MULTI LIGAND CONTROL-TRI LEVEL **PRODUCT CODE: ML-300**
LOT#: MLAC1H1 **EXP: 2024-08-26**

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 -20ºC.

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 Outdated material should be discarded as a biohazardous component.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

Revision:0 **Date: 2021-09-16** **Product Code: ML-300**

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Please visit our website to learn more about our products and services.

Glossary of Symbols (EN ISO 15223)

IVD In Vitro - Diagnostic Medical Device; Temperature Limitation Storage Condition (2-8° C); Consult Instructions for Use; REF Catalogue Number; Date of Manufacturer; LOT Batch Code; Used By (Expiration Day); Manufacturer; European Conformity; EC REP Authorized Rep in European Country

DOCUMENT HISTORY

PREPARED BY: _____ DEPT: QC VERIFIED BY: _____ DEPT: QA

APPROVED BY: _____ DEPT: Administration EFFECTIVE DATE: 2021-09-16

REVISION: 0 DCO: N/A

EXPECTED RANGE OF VALUES FOR MULTI-LIGAND CONTROL - TRI LEVEL

MASTER LOT:MLAC1H1

Analyte	A Range	B Range	C Range	Method
Allergy				
IgE in IU/ml	15.53 ± 5.12	203.9 ± 67.29	86.58 ± 28.57	MB ACCUBIND ELISA
	13.75 ± 4.54	202.15 ± 66.71	80.5 ± 26.57	MB ACCULITE CLIA
Anemia				
Ferritin in ng/ml	39.8 ± 13.13	76.7 ± 25.31	419.33 ± 138.38	MB ACCUBIND ELISA
	40.39 ± 13.33	76.14 ± 25.13	480.92 ± 158.70	MB ACCULITE CLIA
Vitamin B12 in pg/ml	299.15 ± 98.72	554.73 ± 183.06	1041.71 ± 343.77	MB ACCUBIND ELISA
	330.76 ± 109.15	560.33 ± 184.91	1106.86 ± 365.26	MB ACCULITE CLIA
Folate in ng/ml	2.15 ± 0.71	2.22 ± 0.73	13.04 ± 4.30	MB ACCUBIND ELISA
	1.9 ± 0.63	2.5 ± 0.83	10.3 ± 3.4	MB ACCULITE CLIA
Anemia Vast				
(Vitamin B12) in pg/ml	230.02 ± 75.91	517.05 ± 170.63	1013.01 ± 334.29	MB ACCUBIND ELISA
	241.24 ± 79.61	599.7 ± 197.9	860.18 ± 283.86	MB ACCULITE CLIA
(Folate) in ng/ml	2.2 ± 0.73	3.1 ± 1.02	14.2 ± 4.69	MB ACCUBIND ELISA
	2.13 ± 0.70	2.94 ± 0.97	12.3 ± 4.06	MB ACCULITE CLIA
Bone Metabolism				
Vit D Direct in ng/ml	21.05 ± 6.95	44.68 ± 14.75	98.05 ± 32.36	MB ACCUBIND ELISA
	22.05 ± 7.28	45.66 ± 15.07	115.94 ± 38.26	MB ACCULITE CLIA
Cancer Markers				
AFP in ng/ml	32 ± 10.56	115.3 ± 38.05	228.93 ± 75.55	MB ACCUBIND ELISA
	28 ± 9.24	108 ± 35.64	207 ± 68.31	MB ACCULITE CLIA
CEA in ng/ml	4.28 ± 1.41	15.24 ± 5.03	27.35 ± 9.03	MB ACCUBIND ELISA
	4.8 ± 1.58	17 ± 5.61	30 ± 9.90	MB ACCULITE CLIA
CEA Next Generation in ng/ml	4.18 ± 1.38	16.20 ± 5.35	29.46 ± 9.72	MB ACCUBIND ELISA
	4.09 ± 1.35	16.26 ± 5.36	30.32 ± 10.01	MB ACCULITE CLIA
