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.

BIBLIOGRAPHY

SYMBOLS
- Conformity to the European directive 98/79/EC on in vitro diagnostic medical devices.
- Warnings and precautions
- Consult the Alere Afinion™ user instructions
- In Vitro Diagnostic Medical Device
- Catalogue number
- Lot number
- Expiration date (year-month)
- Storage temperature 2-8° C (36-46° F)
- Control C I
- Control C II
- Biological risk
- Manufacturer
Alere Affinion™ HbA1c Control

For use with the Alere Affinion™ AS100 Analyzer and the Alere Affinion™ HbA1c test.

PRODUCT DESCRIPTION

Intended use
Alere Affinion™ HbA1c Control contains liquid preparations of stabilized porcine whole blood (Control C I) and human whole blood (Control C II). The Alere Affinion™ HbA1c controls have been designed for use with the Alere Affinion™ AS100 Analyzer and the Alere Affinion™ HbA1c test.

Quality control testing using the Alere Affinion™ HbA1c Control should be done to confirm that your Alere Affinion™ 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 Control C I: Stabilized preparation from porcine whole blood (1 x 0.5 mL).
1 Control C II: Stabilized preparation from human whole blood (1 x 0.5 mL).
1 Package Insert

WARNINGS AND PRECAUTIONS

• For in vitro diagnostic use.
• The Alere Affinion™ 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.
• The controls contain sodium azide as a preservative. The concentration is <0.1%, which is below that considered hazardous in normal use¹.
• Do not use the Alere Affinion™ 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. The expiration date is the last day of the month stated on the outer container and vial label.
• 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 expiry date on the vial 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 Alere Affinion™ AS100 Analyzer automatically stores the control results in a separate record. Consult the Alere Affinion™ AS100 Analyzer User Manual.

Frequency of control testing Controls should be analyzed:
• With each new shipment of Alere Affinion™ HbA1c test kits.
• With each new lot of Alere Affinion™ HbA1c test kits.
• At least every 30 days.
• When training new operators in correct use of the Alere Affinion™ HbA1c test kit and Alere Affinion™ AS100 Analyzer.
• Anytime an unexpected test result is obtained (section “Interpretation of results”, Alere Affinion™ HbA1c Package Insert).

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 Alere Affinion™ AS100 Analyzer User Manual for information related to the general operation of the Analyzer and Alere Affinion™ Test Cartridge handling.

• Allow the control material to reach ambient operating temperature 18-30°C (64-86°F) before use, which takes approximately 30 minutes.
• Mix the control material thoroughly by shaking the vial for 30 seconds.
• Inspect the vial and ensure that the solution is homogenous.
• Collect a sample using the Alere Affinion™ 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 Alere Affinion™ HbA1c Quick Guide.

TRACEABILITY

The standardization of Alere Affinion™ HbA1c is traceable to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Reference Method².

Target values of the Alere Affinion™ HbA1c controls are assigned by analyzing each control with three different Alere Affinion™ AS100 Analyzers and two different lots of Alere Affinion™ HbA1c test kit to a total of 18 runs for each level. The range of each control level is based on Tonks Limit (allowable limits of error - A.L.E.) for HbA1c and set to average ±10 %.

The target values of the Alere Affinion™ HbA1c controls are determined in accordance with the standardization of HbA1c at Diabetes Control and Complications Trial (DCCT) level. The % HbA1c target values and acceptable ranges for the two controls are stated on the front page of this Package Insert. Patient samples are not analysed until control results are within acceptable limits.

INTERPRETATION OF RESULTS

If a control result outside the acceptable range is obtained, follow the recommendations given in the Alere Affinion™ HbA1c Package Insert (section “Verifying the control results”).

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