



MULTI LIGAND CONTROL-TRI LEVEL
LOT# MLAC1K7

PRODUCT CODE: ML-300
EXP: 2020-11

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, lyophilized 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

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, 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

- 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

This product will be stable until the expiration date when stored unopened at 2 to 8°C. Once the control is reconstituted, all analytes will be stable for 7 days when stored tightly capped at 2 to 8°C with the following exceptions: 1) C-Peptide should be assayed immediately after reconstitution, and 2) Folate and Insulin will be 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 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 thawed, do not refreeze 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 Outdated material should be discarded as a biohazardous component.

STORAGE	STABILITY	TEMPERATURE
Lyophilized, Unopened	Three (3) years	< 8°C
Reconstituted, Opened	Seven (7) days	2 - 8°C
Reconstituted, Opened	Ninety (90) days	< -10°C

EXPECTED RANGE OF VALUES

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 QA using representative lots of this product, as well as those of Monobind's AccuBind® ELISA and AccuLite® CLIA reagents.

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 Monobind's assignment 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 a) differences in laboratory personnel, b) improper technique, c) instrumentation and reagents, d) improper dilutions from the stated manufacturer's procedure, and/ or e) modifications in the manufacturer's test procedure.

Refer to <http://www.monobind.com/site/qc-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-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, 1986, HHS Publication No. (CDC) 88-3895.

Revision: 2 Date: 2019-Jan-02 Product Code: ML-300

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Glossary of Symbols (in reference to logo)

IVD - In Vitro - Diagnostic Medical Device

REF - Catalogue Number

LOT - Batch Code

CE - European Conformity

EC REP - Authorized Reseller in European Country

ISO - Temperature Limitation Condition (2-8°C)

