



Audit™ MicroTUBE™ Ammonia/Ethanol Control

Cat. No. **K062M-6**
Contents 6 x 3mL (Level 1 and 2)

Lot No. Level 1 – 04737
Level 2 – 04738

Expires 09/14/06

For In Vitro Diagnostic Use Only.

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INTENDED USE

Audit™ MicroTUBE™ Ammonia/Ethanol Control is an unassayed, stable, ready-to-use liquid, bi-level reference control for use with assays designed to quantitate Ammonia and Ethanol.

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™ MicroTUBE™ Ammonia/Ethanol Control may be used as one would use human serum to obtain the stated Ammonia and Ethanol values. This control will assist in the evaluation of proper performance of Ammonia and Ethanol assays.

REAGENTS

Audit™ MicroTUBE™ Ammonia/Ethanol Control is prepared using human serum with purified Ammonia and Ethanol added to achieve the desired concentration levels, and 0.1% sodium azide as a preservative. Audit™ MicroTUBE™ Ammonia/Ethanol Control is a ready to use liquid 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 may contain 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™ MicroTUBE™ Ammonia/Ethanol 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™ MicroTUBE™ Ammonia/Ethanol 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. Audit™ MicroTUBE™ Ammonia/Ethanol Control has an open vial stability of up to 30 days under the proper storage conditions. Leaving the vial uncapped will void this open vial stability claim.

PROCEDURE

Follow the manufacturer's instructions provided for Ammonia and Ethanol procedures. Verify that the lot number on the vial matches the package insert. 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.

TARGET VALUES

A target value for each level, based on data from Q.A. analyses, is provided below. 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. Do not shake. Do not mix mechanically.
2. Insert the needle of a syringe into the septum of the vial for sample transfer.
3. Refer to instrument or assay instruction manual for analyzing control material.
4. After sampling, return to original package at 2-8°C to obtain the maximum open vial stability.

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
K062M-6	Audit™ MicroTUBE™ Ammonia/Ethanol Control, Level 1 and 2	6 x 3mL

Target Values		
Level 1 (Lot No. 04737)	Ammonia	72 µmol/L
	Ethanol	37 mg/dL
Level 2 (Lot No. 04738)	Ammonia	398 µmol/L
	Ethanol	125 mg/dL