fPSA in ng/ml	0.30 ± 0.10	1.81 ± 0.60	11.03 ± 3.64	MB ACCUBIND ELISA
	0.43 ± 0.14	1.98 ± 0.65	13.23 ± 4.46	MB ACCULITE CLIA
tPSA-XS in ng/ml	1.39 ± 0.46	3.03 ± 1.00	17.03 ± 5.62	MB ACCUBIND ELISA
	1.28 ± 0.42	3.01 ± 0.99	18.51± 6.11	MB ACCULITE CLIA
tPSA in ng/ml	1.81 ± 0.60	4.27 ± 1.41	20.13 ± 6.64	MB ACCUBIND ELISA
	1.58 ± 0.52	4.46 ± 1.47	18.99 ± 6.27	MB ACCULITE CLIA
Cancer Markers Vast				
(CEA) in ng/ml	4.45 ± 1.47	15.83 ± 5.22	26.17 ± 8.64	MB ACCUBIND ELISA
	4.26 ± 1.40	18.29 ± 6.04	27.98 ± 9.23	MB ACCULITE CLIA
(AFP) in ng/ml	25.12 ± 8.29	98.90 ± 32.64	192.94 ± 63.67	MB ACCUBIND ELISA
	25.18 ± 9.40	95.78 ± 31.61	183.31 ± 60.49	MB ACCULITE CLIA
(tPSA) in ng/ml	1.44 ± 0.48	4.23 ± 1.39	23.86 ± 7.87	MB ACCUBIND ELISA
	1.15 ± 0.38	3.90 ± 1.29	22.73 ± 7.50	MB ACCULITE CLIA
Cardiac Markers				
Dig in ng/ml	0.45 ± 0.15	1.55 ± 0.51	3.10 ± 1.02	MB ACCUBIND ELISA
	0.47 ± 0.15	1.51 ± 0.50	2.99 ± 0.99	MB ACCULITE CLIA
Diabetes				
C-Peptide in ng/ml	0.55 ± 0.18	2.71 ± 0.89	3.89 ± 1.28	MB ACCUBIND ELISA
	0.59 ± 0.19	2.72 ± 0.90	4 ± 1.32	MB ACCULITE CLIA
Insulin in µlU/ml	18.15 ± 5.99	46.65 ± 15.39	101.99 ± 33.66	MB ACCUBIND ELISA
	20.5 ± 6.77	46 ± 15.18	112 ± 36.96	MB ACCULITE CLIA
Rapid Insulin in µlU/ml	21.3 ± 7.03	48 ± 15.84	117 ± 38.61	MB ACCUBIND ELISA
Fertility				
FSH in mIU/ml	4.89 ± 1.61	24.53 ± 8.10	38.78 ± 12.80	MB ACCUBIND ELISA
	4.41 ± 1.46	23.78 ± 7.85	37.86 ± 12.49	MB ACCULITE CLIA
hCG in mIU/ml	6.08 ± 2.01	31.48 ± 10.39	164.71 ± 54.35	MB ACCUBIND ELISA
	4.5 ± 1.49	41.2 ± 13.60	217.4 ± 71.74	MB ACCULITE CLIA
hCG-XR in mIU/ml	4.40 ± 1.45	24.95 ± 8.23	158.90 ± 52.44	MB ACCUBIND ELISA
	3.89 ± 1.28	23.99 ± 7.92	147.32 ± 48.62	MB ACCULITE CLIA
LH in mIU/ml	4.43 ± 1.46	23.60 ± 7.79	51.47 ± 16.99	MB ACCUBIND ELISA
	4.18 ± 1.38	24.05 ± 7.94	51.63 ± 17.04	MB ACCULITE CLIA
PRL in ng/ml	4.9 ± 1.62	15.57 ± 5.14	37.13 ± 12.25	MB ACCUBIND ELISA
	4.2 ± 1.39	15.2 ± 5.02	37 ± 12.21	MB ACCULITE CLIA
PRL-seq in ng/ml	3.94 ± 1.49	13.17 ± 4.35	33.68 ± 11.11	MB ACCUBIND ELISA
	3.91 ± 1.29	12.79 ± 4.22	29.35 ± 9.68	MB ACCULITE CLIA
Rapid HCG in mIU/ml	6.05 ± 2.00	32.04 ± 10.57	166.16 ± 54.83	MB ACCUBIND ELISA
Fertility Vast				
(FSH) in mIU/ml	27.19 ± 8.97	115.80 ± 38.21	212.27 ± 70.05	MB ACCUBIND ELISA
	25.18 ± 8.31	110.00 ± 36.30	216.40 ± 71.41	MB ACCULITE CLIA
(LH) in mIU/ml	1.03 ± 0.34	2.90 ± 0.96	6.11 ± 2.01	MB ACCUBIND ELISA
	1.19 ± 0.39	2.58 ± 0.85	5.81 ± 1.92	MB ACCULITE CLIA
(hCG) in mIU/ml	4.05 ± 1.34	27.80 ± 9.17	139.0 ± 45.87	MB ACCUBIND ELISA
	4.74 ± 1.56	25.43 ± 8.39	141.98 ± 46.85	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	110.00 ± 36.30	216.40 ± 71.41	MB ACCULITE CLIA