MA - Manufacturer

EXP - Expiration Date

CI - Contact Instructions for Use

DOCUMENT HISTORY

PREPARED BY: *[Signature]* DEPT: QC VERIFIED BY: *[Signature]* DEPT: QA

APPROVED BY: *[Signature]* DEPT: Administration EFFECTIVE DATE: 2019-Jan-02

REVISION: 2 DCO: 1319

EXPECTED RANGE OF VALUES FOR MULTI-LIGAND CONTROL - TRI LEVEL				
MASTER LOT MLAC1K7				
Analyte	Range			Method
	A	B	C	
Allergy				
IgE in IU/ml	42.71 ± 14.09 38.08 ± 12.57	97.74 ± 32.25 97.37 ± 32.13	213.09 ± 70.32 205.25 ± 67.73	MB ACCURIND ELISA MB ACCULITE CLIA
Anemia				
Ferritin in ng/ml	33.64 ± 11.10 37.94 ± 12.22	189.71 ± 20.76 163.90 ± 54.10	421.46 ± 138.08 452.28 ± 140.26	MB ACCURIND ELISA MB ACCULITE CLIA
Vitamin B12 in pg/ml	229.27 ± 75.66 216.10 ± 71.31	502.34 ± 165.77 479.04 ± 158.08	983.87 ± 324.68 949.42 ± 313.31	MB ACCURIND ELISA MB ACCULITE CLIA
Folate in ng/ml	1.70 ± 0.56 1.55 ± 0.51	7.55 ± 2.49 7.29 ± 2.41	12.92 ± 4.27 11.11 ± 3.67	MB ACCURIND ELISA MB ACCULITE CLIA
Anemia VAST				
Vitamin B12 in pg/ml	300.81 ± 99.27 3.03 ± 1	634.14 ± 209.27 8.41 ± 2.77	1061.62 ± 360.34 14.28 ± 4.70	MB ACCURIND ELISA MB ACCULITE CLIA
Bone Metabolism				
Vit D Direct in ng/ml	8.43 ± 2.78 9.12 ± 3.01	71.04 ± 28.71 67.05 ± 22.13	103.00 ± 39.22 84.83 ± 27.99	MB ACCURIND ELISA MB ACCULITE CLIA
Cancer Markers				
AFP in ng/ml	37.80 ± 12.47 26.26 ± 9.26	84.39 ± 27.85 74.94 ± 26.28	161.68 ± 53.32 168.03 ± 60.37	MB ACCURIND ELISA MB ACCULITE CLIA
CEA in ng/ml	4.76 ± 1.57 4.33 ± 1.43	19.03 ± 6.27 19.33 ± 6.38	42.87 ± 14.15 44.50 ± 14.68	MB ACCURIND ELISA MB ACCULITE CLIA
CEA Next Generation in ng/ml	5.41 ± 1.79 4.25 ± 1.40	23.98 ± 7.91 23.02 ± 7.60	54.22 ± 17.89 53.03 ± 17.50	MB ACCURIND ELISA MB ACCULITE CLIA
IPSA in ng/ml	0.76 ± 0.25 0.69 ± 0.23	3.48 ± 1.14 3.00 ± 0.99	>10 >10	MB ACCURIND ELISA MB ACCULITE CLIA
IPSA-XS in ng/ml	1.42 ± 0.47 1.40 ± 0.47	5.03 ± 1.66 5.43 ± 1.79	22.26 ± 7.54 23.87 ± 7.92	MB ACCURIND ELISA MB ACCULITE CLIA
IPSA in ng/ml	1.72 ± 0.57 1.35 ± 0.44	5.98 ± 1.97 6.22 ± 2.05	24.41 ± 8.05 25.26 ± 8.34	MB ACCURIND ELISA MB ACCULITE CLIA
Cancer Vast				
AFP in ng/ml	30.90 ± 10.20 29.85 ± 9.85	79.50 ± 26.23 82.78 ± 27.32	151.49 ± 49.99 158.65 ± 52.36	MB ACCURIND ELISA MB ACCULITE CLIA
CEA in ng/ml	4.28 ± 1.56 4.20 ± 1.42	20.02 ± 6.61 18.99 ± 6.24	44.86 ± 14.80 46.19 ± 15.23	MB ACCURIND ELISA MB ACCULITE CLIA
IPSA in ng/ml	1.58 ± 0.54 1.45 ± 0.48	5.38 ± 1.77 5.61 ± 1.85	22.88 ± 7.48 23.67 ± 7.81	MB ACCURIND ELISA MB ACCULITE CLIA
Cardiac Markers				
Dig in ng/ml	0.32 ± 0.10 0.37 ± 0.12	1.34 ± 0.44 1.29 ± 0.43	2.65 ± 0.88 2.67 ± 0.88	MB ACCURIND ELISA MB ACCULITE CLIA
Diabetes				
