

PRODUCT CODE: ML-300 EXP: 2024-05-03 LOT#:MLAC1E1

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 a human-serum based, hyophilized control, stabilized with preservatives and can be used with all ELISA and CLIA 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

Minchind'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, dried. 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

- In Bird Nutr Univer TV U.S. It is all to room temperature before use.

 2) Carefully unscrew and remove cap.

 3) Add tree (3) in oil distilled or desionized water to each vial. Close the cap tightly and let the contents mix throughly for 30 minutes

 4) Allquot the materials in O.S. mil alliquots in cryo vials and store at -20°C.

This product will be stable until the equivalent and the state durapened at 2 to 8°C. Once the control is reconstructed, all analytes will be stable for 7 days when stored tiply; capped at 2 to 8°C with the following exceptions: 10 Peptide should be assayed immediately after reconstitution, and 2 Follate and fusual mild the stable for 1 day. To avoid contamination, it is recommended labs aliquot required quantities into vials before each use.

After reconstituting, controls should be tightly capped and returned to retrigerator 2 to 8° C as soon as practical after stages. Long learn more interpretative storage is not supported.) After reconstituting, controls should be tightly capped and fozors within 2-hours. Once thawed, do not reflereze the control, discard remaining material. It is recommended that costioners aliquot control into separate containers before freezing to allow for usage on different days. Outstated material should be discarded as a biohazordous composition.

| STORAGE | STABILITY | TEMPERATURE |
|-----------------------|------------------|-------------|
| Lyophilized, Unopened | Three (3) years | < 8°C |
| Reconstituted, Opened | Seven (7) days | 2 - 8°C |
| Reconstituted Opened | Ninoty (00) days | = 10°C |

EXPECTED RANGE OF VALUES

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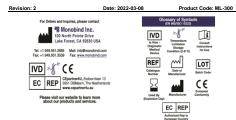
The mean values printed in this insert were derived from replicate analyses and are specific for this lot of product. The tests listed were performed by Monobind OA using representative lots of this product, as well as those of Monobind Accordingly EASA and Accordited CLIA reagents.

Individual laboratory means should fall within the corresponding acceptable range; however laboratory means may very from the lated values during the life of this control. Therefore, each laboratory should establish its own means and acceptable ranges for the product used, uniformly imported only as guide. A trend log should be maintained for batch to batch consistency of the test. Variations over time and between laboratories may be caused by all differences in laboratories may be caused by all differences in laboratories presented, b) improper technique, c) instrumentation and reagents, d) improper distorate from the stated manufacturer's procedure, and/ or e) modifications in the manufacturer's approach.

Refer to http://www.monobind.com/site/qc-documents.html for any updated insert inform

FOR IN VITRO DIAGNOSTIC USE

All products that contain human serum have been found to be non-reactive for HIV 182, HIV-Ag, HBsAg, HCV
and FRPR by FDA required tests. Since no known test can offer complete assurance that infectious agents are
absent, all human serum products should be handed as potentially hazardous and capable of transmitting
desease. Good laboratory procedures for handing blood products can be found in the Center for Disease Control
/ National Institute of Haalth, "Blosately in Microbiological and Biomedical Laboratories," 2nd Edition, 1988, HHS
Publication No. (CLU) 96-958.





