



**MULTI LIGAND CONTROL-TRI LEVEL**  
**LOT# MLAC1E8**

**PRODUCT CODE: ML-300**  
**EXP: 05-2021**

**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 vial 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 Outdated material should be discarded as a biohazardous component.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/gc-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, 1988, HHS Publication No. (CDC) 88-8395.

Revision: 2 Date: 2020-Mar-10 Product Code: ML-300

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**Glossary of Symbols**  
(EN 16070/15229)

**IVD** In Vitro - Diagnostic Medical Device

**REF** Reference Number

**LOT** Lot Code

**CE** European Conformity

**EC REP** Authorized Rep in European Country

**Consult Instructions for Use**

**Temperature Limitation** Storage Condition (2-8°C)

**Manufacturer**

**Use by (Expiration Date)**

DOCUMENT HISTORY			
PREPARED BY: <u>MM</u>	DEPT: QC	VERIFIED BY: <u>ASH</u>	DEPT: QA
APPROVED BY: <u>Fred</u>	DEPT: Administration	EFFECTIVE DATE: 2020-03-10	
REVISION: 2		DCO: 1390	

EXPECTED RANGE OF VALUES FOR MULTI-LIGAND CONTROL - TRI LEVEL				
MASTER LOT MLAC1E8				
Analyte	Range			Method
	A	B	C	
<b>Allergy</b>				
IgE in IU/ml	15.09 ± 4.98	97.01 ± 32.01	170.79 ± 56.36	MB ACCUBIND ELISA
	14.02 ± 4.63	106.20 ± 35.05	176.31 ± 58.18	MB ACCULITE CLIA
<b>Anemia</b>				
Ferritin in ng/ml	16.00 ± 5.28	80.03 ± 29.71	236.68 ± 78.10	MB ACCUBIND ELISA
	16.60 ± 5.48	84.57 ± 27.91	257.22 ± 84.33	MB ACCULITE CLIA
Folate in ng/ml	1.85 ± 0.74	7.76 ± 2.56	12.81 ± 4.23	MB ACCUBIND ELISA
	1.96 ± 0.65	7.74 ± 2.55	13.01 ± 4.49	MB ACCULITE CLIA
Folate in ng/ml	1.74 ± 0.57	6.89 ± 2.27	13.25 ± 4.37	MB ACCUBIND ELISA
	2.20 ± 0.73	7.81 ± 2.58	16.34 ± 4.39	MB ACCULITE CLIA
<b>Anemia Vast</b>				
Vitamin B12 in pg/ml	325.07 ± 107.27	484.95 ± 160.03	880.06 ± 290.42	MB ACCUBIND ELISA
	349.18 ± 115.23	416.01 ± 137.28	894.54 ± 295.20	MB ACCULITE CLIA
Folate in ng/ml	1.76 ± 0.58	8.24 ± 2.72	13.35 ± 5.58	MB ACCUBIND ELISA
	2.21 ± 0.99	7.96 ± 2.43	13.24 ± 4.37	MB ACCULITE CLIA
<b>Cancer Markers</b>				
AFP in ng/ml	33.20 ± 10.96	118.18 ± 39.0	236.73 ± 78.12	MB ACCUBIND ELISA
	32.50 ± 10.73	108.05 ± 35.66	228.33 ± 72.35	MB ACCULITE CLIA
CEA in ng/ml	4.53 ± 1.66	22.77 ± 7.52	33.31 ± 10.99	MB ACCUBIND ELISA
