



Audit™ MicroTUBE™ Homocysteine Control

Cat. No. **K020**
Contents 30 x 2mL (Level 1) K0201-30
30 x 2mL (Level 2) K0202-30

Lot No. Level 1 – 03151
Level 2 – 03152

Expires 02/27/05

For In Vitro Diagnostic Use Only.

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INTENDED USE

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

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

REAGENTS

Audit™ MicroTUBE™ Homocysteine Control is prepared using human serum with purified homocysteine added to achieve the desired concentration levels, and 0.1% sodium azide as a preservative. Audit™ MicroTUBE™ Homocysteine 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™ Homocysteine 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™ Homocysteine Control is stored at 2-8°C and will remain stable in the unopened microtube for two years 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. Audit™ MicroTUBE™ Homocysteine Control has an open microtube stability of up to 14 days under the proper storage conditions. Leaving the microtube uncapped will void this open tube stability claim.

PROCEDURE

Follow the manufacturer's instructions provided for Homocysteine procedures. Verify that the lot number on the microtube matches the assay sheet. To avoid evaporation, do not leave the microtube 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 microtube from the package and mix by inversion. Do not shake. Do not mix mechanically.
2. Remove the cap and clip off the end of the microtube with scissors.
3. Refer to instrument or assay instruction manual for analyzing control material.
4. After sampling, replace cap 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 microtube is brought to room temperature before testing. If the liquid in the microtube becomes frozen, discard and use another microtube, as the results will not be valid.

ORDERING INFORMATION

Product Number	Product Description	Product Packaging
K0201-6	Audit™ MicroTUBE™ Homocysteine Control, Level 1	6 x 2mL
K0201-30	Audit™ MicroTUBE™ Homocysteine Control, Level 1	30 x 2mL
K0202-6	Audit™ MicroTUBE™ Homocysteine Control, Level 2	6 x 2mL
K0202-30	Audit™ MicroTUBE™ Homocysteine Control, Level 2	30 x 2mL
K020M-6	Audit™ MicroTUBE™ Homocysteine Control, Level 1 and 2	6 x 2mL
K020M-30	Audit™ MicroTUBE™ Homocysteine Control, Level 1 and 2	30 x 2mL

Target Values

Level 1 (Lot No. 03151)	8 µmol/L
Level 2 (Lot No. 03152)	43 µmol/L