EXPECTED RANGE OF VALUES FOR MULTI-LIGAND CONTROL - TRI LEVEL MASTER LOT:MLAC1E1

| Analyte | Range | Range | Range | Method |
|--------------------------------------|--------------------------------|----------------------------------|-------------------------------------|---------------------------------------|
| Allergy IgE in IU/ml | 14.73 ± 4.86 | 232.76 ± 76.81 | | MB ACCUBIND ELISA |
| Anemia Anemia | 13.50 ± 4.45 | 203.65 ± 67.20 | 83.70 ± 27.62 | MB ACCULITE CLIA |
| Ferritin in ng/ml | 39.05 ± 12.89 39.69 ± 13.10 | 62.54 ± 20.64 58.31 ± 19.24 | 349.38 ± 115.3 361.89 ± 119.42 | MB ACCUBIND ELISA MB ACCULITE CLIA |
| Vitamin B12 in pg/ml | 299.15 ± 98.72 | 554.73 ± 183.06 | 1041.71 ± 343.77 | MB ACCUBIND ELISA |
| Folate in ng/ml | 330.76 ± 109.15 1.71 ± 0.56 | 560.33 ± 184.91 2.56 ± 0.84 | 1106.86 ± 365.26 12.09 ± 3.99 | MB ACCUBIND ELISA |
| Anemia Vast | 1.48 ± 0.49 | 2.68 ± 0.88 | 10.78 ± 3.56 | MB ACCULITE CLIA |
| (Vitamin B12) in pg/ml | 230.02 ± 75.91 | 517.05 ± 170.63 599.7 ± 197.9 | 1013.01 ± 334.29 860.18 ± 283.86 | MB ACCUBIND ELISA |
| (Folate) in ng/ml | 241.24 ± 79.61 2.67 ± 0.88 | 4.42 ± 1.46 | 12.59 ± 4.15 | MB ACCUBIND ELISA |
| Bone Metabolism | 1.89 ± 0.62 | 3.25 ± 1.07 | 11.12 ± 3.67 | MB ACCULITE CLIA |
| Vit D Direct in ng/ml | 21.05 ± 6.95 22.05 ± 7.28 | 44.68 ± 14.75 45.66 ± 15.07 | 98.05 ± 32.36 115.94 ± 38.26 | MB ACCUBIND ELISA MB ACCULITE CLIA |
| Cancer Markers | | | | MB ACCUBIND ELISA |
| AFP in ng/ml | 30.23 ± 9.98 28.15 ± 9.29 | 98.96 ± 32.66 95.48 ± 31.51 | 189.46 ± 62.52 197.83 ± 65.28 | MB ACCULITE CLIA |
| CEA in ng/ml | 5.08 ± 1.68 5.13 ± 1.69 | 19.87 ± 6.56 19.68 ± 6.49 | 31.94 ± 10.54 39.03 ± 12.88 | MB ACCUBIND ELISA MB ACCULITE CLIA |
| CEA Next Generation in ng/ml | 5.0 ± 1.65 5.0 ± 1.65 | 21.08 ± 6.96 17.11 ± 5.64 | 34.66 ± 11.44 30.95 ± 10.21 | MB ACCUBIND ELISA MB ACCULITE CLIA |
| fPSA in ng/ml | 0.30 ± 0.10 0.43 ± 0.14 | 1.81 ± 0.60 | 11.03 ± 3.64 | MB ACCUBIND ELISA MB ACCULITE CLIA |
| tPSA-XS in ng/ml | 1.39 ± 0.46 | 1.98 ± 0.65 3.03 ± 1.00 | 17.03 ± 5.62 | MB ACCUBIND ELISA |
| tPSA in ng/ml | 1.28 ± 0.42 1.61 ± 0.53 | 3.01 ± 0.99 4.03 ± 1.33 | 18.51±6.11 20.31±6.70 | MB ACCULITE CLIA MB ACCUBIND ELISA |