	4.12 ± 1.36	21.20 ± 7	34.36 ± 11.34	MB ACCULITE CLIA
CEA Next Generation in ng/ml	4.8 ± 1.58	25.51 ± 8.07	42.13 ± 13.90	MB ACCUBIND ELISA
	4.73 ± 1.56	27.66 ± 8.13	47.99 ± 15.84	MB ACCULITE CLIA
iPSA in ng/ml	0.83 ± 0.27	2.66 ± 0.88	> 10	MB ACCUBIND ELISA
	0.77 ± 0.27	2.55 ± 0.84	> 10	MB ACCULITE CLIA
iPSA-XS in ng/ml	1.37 ± 0.45	4.39 ± 1.45	19.83 ± 6.55	MB ACCUBIND ELISA
	1.61 ± 0.53	5.04 ± 1.66	19.97 ± 6.59	MB ACCULITE CLIA
iPSA in ng/ml	2.15 ± 0.78	5.89 ± 1.95	21.16 ± 6.95	MB ACCUBIND ELISA
	1.68 ± 0.56	6.2 ± 2.05	20.93 ± 6.91	MB ACCULITE CLIA
<b>Cancer Markers Vast</b>				
CEA in ng/ml	4.20 ± 1.39	21.12 ± 6.97	30.33 ± 10.01	MB ACCUBIND ELISA
	3.92 ± 1.29	20.34 ± 6.71	32.43 ± 10.78	MB ACCULITE CLIA
AFP in ng/ml	27.89 ± 9.14	91.46 ± 30.18	177.73 ± 58.65	MB ACCUBIND ELISA
	26.39 ± 8.71	89.89 ± 29.60	175.80 ± 62.80	MB ACCULITE CLIA
iPSA in ng/ml	1.65 ± 0.54	4.58 ± 1.54	20.72 ± 6.84	MB ACCUBIND ELISA
	1.54 ± 0.51	4.29 ± 1.42	21.26 ± 7.02	MB ACCULITE CLIA
<b>Cardiac Markers</b>				
Dig in ng/ml	0.31 ± 0.11	1.12 ± 0.39	2.46 ± 0.81	MB ACCUBIND ELISA
	0.44 ± 0.15	1.45 ± 0.48	2.76 ± 0.91	MB ACCULITE CLIA
<b>Diabetes</b>				
C-Peptide in ng/ml	0.42 ± 0.14	1.94 ± 0.64	5.03 ± 1.68	MB ACCUBIND ELISA
	0.36 ± 0.12	1.94 ± 0.64	4.73 ± 1.56	MB ACCULITE CLIA
Insulin in µU/ml	19.13 ± 6.31	53.65 ± 17.71	124.99 ± 41.24	MB ACCUBIND ELISA
	19.06 ± 6.29	53.8 ± 17.75	122.78 ± 40.52	MB ACCULITE CLIA
Rapid Insulin in µU/ml	19.91 ± 6.57	51.37 ± 16.95	116.29 ± 38.38	MB ACCUBIND ELISA
<b>Fertility</b>				
FSH in mIU/ml	3.93 ± 1.30	19.33 ± 6.38	36.73 ± 12.12	MB ACCUBIND ELISA
	3.45 ± 1.14	19.98 ± 6.59	39.54 ± 12.72	MB ACCULITE CLIA
hCG in mIU/ml	5.10 ± 1.68	26.05 ± 8.60	168.50 ± 55.60	MB ACCUBIND ELISA
	4.56 ± 1.51	23.76 ± 7.84	156.55 ± 51.66	MB ACCULITE CLIA
hCG-XR in mIU/ml	<5	23.84 ± 7.87	142.77 ± 47.11	MB ACCUBIND ELISA
	<5	23.41 ± 7.73	131.11 ± 43.26	MB ACCULITE CLIA
LH in mIU/ml	4.65 ± 1.54	24.62 ± 8.12	53.50 ± 17.65	MB ACCUBIND ELISA
	4.99 ± 1.65	22.78 ± 7.52	52.94 ± 17.47	MB ACCULITE CLIA
PRL in ng/ml	3.89 ± 1.28	18.70 ± 6.17	35.19 ± 11.81	MB ACCUBIND ELISA
	3.84 ± 1.27	18.53 ± 6.12	39.79 ± 13.13	MB ACCULITE CLIA
PRL-seq in ng/ml	3.15 ± 1.04	14.51 ± 4.79	37.8 ± 12.47	MB ACCUBIND ELISA