C-Peptide in ng/ml	0.53 ± 0.17 0.54 ± 0.18	2.99 ± 0.99 3.06 ± 1.01	6.18 ± 2.04 6.26 ± 2.06	MB ACCURIND ELISA MB ACCULITE CLIA
Insulin in µIU/ml	19.98 ± 6.59 19.29 ± 6.37	51.09 ± 16.86 53.74 ± 17.74	112.13 ± 37.00 106.43 ± 35.12	MB ACCURIND ELISA MB ACCULITE CLIA
Rapid Insulin in µIU/ml	19.40 ± 6.40	50.93 ± 16.81	108.55 ± 35.82	MB ACCURIND ELISA
Fertility				
FSH in mIU/ml	5.51 ± 1.82 4.51 ± 1.49	26.19 ± 8.64 23.31 ± 7.89	41.42 ± 13.67 39.67 ± 13.06	MB ACCURIND ELISA MB ACCULITE CLIA
hCG in mIU/ml	5.03 ± 1.66 5.09 ± 1.68	22.57 ± 7.45 25.91 ± 8.55	163.05 ± 53.81 48.69 ± 16.07	MB ACCULITE CLIA MB ACCURIND ELISA
LH in mIU/ml	5.03 ± 1.66 5.60 ± 1.85	25.23 ± 8.32 22.95 ± 7.57	47.19 ± 15.57 53.36 ± 17.61	MB ACCULITE CLIA MB ACCURIND ELISA
PRL in ng/ml	5.48 ± 1.81 3.75 ± 1.24	22.95 ± 7.57 17.74 ± 5.85	52.78 ± 17.42 46.39 ± 13.66	MB ACCULITE CLIA MB ACCURIND ELISA
PRL-seq in ng/ml	2.77 ± 0.91 5.57 ± 1.91	15.56 ± 5.14 25.47 ± 8.41	39.89 ± 13.16 147.96 ± 48.82	MB ACCURIND ELISA MB ACCULITE CLIA
Rapid hCG in mIU/ml	4.51 ± 1.49 3.22 ± 1.06	21.94 ± 7.24 21.82 ± 7.20	122.67 ± 40.48 122.42 ± 40.40	MB ACCURIND ELISA MB ACCULITE CLIA
Fertility VAST				
FSH in mIU/ml	4.23 ± 1.40 4.78 ± 1.60	26.86 ± 8.86 26.54 ± 8.71	45.34 ± 14.95 48.47 ± 15.93	MB ACCURIND ELISA MB ACCULITE CLIA
hCG in mIU/ml	2.12 ± 0.7 5.40 ± 1.78	19.54 ± 6.45 22.36 ± 7.38	148.12 ± 48.88 41.81 ± 13.73	MB ACCULITE CLIA MB ACCURIND ELISA
LH in mIU/ml	5.24 ± 1.73	21.89 ± 7.22	42.43 ± 14.0	MB ACCULITE CLIA
Triple Screen VAST				
(AFP) in ng/ml	36.61 ± 12.08 33.68 ± 11.12	88.04 ± 29.05 85.93 ± 28.36	150.88 ± 49.79 144.01 ± 47.54	MB ACCURIND ELISA MB ACCULITE CLIA
(uE3) in ng/ml	0.83 ± 0.28 4.85 ± 1.60	3.95 ± 1.17 22.10 ± 7.29	8.15 ± 2.69 140.53 ± 46.37	MB ACCULITE CLIA MB ACCURIND ELISA
(hCG) in mIU/ml	4.21 ± 1.39	20.69 ± 6.93	145.58 ± 48.04	MB ACCULITE CLIA
Growth Deficiency				
hGH in µIU/ml	7.09 ± 2.34 7.07 ± 2.33	26.87 ± 8.87 26.22 ± 8.65	58.28 ± 19.23 54.35 ± 17.94	MB ACCURIND ELISA MB ACCULITE CLIA
Steroids				
Cortisol in µg/dl	2.82 ± 0.93 3.42 ± 1.13	15.06 ± 4.97 17.22 ± 5.68	28.70 ± 9.47 29.56 ± 9.75	MB ACCURIND ELISA MB ACCULITE CLIA
DHEA-S in µg/ml	0.31 ± 0.10 0.48 ± 0.16	1.67 ± 0.55 1.82 ± 0.60	4.42 ± 1.46 5.03 ± 1.66	MB ACCURIND ELISA MB ACCULITE CLIA
DHEA in µg/ml	0.55 ± 0.18 0.89 ± 0.28	4.95 ± 1.63 5.15 ± 1.70	12.22 ± 4.03 14.65 ± 4.84	MB ACCURIND ELISA MB ACCULITE CLIA
E2 in pg/ml	30.54 ± 10.08 0.80 ± 0.26	163.03 ± 53.80 9.68 ± 3.26	401.89 ± 132.66 26.93 ± 8.89	MB ACCURIND ELISA MB ACCULITE CLIA
Progesterone in ng/ml	1.09 ± 0.36 0.50 ± 0.16	10.36 ± 3.42 2.27 ± 0.75	27.34 ± 9.02 5.66 ± 1.87	MB ACCURIND ELISA MB ACCULITE CLIA