| Cancer Markers Vast | 1.39 ± 0.46 | 4.10 ± 1.35 | 19.20 ± 6.34 | MB ACCULITE CLIA |
| (CEA) in ng/ml | 4.45 ± 1.47 | 15.83 ± 5.22 | 26.17 ± 8.64 | MB ACCUBIND ELISA |
| (AFP) in ng/ml | 4.26 ± 1.40 25.12 ± 8.29 | 18.29 ± 6.04 98.90 ± 32.64 | 27.98 ± 9.23 192.94 ± 63.67 | MB ACCULITE CLIA MB ACCUBIND ELISA |
| | 25.18 ± 9.40 1.44 ± 0.48 | 95.78 ± 31.61 4.23 ± 1.39 | 183.31 ± 60.49 23.86 ± 7.87 | MB ACCULITE CLIA MB ACCUBIND ELISA |
| (tPSA) in ng/ml Cardiac Markers | 1.15 ± 0.38 | 3.90 ± 1.29 | 22.73 ± 7.50 | MB ACCULITE CLIA |
| Dig in ng/ml | 0.45 ± 0.15 | 1.55 ± 0.51 | 3.10 ± 1.02 | MB ACCUBIND ELISA |
| Diabetes | 0.47 ± 0.15 | 1.51 ± 0.50 | 2.99 ± 0.99 | MB ACCULITE CLIA |
| C-Peptide in ng/ml | 0.49 ± 0.16 0.53 ± 0.18 | 2.64 ± 0.87 2.70 ± 0.89 | 4.89 ± 1.62 5.54 ± 1.83 | MB ACCUBIND ELISA MB ACCULITE CLIA |
| Insulin in µIU/mI | 19.63 ± 6.48 21.69 ± 7.16 | 50.90 ± 16.80 49.88 ± 16.46 | 134.96 ± 44.54 147.59 ± 48.70 | MB ACCUBIND ELISA MB ACCUBIND ELISA |
| Rapid Insulin in µIU/mI | 19.14 ± 6.32 | 47.14 ± 15.56 | 134.18 ± 44.28 | MB ACCUBIND ELISA |
| Fertility FSH in mIU/mI | 4.89 ± 1.61 | 24.53 ± 8.10 | 38.78 ± 12.80 | MB ACCUBIND ELISA |
| | 4.41 ± 1.46 5.67 ± 1.87 | 23.78 ± 7.85 28.70 ± 9.47 | 37.86 ± 12.49 157.18 ± 51.87 | MB ACCULITE CLIA MB ACCUBIND ELISA |
| hCG in mIU/mI | 5.33 ± 1.76 4.27 ± 1.41 | 25.65 ± 8.46 29.53 ± 9.74 | 170.70 ± 56.33 150.74 ± 49.74 | MB ACCULITE CLIA MB ACCUBIND ELISA |
| hCG-XR in mIU/mI | 3.89 ± 1.28 | 23.99 ± 7.92 | 147.32 ± 48.62 | MB ACCULITE CLIA |
| LH in mIU/mI | 4.43 ± 1.46 4.18 ± 1.38 | 23.60 ± 7.79 24.05 ± 7.94 | 51.47 ± 16.99 51.63 ± 17.04 | MB ACCUBIND ELISA MB ACCULITE CLIA |
| PRL in ng/ml | 6.52 ± 2.15 6.61 ± 2.18 | 18.98 ± 6.26 19.78 ± 6.53 | 37.06 ± 12.23 38.67 ± 12.76 | MB ACCUBIND ELISA MB ACCULITE CLIA |
| PRL-seq in ng/ml | 3.94 ± 1.49 | 13.17 ± 4.35 | 33.68 ± 11.11 | MB ACCUBIND ELISA MB ACCULITE CLIA |
| Rapid HCG in mIU/mI | 3.91 ± 1.29 6.05 ± 2.00 | 12.79 ± 4.22 32.04 ± 10.57 | 29.35 ± 9.68 166.16 ± 54.83 | MB ACCUBIND ELISA |
| Fertility Vast (FSH) in mIU/mI | 4.11 ± 1.35 | 24.94 ± 8.23 | 39.55 ± 13.05 | MB ACCUBIND ELISA |
