



AFINION™ HbA1c CALIBRATION VERIFICATION

REF 1116792

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

1116911 Rev. A 2019/03



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.
2. Weykamp et al., The IFCC Reference Measurement System for HbA1c: a 6-year progress report. Clin Chem 2008; 54(2):240-248.
3. Hoelzel W et al., IFCC reference system for measurement of haemoglobin A1c in human blood and the national standardization schemes in the United States, Japan and Sweden: a method comparison study. Clin Chem 2004; 50(1):166-174.
4. The Diabetes Control and Complications Trial Research Group, The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus. N Engl J Med 1993; 329:977-986.

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

Symbols used in the labeling of Afinion HbA1c Calibration Verification.

	Conformity to the European directive 98/79/EC on in vitro diagnostic medical devices.
	Warnings and precautions
	Consult the Afinion™ User Instructions
	In Vitro Diagnostic Medical Device
	Catalogue number
	Lot number
	Expiration date (year-month-day)
	Storage temperature 2-8° C (36-46° F)
	Calibration Verification L1
	Calibration Verification L2
	Calibration Verification L3
	Biological risk
	Manufacturer
	Date of manufacture (year-month-day)



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AFINION™ HbA1c CALIBRATION VERIFICATION

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

PRODUCT DESCRIPTION

Intended use

Afinion HbA1c Calibration Verification contains liquid preparations of stabilized porcine whole blood and human whole blood.

The Afinion HbA1c Calibration Verification materials are to be used with the Alere Afinion AS100 Analyzer/Afinion 2 Analyzer System to verify the calibration of the Afinion HbA1c Dx Test throughout the measurable range.

Kit contents

1 x 0.5 mL Calibration Verification L1: Stabilized preparation from porcine whole blood.
1 x 0.5 mL Calibration Verification L2: Stabilized preparation from human whole blood.
1 x 0.5 mL Calibration Verification L3: Stabilized preparation from human whole blood.
1 package insert

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- The Afinion HbA1c Calibration Verification materials are potentially infectious. Proper handling and disposal methods should be followed in accordance with local, state and federal regulations. Use personal protective equipment.
- Cal Ver L2 and Cal Ver L3 source material was found to be non-reactive for HbsAg, HCV, HIV-I and HIV-II.
- Do not use the Afinion HbA1c Calibration Verification materials 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 vials

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

Opened vials

- Opened calibration verification vials are stable for 15 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 vials refrigerated 2-8°C (36-46°F) when not in use.
- Opened vials should be stored in an upright position.

FREQUENCY OF CALIBRATION VERIFICATION TESTING

Since the Afinion Analyzer System does not allow user calibration, calibration verification is not required every six months by CMS, COLA and TJC. However, CAP still requires it. Even though periodic calibration verification may not be required by CMS, COLA, and TJC it is considered good laboratory practice and may be useful when troubleshooting a test system.

Any state and local requirements for calibration verification testing every 6 months must be followed.

TEST PROCEDURE

It is recommended to keep a permanent record of calibration verification results. Consult the Afinion Analyzer User Manual for operation of the analyzer and general handling of the test cartridge.

- Allow the calibration verification material to reach ambient operating temperature 18-30°C (64-86°F) before use, which takes approximately 45 minutes.
- Mix the calibration verification 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 Dx Test Cartridge sampling device. The sample can be extracted from the vial or the cap.
- Clean the outside of the vial neck and replace the cap.
- Immediately return the vial back to the refrigerator after use.
- Select the Afinion Analyzer patient sample mode for processing the calibration verification material. Control mode should not be used for this material. Consult the Afinion Analyzer User Manual.

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

TRACEABILITY

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

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

PERFORMANCE CHARACTERISTICS

The % HbA1c acceptable ranges for the three calibration verification materials are stated on the front page of this package insert. The values represent the results that should be obtained using the Afinion HbA1c Dx Test. The performance of this product has not been determined using other systems.

CALIBRATION VERIFICATION AND ACCEPTABILITY OF RESULTS



If one or more of the calibration verifications results fall outside the acceptable range, test another vial of the same calibration verification material. If the material does not fall into the acceptable range after retesting, contact Technical Support.

LIMITATIONS OF THE PROCEDURE

The % HbA1c acceptable ranges were obtained using test kits that were available at the time this product was manufactured.