17-OHP in ng/ml	0.55 ± 0.18 0.28 ± 0.08	2.27 ± 0.75 1.15 ± 0.38	5.00 ± 1.65 2.7 ± 0.89	MB ACCULITE CLIA MB ACCURIND ELISA
17-OHP-SI in ng/ml	0.55 ± 0.18 0.28 ± 0.08	2.27 ± 0.75 1.15 ± 0.38	5.00 ± 1.65 2.7 ± 0.89	MB ACCULITE CLIA MB ACCURIND ELISA
Testosterone in ng/ml	0.36 ± 0.11 0.78 ± 0.26	1.43 ± 0.47 3.85 ± 1.27	6.68 ± 2.20 20.96 ± 7.54	MB ACCULITE CLIA MB ACCURIND ELISA
Free Testosterone (0-37pg/ml calibration)	0.88 ± 0.29 0.9x 0.30	4.80 ± 1.58 2.41 ± 0.79	32.88 ± 10.85 10.08 ± 3.32	MB ACCULITE CLIA MB ACCURIND ELISA
Free Testosterone (0-60pg/ml calibration)	0.53 ± 0.18 1.02 ± 0.34	2.87 ± 0.98 3.50 ± 1.15	6.28 ± 2.15 8.49 ± 8.80	MB ACCURIND ELISA MB ACCULITE CLIA
SHBG in nmol/L	14.16 ± 4.67 13.71 ± 4.52	16.85 ± 5.69 16.10 ± 5.31	11.87 ± 3.92 11.34 ± 3.74	MB ACCURIND ELISA MB ACCULITE CLIA
Thyroid				
Free T3 in pg/ml	1.85 ± 0.77 1.58 ± 0.52	3.87 ± 1.28 3.59 ± 1.18	8.94 ± 2.95 8.56 ± 2.89	MB ACCURIND ELISA MB ACCULITE CLIA
Free T4 in ng/dl	0.28 ± 0.09 1.80 ± 0.59	1.36 ± 0.45 4.24 ± 1.40	4.45 ± 1.47 10.24 ± 3.38	MB ACCULITE CLIA MB ACCURIND ELISA
Strept FT3 in pg/ml	1.80 ± 0.59 0.44 ± 0.15	4.31 ± 1.42 1.32 ± 0.44	10.81 ± 3.57 4.40 ± 1.45	MB ACCULITE CLIA MB ACCURIND ELISA
Strept FT4 in ng/dl	0.45 ± 0.15 0.44 ± 0.14	1.28 ± 0.42 1.21 ± 0.40	4.61 ± 1.52 3.58 ± 1.18	MB ACCULITE CLIA MB ACCURIND ELISA
Total T3 in ng/ml	0.38 ± 0.13 2.71 ± 0.93	1.28 ± 0.41 7.57 ± 2.59	3.93 ± 1.38 13.84 ± 4.57	MB ACCULITE CLIA MB ACCURIND ELISA
Total T4 in µg/dl	3.09 ± 0.99 0.58 ± 0.18	6.92 ± 2.28 1.60 ± 0.53	12.32 ± 4.07 3.35 ± 1.11	MB ACCULITE CLIA MB ACCURIND ELISA
Strept T3 in ng/ml	0.59 ± 0.19 3.04 ± 1	1.55 ± 0.51 8.43 ± 2.78	3.19 ± 1.05 14.90 ± 4.92	MB ACCULITE CLIA MB ACCURIND ELISA
Strept T4 in µg/dl	3.01 ± 0.99 27.80 ± 9.25	8.35 ± 2.76 31.67 ± 3.18	13.81 ± 4.56 41.13 ± 3.77	MB ACCULITE CLIA MB ACCURIND ELISA
T3-Uptake in %U	27.23 ± 2.53 0.60 ± 0.20	32.01 ± 3.03 5.52 ± 1.82	42.29 ± 2.55 28.11 ± 9.28	MB ACCURIND ELISA MB ACCULITE CLIA
TSH in µIU/ml	0.50 ± 0.17 0.56 ± 0.19	5.48 ± 1.81 5.47 ± 1.80	26.63 ± 8.79 24.93 ± 8.23	MB ACCURIND ELISA MB ACCULITE CLIA
Rapid TSH in µIU/ml	0.35 ± 0.12 0.59 ± 0.20	5.20 ± 1.72 5.34 ± 1.76	24.46 ± 8.07 29.49 ± 9.73	MB ACCULITE CLIA MB ACCURIND ELISA
TSH-RC in µIU/ml	11 ± 3.63 10.10 ± 3.33	9.9 ± 3.27 8.77 ± 2.89	6.20 ± 2.04 6.63 ± 2.19	MB ACCURIND ELISA MB ACCULITE CLIA
TBG in µg/ml	0.40 ± 0.13 0.45 ± 0.15	5.66 ± 1.87 6.08 ± 2.01	28.97 ± 9.56 28.07 ± 9.26	MB ACCURIND ELISA MB ACCULITE CLIA
Thyroid VAST				
(TSH) in µIU/ml	0.59 ± 0.19 0.55 ± 0.18	6.63 ± 2.19 6.61 ± 2.18	33.43 ± 11.03 33.54 ± 11.07	MB ACCURIND ELISA MB ACCULITE CLIA