Dx is categorized as moderate complexity under the Clinical Improvement Amendment of 1988 (CLIA'88).

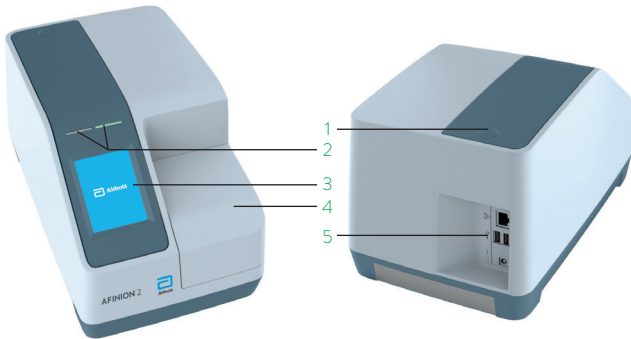
Important!

- Read the entire Afinion™ HbA1c Dx Quick Guide before testing patient samples or controls.
- See the AFINION™ 2 Analyzer User Manual for more information about the operation of the analyzer and test cartridge.
- See the Afinion HbA1c Dx Package Insert for more information about the HbA1c Dx 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™ 2 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”.

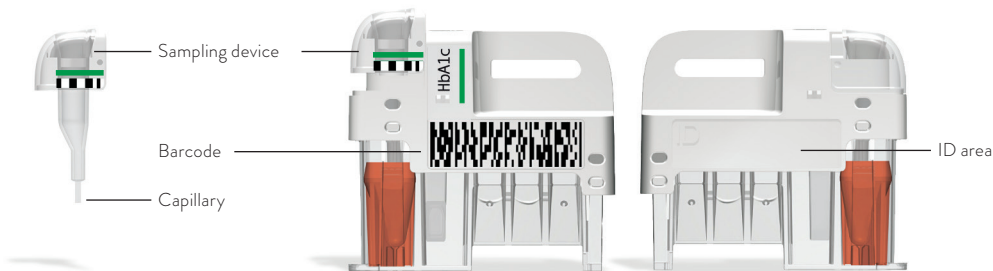
Important Touch Buttons

- Patient sample mode
- Control mode
- Patient ID
- Control ID
- Enter
- Accept

Assay Specific Information Codes

Code	Cause
103	Hemoglobin below 6.0 g/dL
104	Hemoglobin above 20.0 g/dL
105	HbA1c below 4.00%
106	HbA1c above 15.00%

AFINION™ HbA1c Dx Test Cartridge



## 2 Prepare for Testing

- Switch the analyzer on.
- Allow 15 minutes for the test cartridge to reach operating temperature 18-30°C (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.



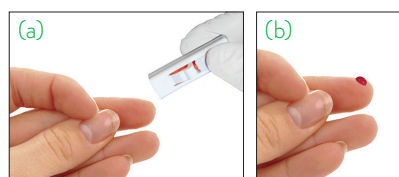
## 3 Procedure for Collecting the Sample

### Sampling from a Control Vial

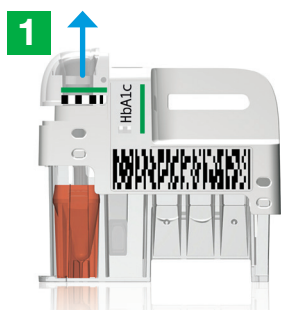
Follow the procedure described below. See page 4 for control testing recommendations.

### Sampling from Finger

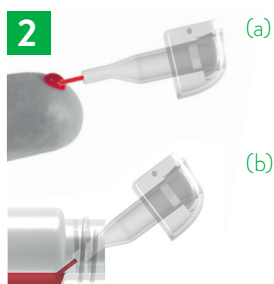
- Always use gloves.
- Cleanse the finger using alcohol. Allow the area to air dry.
- Use a lancet and firmly prick the finger (a). Properly dispose the lancet.
- Allow a good drop of blood to form before sampling (b).
- Apply direct pressure to the wound site with a clean gauze pad.



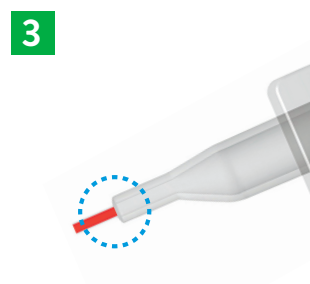
## Specimen Collection using the AFINION™ HbA1c Dx Test Cartridge



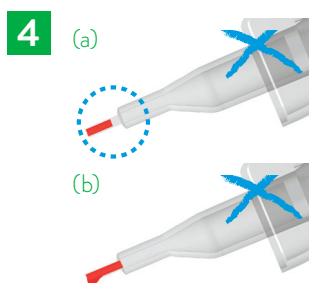
Pull up the sampling device.



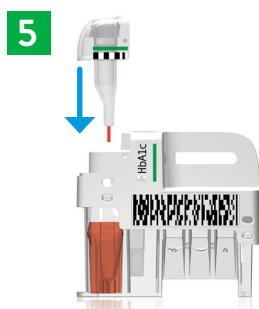
Touch the surface of the blood drop (a) or control (b).



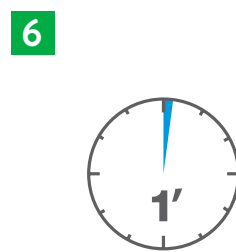
Fill the capillary to the end. It is not possible to overfill.



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



Insert the sampling device immediately.



Within 1 minute place the test cartridge in the analyzer.

## 4 Running Samples on the Analyzer

**Patient Sample:**

Touch  for patient samples.

**Control:**

Touch  for controls.



The lid opens automatically. Insert the test cartridge. The barcode should face left.




Close the lid manually to start the test.

**Patient Sample:**

Touch  and enter patient ID.

**Control:**

Touch  and enter control ID.

Enter ID during processing.

Touch  to confirm.



Record the result when it appears on the screen.

Touch  to accept.



The lid opens automatically. Remove and discard the cartridge.

Close the lid manually.

### Assay specific Codes

Assay specific information codes are listed on page 1. Consult the AFINION 2 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 Afinion HbA1c Dx 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 1-866-216-9505. This is a toll free number.  
Available for use only in the United States of America.

## Control Testing

Read the entire Afinion HbA1c Control Package Insert before use.

### How often do I have to run controls?

It is recommended analyzing controls:

- With each new shipment of HbA1c Dx kits.
- With each new lot of HbA1c Dx 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 45 minutes.
- Mix the control material thoroughly by shaking the vial for 30 seconds. A Vortex mixer may be used.
- 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. Retest 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 Technical Support.

### Technical Support?

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