| | 4.16 ± 1.37 4.42 ± 1.46 | 26.99 ± 8.91 23.35 ± 7.70 | 41.48 ± 13.69 49.79 ± 16.43 | MB ACCULITE CLIA MB ACCUBIND ELISA |
| (LH) in mIU/mI | 4.27 ± 1.41 5.59 ± 1.84 | 22.97 ± 7.58 25.35 ± 8.36 | 50.93 ± 16.81 142.34 ± 46.97 | MB ACCULITE CLIA MB ACCUBIND ELISA |
| (hCG) in mIU/mI | 5.59 ± 1.84 5.02 ± 1.66 | 25.35 ± 8.36 29.11 ± 9.61 | 142.34 ± 46.97 157.83 ± 52.08 | MB ACCULITE CLIA |
| Triple Screen VAST (AFP) in ng/ml | 27.19 ± 8.97 | 115.80 ± 38.21 | 212.27 ± 70.05 | MB ACCUBIND ELISA |
| | 25.18 ± 8.31 1.03 ± 0.34 | 110.00 ± 36.30 2.90 ± 0.96 | 216.40 ± 71.41 6.11 ± 2.01 | MB ACCULITE CLIA MB ACCUBIND ELISA |
| (uE3) in ng/ml | 1.19 ± 0.39 | 2.58 ± 0.85 | 5.81 ± 1.92 | MB ACCULITE CLIA |
| (hCG) in mIU/mI | 4.05 ± 1.34 4.74 ± 1.56 | 27.80 ± 9.17 25.43 ± 8.39 | 139.0 ± 45.87 141.98 ± 46.85 | MB ACCUBIND ELISA MB ACCULITE CLIA |
| Growth Deficiency | 6.24 ± 2.06 | 27.79 ± 9.17 | 56.13 ± 18.52 | MB ACCUBIND ELISA |
| hGH in µIU//mI Steroids | 5.58 ± 1.84 | 27.20 ± 8.98 | 56.68 ± 18.70 | MB ACCULITE CLIA |
| Cortisol in µg/dl | 2.79 ± 0.92 | 15.30 ± 5.05 | 29.40 ± 9.70 | MB ACCUBIND ELISA |
| DHEA-S in µg/ml | 2.83 ± 0.94 0.33 ± 0.11 | 13.64 ± 4.50 1.64 ± 0.54 | 28.56 ± 9.42 4.71 ± 1.55 | MB ACCUBIND ELISA |
| | 0.54 ± 0.18 0.73 ± 0.33 | 1.89 ± 0.62 4.03 ± 1.33 | 4.82 ± 1.59 9.09 ± 3.0 | MB ACCULITE CLIA MB ACCUBIND ELISA |
| DHEA in ng/ml | 0.72 ± 0.24 30.26 ± 9.98 | 4.58 ± 1.51 169.49 ± 55.93 | 9.51 ± 3.14 329.01 ± 108.57 | MB ACCULITE CLIA MB ACCUBIND ELISA |
| E2 in pg/ml | 28.75 ± 9.49 | 171.0 ± 56.43 | 348.85 ± 115.12 | MB ACCULITE CLIA |
| Progesterone in ng/ml | 0.99 ± 0.39 1.41 ± 0.47 | 7.80 ± 2.57 9 ± 2.97 | 23.93 ± 7.90 26.29 ± 8.68 | MB ACCULITE CLIA |
| 17-OHP in ng/ml | 0.50 ± 0.17 0.55 ± 0.18 | 2.09 ± 0.69 2.14 ± 0.71 | 5.33 ± 1.87 5.34 ± 1.76 | MB ACCUBIND ELISA MB ACCULITE CLIA |
| 17-OHP-SI in ng/ml | 0.35 ± 0.12 0.31 ± 0.10 | 1.13 ± 0.37 1.33 ± 0.44 | 3.15 ± 1.04 3.66 ± 1.21 | MB ACCUBIND ELISA MB ACCULITE CLIA |
| Testosterone in ng/ml | 0.29 ± 0.09 | 1.21 ± 0.40 | 6.62 ± 2.18 | MB ACCUBIND ELISA |
| uE3 in ng/ml | 0.37 ± 0.12 1.13 ± 0.42 | 1.28 ± 0.42 2.40 ± 0.79 | 7.34 ± 2.42 6.27 ± 2.07 | MB ACCULITE CLIA MB ACCUBIND ELISA |
