



Audit™ MicroFD™ Glycohemoglobin A1c Control

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

Lot No. Level 1 – 04483
Level 2 – 04484

Expires 07/31/06

For In Vitro Diagnostic Use Only.

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INTENDED USE

Audit™ MicroFD™ Glycohemoglobin A1c Control is a bi-level reference 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.

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 an in vitro diagnostic control composed of a buffered bacteriostatic and fungistatic human serum matrix.

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 for twenty-four months from the date of manufacture. 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 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

Materials required (but not provided)

- Distilled or deionized water

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

INSTRUCTIONS FOR USE

1. Remove a vial from the package, reconstitute with 0.5mL of deionized water 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 A1c Control	8 x 0.5mL

Assay Values		
Level 1 (Lot No. 04483)	Dade Dimension®	4.6 – 7.0 %
	Bio-Rad VARIANT II™	4.2 – 6.2 %
	Roche COBAS INTEGRA®	4.5 – 6.7 %
	Tosoh G7	5.3 – 7.9 %
	Tosoh 2.2	4.3 – 6.5 %
Level 1 (Lot No. 04484)	Dade Dimension®	7.3 – 10.9 %
	Bio-Rad VARIANT II™	7.0 – 10.6 %
	Roche COBAS INTEGRA®	7.7 – 11.5 %
	Tosoh G7	8.2 – 12.4 %
	Tosoh 2.2	7.3 – 10.9 %

Dimension® is a registered trademark of Dade-Behring, Inc. VARIANT™ is a registered trademark of Bio-Rad Laboratories, Inc. COBAS INTEGRA® is a registered trademark of Roche Diagnostics.