



MLT LIGAND CONTROL - TRI LEVEL PRODUCT CODE ML-3008  
LOT MLAC144 EXP: 2027-01-16

INTENDED USE

The Multi-Target Controls are intended for use as an assigned quality control material to monitor the consistency of performance of laboratory test procedures associated with determination. This product is a human-serum based, lyophilized control stabilized with preservatives and can be used with all ELISA and CLIA methods.

SUMMARY AND EXPLANATION

The use of quality control material is essential in the assessment of precision in the clinical laboratory in an integral part of laboratory practice. Controls that contain varied levels of analytes are necessary to insure precision and accuracy in immunoassay systems.

REAGENTS

Manufacturer's Multi-Target Controls are intended to be used in the exact manner as patient samples. The control is packaged at a fill of 2.0 mL each. The analyte activities are adjusted to concentrations in the low, middle and high range in order to monitor the efficacy of the procedure in use.

INSTRUCTIONS FOR USE

- 1) Bring the vials to room temperature before use.
2) Carefully remove and remove cap.
3) Add 0.5 mL of distilled or deionized water to each vial. Close the cap tightly and let the contents mix thoroughly for 30 minutes.
4) Aliquot the materials in 0.5 mL aliquots in cryo vials and store at -20°C.

STORAGE, STABILITY AND DISPOSAL

This product will be stable until the expiration date when stored unopened at 2 to 8°C. Once the control is reconstituted, all analyses will be stable for 7 days when stored tightly capped at 2 to 8°C, with the following exceptions: 1) C-Peptide, PRL, PRL-Seg, should be assayed immediately after reconstitution, and 2) Folate and Insulin will be stable for 1 day. To avoid contamination, do not reconstituted into aliquot required quantities the vials before each use.

After reconstituting, controls should be tightly capped and returned to refrigerator 2 to 8°C as soon as practical after usage. (Long term room temperature storage is not supported.) After reconstituting, controls should be tightly capped and frozen within 2 hours. Once frozen, do not rethaw the control; discard remaining material. It is recommended that customers aliquot control into separate containers before freezing to allow for usage on different days. Outdated material should be discarded as a biohazardous component.

Table with 3 columns: STORAGE, STABILITY, TEMPERATURE. Rows include Unopened, Reconstituted, Opened, and Reconstituted, Opened with corresponding stability and temperature ranges.

EXPECTED RANGE OF VALUES

The mean values printed in this insert were derived from replicate analyses and are specific for the lot of product. The tests listed were performed by Monoclonal QA using representative lots of this product, as well as those of Monoclonal's Accredited CLIA and Accredited CLIA recipients.

Individual laboratory means should fall within the corresponding acceptable range. However, laboratory means may vary from the listed values during the life of this control. Therefore, each laboratory should establish its own means and acceptable ranges for the product used, using Monoclonal's assignment only as a guide. A mean is stated to be measured for each of each consistency of the test. Variations over time and between laboratories may be caused by differences in laboratory personnel, (1) sample technique, (2) instrumentation and reagents, (3) storage duration from the stated manufacturer's procedure, and (4) modifications in the manufacturer's test procedure.

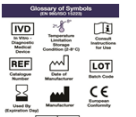
Refer to http://www.monoclonal.com/html/documents.html for any updated insert information.

WARNING AND PRECAUTIONS

FOR IN VITRO DIAGNOSTIC USE. All products that contain human serum have been found to be non-infective for HIV-1,2, HBV, HCV and PRP by FDA required tests. Since no known test can offer complete assurance that infectious agents are absent, all human serum products should be handled as potentially infectious and capable of transmitting disease. General laboratory procedures for handling blood products can be found in the Center for Disease Control / National Institute of Health, "Manual of Microbiological and Biomedical Laboratories", 2nd Edition, 1986, HSP Publication No. CDC 80-8395.

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Table titled 'EXPECTED RANGE OF VALUES FOR MULTILIGAND CONTROL - TRI LEVEL MASTER LOT MLAC144'. Columns include Analyte, Range, and Method. Rows list various analytes such as AFP, ALB, ALT, AST, BUN, C-peptide, etc., with their respective ranges and methods.