



Abbott

AFINION™ HbA1c CONTROL

REF 1116975

For use with the Alere Afinion AS100 Analyzer/
Afinion 2 Analyzer, the Afinion HbA1c Test and
the Afinion HbA1c Dx Test.



1116913 Rev. A 2019/01

BIBLIOGRAPHY

1. Jeppsson, JO et al., Approved IFCC Reference Method for the Measurement of HbA1c in Human Blood, Clin Chem Lab Med. 2002; 40(1):78-89.

TECHNICAL SUPPORT

The manufacturer provides a toll free line for technical assistance. Call 1-866-216-9505. The toll free number is available for use only in the United States of America.

SYMBOLS

The following symbols are used in the labeling of Afinion HbA1c Control.

	Conformity to the European directive 98/79/EC on <i>in vitro</i> diagnostic medical devices.
	Warnings and precautions
	Consult the Afinion User Instructions
	<i>In Vitro</i> Diagnostic Medical Device
	Catalogue number
	Lot number
	Expiration date (year-month-day)
	Storage temperature 2-8° C (36-46° F)
	Control C I
	Control C II
	Biological risk
	Manufacturer
	Date of manufacture



Abbott Diagnostics Technologies AS

Kjelsåsveien 161
P.O. Box 6863 Rodeløkka
NO-0504 Oslo, Norway
www.abbott.com/poct

ISO 13485 certified company

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AFINION™ HbA1c CONTROL

For use with the Alere Afinion™ AS100 Analyzer/Afinion™ 2 Analyzer, the Afinion™ HbA1c Test and the Afinion™ HbA1c Dx Test.

PRODUCT DESCRIPTION

Intended use

Afinion™ HbA1c Control contains liquid preparations of stabilized porcine whole blood (Control C I) and human whole blood (Control C II). The Afinion HbA1c Controls have been designed for use with the Afinion™ Analyzer, the Afinion™ HbA1c Test and the Afinion™ HbA1c Dx Test.

Quality control testing using the Afinion HbA1c Control should be done to confirm that your Afinion Analyzer System is working properly and provides reliable results. Only when controls are used routinely and the values obtained are within acceptable ranges can accurate results for patient samples be assured.

Kit contents

1 x 0.5 mL Control C I: Stabilized preparation from porcine whole blood.
1 x 0.5 mL Control C II: Stabilized preparation from human whole blood.
1 package insert

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- The Afinion HbA1c Controls are potentially infectious. Proper handling and disposal methods should be followed in accordance with local, state and federal regulations. Use personal protective equipment.
- Control C II source material was found to be non-reactive for HbsAg, HCV, HIV-I and HIV-II.
- Do not use the Afinion HbA1c Controls after their expiration date or if they have not been stored in accordance with recommendations.
- Discard the vial if there is evidence of microbial or fungal contamination.

STORAGE INSTRUCTIONS

- The expiration date of the kit only applies if the product is stored at 2-8°C (36-46°F) in the original container.
- Avoid exposure to direct sunlight and temperatures above 30°C (86°F).
- Do not freeze.

Unopened control vials

Unopened control vials are stable until expiration date indicated on the vial label when stored refrigerated 2-8°C (36-46°F).

Opened control vials

- Opened control vials are stable for 60 days when stored refrigerated 2-8°C (36-46°F). It is recommended to note the date of opening and the new expiration date on the vial label and on the kit label.
- Replace the cap immediately after use.
- Always store the control vials refrigerated 2-8°C (36-46°F) when not in use.
- Opened control vials should be stored in an upright position.

ANALYZING A CONTROL

It is recommended to keep a permanent record of all quality control results. The Afinion Analyzer automatically stores the control results in a separate record. Consult the Afinion Analyzer User Manual.

Frequency of control testing

Controls should be analyzed:

- with each new shipment of Afinion HbA1c or Afinion HbA1c Dx Test Kits.
- with each new lot of Afinion HbA1c or Afinion HbA1c Dx Test Kits.
- at least every 30 days.
- when training new operators in correct use of the Afinion HbA1c Test Kit and Afinion Analyzer.
- anytime an unexpected test result is obtained. Consult the package insert for the Afinion HbA1c test in use, section "Interpretation of results".

If local, state and/or federal regulations require more frequent testing of control materials, then quality control should be performed in compliance with these regulations.

CLIA Waived laboratories should follow the manufacturer's quality control guidelines.

Test Procedure

Consult the Afinion Analyzer User Manual for operation of the analyzer and general handling of the test cartridge.

- Allow the control material to reach ambient operating temperature 18-30°C (64-86°F) before use, which takes approximately 45 minutes.
- Mix the control material thoroughly by shaking the vial for 30 seconds. A Vortex mixer may be used.
- Inspect the vial and ensure that the solution is homogenous.
- Collect a sample using the Afinion HbA1c Test Cartridge sampling device. The sample can be extracted from the vial or the cap.
- Clean the outside of the control vial neck and replace the cap.
- Immediately return the control vial back to the refrigerator after use.

A detailed, illustrated instruction on how to analyze a control sample is provided in the Afinion HbA1c Quick Guide.

TRACEABILITY

The standardization of Afinion HbA1c / Afinion HbA1c Dx is traceable to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Reference Method¹.

The target values for Afinion HbA1c Control C I and Control C II are determined by analyzing each control with one lot Afinion HbA1c in a minimum of 12 runs per control level, using minimum 4 analyzers. The range of each control level is set to average $\pm 10\%$.

The target values of the Afinion HbA1c Controls are determined in accordance with the standardization of HbA1c at Diabetes Control and Complications Trial (DCCT) level. The % HbA1c acceptable ranges for the two controls are stated on the front page of this package insert.

INTERPRETATION OF RESULTS



If a control result outside the acceptable range is obtained, follow the recommendations given in the package insert for the Afinion HbA1c test in use, section "Verifying the control results".

Patient results must be declared invalid if the control does not perform as expected. If the problem persists, contact Afinion Technical Support for advice before analyzing patient samples.