



Audit® MicroFD™ Glycohemoglobin A1c Control

Cat. No. **K061M-8**
 Contents 8 x 0.5mL (Multi-Level)

Lot No. 06126

Expires 1/20/11

For In Vitro Diagnostic Use Only.

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INTENDED USE

Audit® MicroFD™ Glycohemoglobin A1c Control is a bi-level assayed control consisting of human serum based solutions. It is intended to simulate human patient serum samples for the purpose of monitoring the precision of laboratory testing procedures for Glycohemoglobin A1c assays. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides.

SUMMARY AND PRINCIPLE

Good laboratory practices require that stable reference materials be used to verify the accuracy and precision of testing methods and techniques. Audit® MicroFD™ Glycohemoglobin A1c Control may be used as one would use human serum to obtain the stated Glycohemoglobin A1c values.

REAGENTS

Audit® MicroFD™ Glycohemoglobin A1c Control is prepared using human whole blood with Glycohemoglobin A1c added to achieve the desired concentration levels, and 0.1% sodium azide as a preservative. Audit® MicroFD™ Glycohemoglobin A1c Control is a lyophilized product manufactured according to standard quality control procedures. The manufacturer guarantees stability and consistency of this product.

WARNINGS AND PRECAUTIONS

Because this product is of human origin, it should be handled as though capable of transmitting infectious diseases. Each serum, plasma or whole blood donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV and nonreactive for HBSAg. Because no test method can offer complete assurance that HIV, hepatitis B virus, and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples be handled at the Centers for Disease Control's Biosafety Level 2.

This product contains less than 0.1% sodium azide that may react with lead and copper plumbing to form potentially explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.

Audit® MicroFD™ Glycohemoglobin A1c Control is intended solely for in vitro diagnostic use for the purpose described on the labeling. Audit® MicroControls™, Inc. shall not be liable for any unclaimed damages arising from any other usage.

STORAGE AND STABILITY

Audit® MicroFD™ Glycohemoglobin A1c Control is stored at 2-8°C and will remain stable in the unopened vial until the expiration date. After opening, the contents should be used according to the instrument manufacturer's instructions and immediately returned to 2-8°C.

When used to monitor the precision of laboratory testing procedures for Glycohemoglobin A1c assays, Audit® MicroFD™ Glycohemoglobin A1c Control has an open vial stability of up to 7 days for non-Dade instruments and 21 days for Dade instruments under the proper storage conditions. Leaving the vial uncapped, or prolonging its time at room temperature, will void this open vial stability claim. Make sure the contents of the vial are well mixed before use.

PROCEDURE

Follow the manufacturer's instructions provided for Glycohemoglobin A1c procedures. Verify that the lot number on the vial matches the assay sheet. To avoid evaporation, do not leave the vial uncapped. Controls should be run:

1. daily, in conjunction with patient samples.
2. as recommended by the instrument manufacturer.
3. as required by the relevant regulatory agency.

Materials provided

- Audit® MicroFD™ Glycohemoglobin A1c Control, Multi-Level, 8 x 0.5mL

EXPECTED VALUES

The performance range for each level, based on data by combining estimates of assay variance as determined by participating laboratories using approved FDA instruments and reagents, is provided below. Average values obtained in the laboratory should fall within the performance range although the recovery may not be identical with the mean value listed. Variation between labs will be greater than the precision for any one instrument. Accuracy and precision depend on differences in equipment, reagents, supplies and techniques. Therefore, a lab must establish its own acceptable target values and ranges.

Raw data may be entered via the AUDITOR™ QC Program at www.auditmicro.com. Call (866) 25-AUDIT for more information.

INSTRUCTIONS FOR USE

1. Remove a vial from the package, reconstitute with 0.5mL of deionized water using a volumetric pipet, and gently swirl occasionally for 10 minutes. Do not shake. Do not mix mechanically.
2. Refer to instrument or assay instruction manual for analyzing control material.
3. After sampling, replace stopper and return to original package for maximum open vial stability at 2-8°C.

LIMITATIONS OF THE PROCEDURE

Variations in instruments and in the temperature of the testing material may result in accuracy and linearity differences. Make sure that the vial is brought to room temperature before testing. If the liquid in the vial becomes frozen, discard and use another vial, as the results will not be valid.

ORDERING INFORMATION

Product Number	Product Description	Product Packaging
K061M-8	Audit® MicroFD™ Glycohemoglobin Control, Level 1 and 2	8 x 0.5mL

Assay Values

Level 1 (Lot No. 06124)	Abbott ARCHITECT®	4.0 – 5.4%
	Beckman Synchron® CX® and DxC Systems	3.8 – 5.1%
	Alfa Wassermann ACE®/ACE Alera®	4.8 – 6.6%
	Bio-Rad VARIANT II™	4.8 – 6.4%
	Dade Dimension®	4.7 – 6.3%
	Primus® PDQ™	4.8 – 6.6%
	Roche COBAS INTEGRA®	4.8 – 6.6%
	Tosoh G7	4.8 – 6.4%
	Tosoh 2.2	5.0 – 6.8%
	Level 2 (Lot No. 06125)	Abbott ARCHITECT®
Beckman Synchron® CX® and DxC Systems		9.1 – 12.3%
Alfa Wassermann ACE®/ACE Alera®		10.4 – 14.0%
Bio-Rad VARIANT II™		9.3 – 12.5%
Dade Dimension®		9.9 – 13.5%
Primus® PDQ™		12.8 – 17.4%
Roche COBAS INTEGRA®		9.9 – 13.5%
Tosoh G7		9.4 – 12.8%
Tosoh 2.2		9.9 – 13.3%