| | 1.15 ± 0.38 42.69 ± 14.09 | 2.51 ± 0.83 191.59 ± 63.22 | 5.78 ± 1.91 508.55 ± 167.82 | MB ACCULITE CLIA MB ACCUBIND ELISA |
| E1 in ng/ml ANST in ng/ml | 43.68 ± 14.41 0.27 ± 0.09 | 213.38 ± 70.42 | 488.08 ± 161.06 | MB ACCULITE CLIA MB ACCUBIND ELISA |
| Aldosterone in ng/ml | 50.13 ± 16.54 | 1.03 ± 0.34 342.51 ± 113.03 | 5.68 ± 1.87 911.30 ± 300.73 | MB ACCUBIND ELISA |
| Free Testosterone | 44.61 ± 14.72 0.93 ± 0.31 | 297.13 ± 98.05 2.63 ± 0.87 | 855.55 ± 282.33 20.29 ± 6.70 | MB ACCULITE CLIA MB ACCUBIND ELISA |
| (0-60pg/ml calibration) Thyroid | 0.97 ± 0.32 | 2.66 ± 0.88 | 27.24 ± 8.99 | MB ACCULITE CLIA |
| T3 in ng/ml | 0.51 ± 0.17 0.59 ± 0.24 | 1.35 ± 0.45 1.43 ± 0.47 | 3.43 ± 1.13 3.27 ± 1.08 | MB ACCUBIND ELISA MB ACCULITE CLIA |
| T4 in μg/dl | 2.82 ± 0.93 | 6.54 ± 2.16 | 16.48 ± 5.44 | MB ACCUBIND ELISA |
| TSH in µIU/mI | 2.75 ± 0.91 0.40 ± 0.13 | 6.60 ± 2.18 4.00 + 1.32 | 15.33 ± 5.06 20.22 ± 6.67 | MB ACCULITE CLIA MB ACCUBIND ELISA |
| | 0.42 ± 0.14 2.01 ± 0.66 | 4.00 ± 1.32 4.11 ± 1.36 | 21.39 ± 7.06 8.53 ± 2.81 | MB ACCULITE CLIA MB ACCUBIND ELISA |
| fT3 in pg/ml | 2.24 ± 0.74 | 4.12 ± 1.36 | 7.98 ± 2.63 | MB ACCULITE CLIA MB ACCULITE CLIA |
| fT4 in ng/dl | 0.66 ± 0.22 0.62 ± 0.20 | 1.34 ± 0.44 1.27 ± 0.42 | 3.79 ± 1.25 3.95 ± 1.30 | MB ACCULITE CLIA |
| T3-Uptake in %U | 32.35 ± 1.86 31.55 ± 2.42 | 30.65 ± 1.86 30.88 ± 2.34 | 46.15 ± 1.85 46.55 ± 2.70 | MB ACCUBIND ELISA MB ACCULITE CLIA |
| Rapid TSH in µIU/mI | 0.59 ± 0.20 0.31 ± 0.12 | 4.17 ± 1.37 | 19.63 ± 648 | MB ACCUBIND ELISA |
| TSH-RC in µIU/mI | 0.31 ± 0.12 0.56 ± 0.18 | 4.05 ± 1.34 4.61 ± 1.52 | 21.0 ± 6.93 21.88 ± 7.22 | MB ACCUBIND ELISA |
| Thyroid VAST | 0.37 ± 0.12 | 4.18 ± 1.38 | 22.95 ± 7.57 | MB ACCUBIND ELISA |
| (TSH) in µIU/mI | 0.31 ± 0.10 0.51 ± 0.17 | 4.32 ± 1.43 1.46 ± 0.48 | 24.24 ± 8.00 3.15 ± 1.04 | MB ACCULITE CLIA MB ACCUBIND ELISA |
| Strep T3 in ng/ml | 0.47 ± 0.16 | 1.32 ± 0.43 | 3.14 ± 1.04 | MB ACCULITE CLIA |
| Character Table 1141 | 3.27 ± 1.08 | 8.54 ± 2.82 | 17.19 ± 5.67 | MB ACCUBIND ELISA |

Strep T4 in µg/dl (TSH) in uIU/ml Strept fT3 in pg/ml Strept fT4 in ng/dl