	2.96 ± 0.98	13.56 ± 4.54	31.77 ± 10.48	MB ACCULITE CLIA
Rapid HCG in mIU/ml	5.93 ± 1.96	25.26 ± 8.34	175.47 ± 57.90	MB ACCUBIND ELISA
<b>Fertility Vast</b>				
FSH in mIU/ml	3.94 ± 1.30	19.69 ± 6.5	38.40 ± 12.67	MB ACCUBIND ELISA
	3.07 ± 1.01	19.99 ± 6.60	41.27 ± 13.62	MB ACCULITE CLIA
LH in mIU/ml	6.27 ± 2.07	23.12 ± 7.63	50.86 ± 16.78	MB ACCUBIND ELISA
	6.04 ± 1.99	22.23 ± 7.37	53.27 ± 17.58	MB ACCULITE CLIA
hCG in mIU/ml	4.39 ± 1.83	24.56 ± 8.11	135.37 ± 44.67	MB ACCUBIND ELISA
	3.12 ± 1.03	23.24 ± 7.87	136.11 ± 44.92	MB ACCULITE CLIA
<b>Triple Screen</b>				
AFP in ng/ml	29.08 ± 9.60	125.18 ± 41.31	231.25 ± 76.31	MB ACCUBIND ELISA
	30.02 ± 9.91	124.19 ± 40.98	209.83 ± 69.28	MB ACCULITE CLIA
uE3 in ng/ml	1.01 ± 0.33	2.48 ± 0.82	5.17 ± 1.71	MB ACCUBIND ELISA
	1 ± 0.33	2.54 ± 0.84	6.01 ± 1.98	MB ACCULITE CLIA
hCG in mIU/ml	4 ± 1.32	23.84 ± 7.87	156.28 ± 49.58	MB ACCUBIND ELISA
	3.19 ± 1.05	23.67 ± 7.81	147.61 ± 48.71	MB ACCULITE CLIA
<b>Growth Deficiency</b>				
IGH in µU/ml	3.36 ± 1.11	14.13 ± 4.66	30.14 ± 10.21	MB ACCUBIND ELISA
	3.55 ± 1.29	15.02 ± 4.96	37.19 ± 12.27	MB ACCULITE CLIA
<b>Steroids</b>				
Cortisol in µg/dl	3.09 ± 1.02	16.33 ± 5.39	24.54 ± 8.10	MB ACCUBIND ELISA
	3.20 ± 1.06	15.91 ± 5.25	25.35 ± 8.37	MB ACCULITE CLIA
DHEA-S in µg/ml	0.25 ± 0.08	1.26 ± 0.41	5.69 ± 1.88	MB ACCUBIND ELISA
	0.27 ± 0.09	1.35 ± 0.44	5.31 ± 1.75	MB ACCULITE CLIA
DHEA in ng/ml	0.69 ± 0.23	3.88 ± 1.28	10.79 ± 3.56	MB ACCUBIND ELISA
	0.89 ± 0.29	4.49 ± 1.48	13.89 ± 5.61	MB ACCULITE CLIA
E2 in pg/ml	33.89 ± 11.05	138.19 ± 45.60	262.89 ± 86.75	MB ACCUBIND ELISA
	38.86 ± 12.82	166.77 ± 55.04	290.98 ± 92.99	MB ACCULITE CLIA
Progesterone in ng/ml	0.79 ± 0.34	5.32 ± 1.76	19.51 ± 6.44	MB ACCUBIND ELISA
	1.06 ± 0.35	6.49 ± 2.14	22.77 ± 7.51	MB ACCULITE CLIA
17-OHP in ng/ml	0.56 ± 0.18	1.93 ± 0.64	5.50 ± 1.92	MB ACCUBIND ELISA
	0.59 ± 0.19	1.89 ± 0.62	6.37 ± 2.30	MB ACCULITE CLIA
17-OHP-SI in ng/ml	0.22 ± 0.07	0.76 ± 0.25	2.81 ± 0.93	MB ACCUBIND ELISA
	0.20 ± 0.07	0.83 ± 0.27	3.07 ± 1.01	MB ACCULITE CLIA
Testosterone in ng/ml	0.27 ± 0.09	0.87 ± 0.29	6.24 ± 2.06	MB ACCUBIND ELISA
	0.27 ± 0.11	0.90 ± 0.30	6.40 ± 2.11	MB ACCULITE CLIA
uE3 in ng/ml	0.96 ± 0.32	2.58 ± 0.85	5 ± 1.65	MB ACCUBIND ELISA
	0.91 ± 0.30	2.65 ± 0.87	4.66 ± 1.60	MB ACCULITE CLIA
