



MULTI LIGAND CONTROL- TRI LEVEL
LOT# MC(A-C)1A5

PRODUCT CODE: ML-300
EXP: 01-10

INTENDED USE

The Multi-ligand Controls are intended for use as an assayed quality control material to monitor the consistency of performance of laboratory test procedures associated with determination and monitoring of the clinical status. This product is human serum based, lyophilized control, stabilized with preservatives and can be used with all RIA, EIA, ELISA or FIA methods.

SUMMARY AND EXPLANATION

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

REAGENTS

Monobind's multi-ligand Controls are intended to be used in the exact manner as patient samples. The control is packaged as 6 vials of 3.0 ml. 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 unscrew and remove cap.
- 3). Add three (3) 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

The expiration date (<-20°C storage) is printed on each vial as well as on the outside container. After opening, any unused material is stable for 30 days when stored at 2-8°C (see below). Outdated material should be discarded as biohazardous component.

| STORAGE | STABILITY | TEMPERATURE |
|----------|------------------|-------------|
| Unopened | Printed on vial | 2 – 8°C |
| Opened | Thirty (30) days | 2 – 8°C |

EXPECTED RANGE OF VALUES

| | A | B | C | Manufacturer/Method |
|-----------------------------|-------------|-------------|-------------|----------------------|
| T3 in ng/ml | 0.89 ± 0.2 | 1.47 ± 0.3 | 3.36 ± 0.75 | Monobind/Elisa |
| T4 in µg/dl | 3.5 ± 0.7 | 8.8 ± 1.6 | 18.5 ± 3.6 | Monobind/Elisa |
| TSH in µU/ml | 0.56 ± 0.2 | 8.0 ± 1.6 | 16.4 ± 3.5 | Monobind/Elisa |
| fT3 in pg/ml | 2.1 ± 0.45 | 3.94 ± 1.0 | 12.0 ± 2.7 | Monobind/Elisa |
| fT4 in ng/dl | 0.26 ± 0.2 | 1.11 ± 0.3 | 4.32 ± 0.9 | Monobind/Elisa |
| TU in %U | 25.4 ± 2.5 | 34.7 ± 4.0 | 46.2 ± 5.0 | Monobind/Elisa |
| LH in mIU/ml | 1.74 ± 0.5 | 18.2 ± 4.0 | 54.7 ± 11.0 | Monobind/Elisa |
| FSH in mIU/ml | 14.5 ± 2.8 | 23.1 ± 5.0 | 79.8 ± 16 | Monobind/Elisa |
| hCG in mIU/ml | 4.9 ± 1.0 | 56.2 ± 12 | 229 ± 45.0 | Monobind/Elisa |
| PRL in ng/ml | 4.2 ± 1.0 | 12.9 ± 3.0 | 43.5 ± 11.0 | Monobind/Elisa |
| CEA in ng/l | 2.2 ± 0.8 | 18.1 ± 5.0 | 34 ± 7 | Monobind/Elisa |
| PSA in ng/ml | 0.6 ± 0.2 | 3.8 ± 1.0 | 22.4 ± 4.0 | Monobind/Elisa |
| fPSA | 0.3 ± 0.15 | 2.41 ± 0.5 | >10 ± | Monobind/Elisa |
| AFP in ng/ml | 11.3 ± 3.0 | 109.5 ± 23 | 190 ± 40 | Monobind/Elisa |
| DIG in ng/ml | 0.54 ± 18 | 1.56 ± 0.28 | 2.75 ± 0.6 | Monobind/Elisa |
| hGH in µIU/ml | 2.3 ± 0.6 | 7.7 ± 1.5 | 19.7 ± 4.0 | Monobind/Elisa |
| Insulin in µU/ml | 8.2 ± 2.5 | 44 ± 10 | 130 ± 30 | Monobind/Elisa |
| IgE in IU/ml | 45 ± 11.0 | 165.0 ± 35 | 330 ± 70 | Monobind/Elisa |
| C-Peptide in ng/ml | 1.1 ± 0.3 | 3.5 ± 1.0 | 6.2 ± 1.5 | Monobind/Elisa |
| Ferritin in ng/ml | 12.7 ± 6.0 | 118 ± 26 | 337 ± 76 | Monobind/Elisa |
| Aldosterone in pg/ml | 75 ± 12 | 250 ± 38 | 500 ± 75 | Target Value |
| 17-OH-Progesterone in ng/ml | 0.55 ± 0.15 | 2.5 ± 0.42 | 6.4 ± 1.4 | DPC/ Coated Tube RIA |
| Cortisol in µg/dl | 2.2 ± 0.4 | 13.9 ± 3 | 22.3 ± 5 | Bayer Centaur/ Chemi |
| Estriol in ng/ml | 2.0 ± 0.4 | 5.0 ± 1.1 | 10 ± 2.5 | Target Value |
| Estradiol in pg/ml | 64 ± 9.6 | 150 ± 25 | 380 ± 60 | Bayer Centaur/ Chemi |
| Progesterone in ng/ml | 1.42 ± 0.22 | 6.11 ± 1.0 | 16.22 ± 2.5 | Bayer Centaur/ Chemi |
| Testosterone in ng/ml | 0.58 ± 0.1 | 4.8 ± 1.0 | 8.19 ± 1.3 | Bayer Centaur/ Chemi |
| Androstenedione in ng/ml | 0.5 ± 0.1 | 3 ± 0.5 | 9 ± 1.5 | Target Value |
| DHEA-S in µg/dL | 27.3 ± 5.5 | 147 ± 30 | 397 ± 80 | DPC/ Coated Tube RIA |
| DHEA ng/mL | 1.5 ± 0.7 | 7.5 ± 1.5 | 20 ± 5.0 | DPC/ Coated Tube RIA |

Each laboratory should establish their own ranges for the product used. A trend log should be maintained for batch to batch consistency of the test. Large variations from the established mean may result from (a) improper technique, (b) improper dilutions from the stated manufacturer's procedure or (c) modifications of the test system by the manufacturer.

WARNING AND PRECAUTIONS

FOR IN VITRO DIAGNOSTIC USE

All products that contain human serum have been found to be non reactive for HIV 1&2, HIV-Ag, HBsAg, HCV and RPR 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 hazardous and capable of transmitting disease. Good laboratory procedures for handling blood products can be found in the Center for Disease Control / National Institute of Health, "Biosafety in Microbiological and Biomedical Laboratories," 2nd Edition, 1988, HHS Publication No. (CDC) 88-8395.

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