

PREPARING FOR ANALYSIS



Patient sample

- Use capillary blood directly from finger, or venous blood (with EDTA, heparin, citrate or NaF).
- Venous whole blood with anticoagulants (except NaF) can be stored refrigerated (2-8°C) for 10 days. Capillary samples cannot be stored.
- Mix the sample by inverting the tube 8-10 times before use.



Afinion™ HbA1c Control

- Store the controls refrigerated (2-8°C). Opened controls are stable for 60 days.
- Allow the control to reach a temperature of 15-25°C before use, which takes approximately 30 minutes.
- Mix the control thoroughly by shaking the vial for 30 seconds before use.
- The measured value should be within the acceptable range stated in the Afinion™ HbA1c Control Package Insert.



Afinion™ HbA1c Test Cartridge

- Store the test kit refrigerated (2-8°C) until the expiry date or at room temperature (15-25°C) for maximum 90 days.
- The Test Cartridge must reach a temperature of 18-30°C before use; leave the unopened foil pouch on the bench for at least 15 minutes.
- Use the Test Cartridge within 10 minutes after opening the foil pouch.
- Hold the Test Cartridge by the handle.



Afinion™ AS100 Analyzer

- Switch on the Analyzer and optionally enter the operator ID.
- Analyse patient samples and controls following the test procedures on the reverse side.
- An information code might be displayed during analysis. The possible causes and actions to take are listed in the Afinion™ AS100 User Manual.
- Information codes specific for the Afinion™ HbA1c assay:



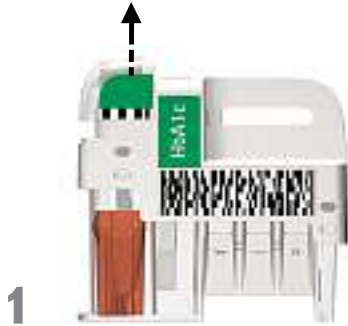
Code	Cause
103	Hemoglobin below 6 g/dL
104	Hemoglobin above 20 g/dL
105	HbA1c below 4.0%
106	HbA1c above 15.0%



Consult the Afinion™ user instructions for complete information:

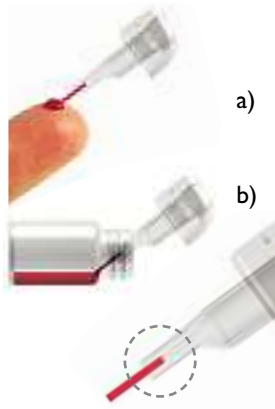
- Afinion™ HbA1c Package Insert
- Afinion™ HbA1c Control Package Insert
- Afinion™ AS100 User Manual

TESTING PROCEDURE



1

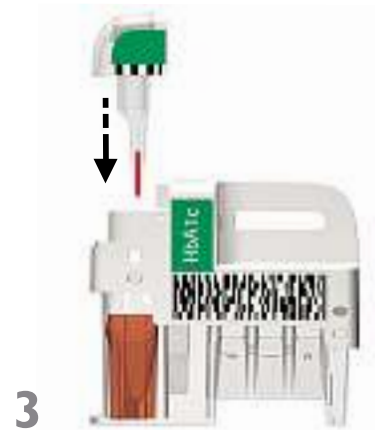
Pull the sampling device straight up from the Test Cartridge.



2

Fill the capillary completely with patient sample (a) or control (b).

Do not wipe off the capillary.



3

Replace the sampling device immediately.

Analysis of the Test Cartridge must start within 1 minute.



4

Touch for patient samples, or touch for controls.

The lid opens automatically.



5

Insert the Test Cartridge with the barcode facing left.



6

Close the lid manually to start analysing.



7

Touch and enter patient ID, or touch and enter control ID.

Touch to confirm.



8

Record the result when it appears on the screen.

Touch to accept.

The lid opens automatically.



9

Remove and immediately discard the used Test Cartridge.

Close the lid manually when the Analyzer is not in use.