



Audit® MicroLQ™ Homocysteine Control

Cat. No. **K020M-6**
Contents 6 x 2mL (Level 1)
6 x 2mL (Level 2)

Lot No. Level 1 – 06074
Level 2 – 06075

Expires 08/27/10

For In Vitro Diagnostic Use Only.

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INTENDED USE

Audit® MicroLQ™ Homocysteine Control is an unassayed, stable, ready-to-use liquid, bi-level reference control for use with assays designed to quantitate Homocysteine. It is intended to simulate human patient samples for the purpose of monitoring the precision of laboratory testing procedures for Homocysteine 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® MicroLQ™ 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® MicroLQ™ 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® MicroLQ™ 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 non-reactive 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® MicroLQ™ 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® MicroLQ™ Homocysteine Control is stored at 2-8°C and will remain stable in the unopened vial 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® MicroLQ™ Homocysteine Control has an open vial stability of up to 14 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 Homocysteine 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® MicroLQ™ Homocysteine Control, Bi-Level, 6 x 2mL

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 and mix by inversion. 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
K020M-6	Audit® MicroLQ™ Homocysteine Control, Level 1 and 2	6 x 2mL

Target Values	
Level 1 (Lot No. 06074)	9 µmol/L
Level 2 (Lot No. 06075)	45 µmol/L