Free Testosterone in pg/ml	0.82 ± 0.27	2.63 ± 0.87	21.14 ± 7.99	MB ACCUBIND ELISA
	0.82 ± 0.27	2.61 ± 0.86	32.60 ± 10.76	MB ACCULITE CLIA
Free Testosterone in pg/ml NEW SYSTEM	1.08 ± 0.36	3.95 ± 0.97	20.42 ± 6.74	MB ACCUBIND ELISA
	1.20 ± 0.40	3.23 ± 1.07	26.29 ± 8.68	MB ACCULITE CLIA
<b>Thyroid</b>				
T3 in ng/ml	0.61 ± 0.20	1.64 ± 0.54	4.22 ± 1.39	MB ACCUBIND ELISA
	0.59 ± 0.19	1.60 ± 0.53	4.13 ± 1.36	MB ACCULITE CLIA
T4 in µg/dl	3.09 ± 1.02	7.81 ± 2.51	15.07 ± 4.97	MB ACCUBIND ELISA
	3.26 ± 1.08	8.22 ± 2.71	16.44 ± 5.52	MB ACCULITE CLIA
TSH in µU/ml	0.45 ± 0.18	3.99 ± 1.32	21.35 ± 7.05	MB ACCUBIND ELISA
	0.41 ± 0.14	3.66 ± 1.21	19.15 ± 6.32	MB ACCULITE CLIA
fT3 in pg/ml	2.38 ± 0.78	5.76 ± 1.90	8.29 ± 2.74	MB ACCUBIND ELISA
	2.34 ± 0.89	6.0 ± 1.98	8.41 ± 2.78	MB ACCULITE CLIA
fT4 in ng/dl	0.71 ± 0.25	3.19 ± 1.05	4.98 ± 1.57	MB ACCUBIND ELISA
	0.66 ± 0.22	3.05 ± 1.01	4.38 ± 1.40	MB ACCULITE CLIA
T3-Uptake in %U	32.20 ± 2.59	37.01 ± 2.61	43.49 ± 2.60	MB ACCUBIND ELISA
	32.5 ± 3.19	37.03 ± 3.19	43.2 ± 3.19	MB ACCULITE CLIA
Rapid TSH in µU/ml	0.44 ± 0.15	3.84 ± 1.27	19.95 ± 6.59	MB ACCUBIND ELISA
	0.44 ± 0.15	3.87 ± 1.28	19.75 ± 6.52	MB ACCULITE CLIA
TGB in µg/ml	6.50 ± 2.15	4.87 ± 1.61	10.44 ± 3.44	MB ACCUBIND ELISA
TSH-R4 in µU/ml	0.46 ± 0.15	4.03 ± 1.33	23.55 ± 7.77	MB ACCUBIND ELISA
<b>Thyroid VAST</b>				
(TSH) in µU/ml	0.38 ± 0.13	4 ± 1.32	21.22 ± 7	MB ACCUBIND ELISA
	0.37 ± 0.12	4.09 ± 1.35	21.47 ± 7.08	MB ACCULITE CLIA
Strep T3 in ng/ml	0.73 ± 0.25	1.36 ± 0.45	3.53 ± 1.17	MB ACCUBIND ELISA
	0.82 ± 0.29	1.36 ± 0.45	3.33 ± 1.10	MB ACCULITE CLIA
Strep T4 in µU/ml	2.96 ± 0.99	8.20 ± 2.71	17 ± 5.61	MB ACCUBIND ELISA

	3.07 ± 1.01	7.21 ± 2.38	15.78 ± 5.21	MB ACCULITE CLIA
<b>Free Thyroid VAST</b>				
(TSH) in µU/ml	0.42 ± 0.14	4.28 ± 1.41	21.13 ± 6.87	MB ACCUBIND ELISA
	0.32 ± 0.10	4.01 ± 1.32	21.08 ± 6.86	MB ACCULITE CLIA
Strept FT3 in pg/ml	2.59 ± 0.88	5.99 ± 1.98	9.41 ± 3.11	MB ACCUBIND ELISA
	2.59 ± 0.85	5.75 ± 1.90	9.41 ± 3.11	MB ACCULITE CLIA
Strept FT4 in ng/dl	0.63 ± 0.21	2.55 ± 0.97	3.58 ± 1.31	MB ACCUBIND ELISA
	0.65 ± 0.21	2.42 ± 0.80	3.34 ± 1.10	MB ACCULITE CLIA
<b>Vitamins</b>				
Vitamin D in ng/ml	10.54 ± 3.48	30.76 ± 10.15	82.36 ± 32.99	MB ACCUBIND ELISA
	11.66 ± 3.85	28.59 ± 9.43	85.01 ± 31.55	MB ACCULITE CLIA