(uE3) in ng/ml	1.03 ± 0.34	2.90 ± 0.96	6.11 ± 2.01	MB ACCUBIND ELISA
	1.19 ± 0.39	2.58 ± 0.85	5.81 ± 1.92	MB ACCULITE CLIA
(hCG) in mIU/ml	4.05 ± 1.34	27.80 ± 9.17	139.0 ± 45.87	MB ACCUBIND ELISA
	4.74 ± 1.56	25.43 ± 8.39	141.98 ± 46.85	MB ACCULITE CLIA
Growth Deficiency				
hGH in µlU/ml	3.58 ± 1.18	19.44 ± 6.42	48.42 ± 15.98	MB ACCUBIND ELISA
	3.9 ± 1.29	16.9 ± 5.58	36.4 ± 12.01	MB ACCULITE CLIA
Steroids				
Cortisol in µg/dl	2.79 ± 0.92	15.30 ± 5.05	29.40 ± 9.70	MB ACCUBIND ELISA
	2.83 ± 0.94	13.64 ± 4.50	28.56 ± 9.42	MB ACCULITE CLIA
DHEA-S in µg/ml	0.54 ± 0.18	1.72 ± 0.57	4.64 ± 1.53	MB ACCUBIND ELISA
	0.54 ± 0.18	1.8 ± 0.59	4.5 ± 1.49	MB ACCULITE CLIA
DHEA in ng/ml	0.73 ± 0.33	4.03 ± 1.33	9.09 ± 3.0	MB ACCUBIND ELISA
	0.72 ± 0.24	4.58 ± 1.51	9.51 ± 3.14	MB ACCULITE CLIA
E2 in pg/ml	30.26 ± 9.98	169.49 ± 55.93	329.01 ± 108.57	MB ACCUBIND ELISA
	28.75 ± 9.49	171.0 ± 56.43	348.85 ± 115.12	MB ACCULITE CLIA
Progesterone in ng/ml	1.1± 0.36	8.44 ± 2.79	24.59 ± 8.11	MB ACCUBIND ELISA
	1.4 ± 0.46	10 ± 3.30	26.5 ± 8.75	MB ACCULITE CLIA
17-OHP in ng/ml	0.50 ± 0.17	2.09 ± 0.69	5.33 ± 1.87	MB ACCUBIND ELISA
	0.55 ± 0.18	2.14 ± 0.71	5.34 ± 1.76	MB ACCULITE CLIA
17-OHP-SI in ng/ml	0.35 ± 0.12	1.13 ± 0.37	3.15 ± 1.04	MB ACCUBIND ELISA
	0.33 ± 0.10	1.35 ± 0.44	3.66 ± 1.21	MB ACCULITE CLIA
Testosterone in ng/ml	0.29 ± 0.09	1.21 ± 0.40	6.62 ± 2.18	MB ACCUBIND ELISA
	0.37 ± 0.12	1.28 ± 0.42	7.34 ± 2.42	MB ACCULITE CLIA
uE3 in ng/ml	1.13 ± 0.42	2.40 ± 0.79	6.27 ± 2.07	MB ACCUBIND ELISA
	1.15 ± 0.38	2.51 ± 0.83	5.78 ± 1.91	MB ACCULITE CLIA
E1 in ng/ml	42.69 ± 14.09	191.59 ± 63.22	508.55 ± 167.82	MB ACCUBIND ELISA
	43.68 ± 14.41	213.38 ± 70.42	488.08 ± 161.06	MB ACCULITE CLIA
ANST in ng/ml	0.31 ± 0.10	1.01 ± 0.33	4.49 ± 1.48	MB ACCUBIND ELISA
Aldosterone in ng/ml	44.69 ± 14.75	297.3 ± 98.11	750 ± 247.5	MB ACCUBIND ELISA
	44.61 ± 14.72	297.13 ± 98.05	855.55 ± 282.33	MB ACCULITE CLIA
Free Testosterone (0-60pg/ml calibration)	0.93 ± 0.31	2.63 ± 0.87	20.29 ± 6.70	MB ACCUBIND ELISA
	0.97 ± 0.32	2.66 ± 0.88	27.24 ± 8.99	MB ACCULITE CLIA
Thyroid				
T3 in ng/ml	0.51 ± 0.17	1.35 ± 0.45	3.43 ± 1.13	MB ACCUBIND ELISA
	0.59 ± 0.24	1.43 ± 0.47	3.27 ± 1.08	MB ACCULITE CLIA
T4 in µg/dl	2.82 ± 0.93	6.54 ± 2.16	16.48 ± 5.44	MB ACCUBIND ELISA
	2.75 ± 0.91	6.60 ± 2.18	15.33 ± 5.06	MB ACCULITE CLIA
TSH in µlU/ml	0.40 ± 0.13	4.00 ± 1.32	20.22 ± 6.67	MB ACCUBIND ELISA
	0.42 ± 0.14	4.00 ± 1.32	21.39 ± 7.06	MB ACCULITE CLIA
fT3 in pg/ml	2.01 ± 0.66	4.11 ± 1.36	8.53 ± 2.81	MB ACCUBIND ELISA
	2.24 ± 0.74	4.12 ± 1.36	7.98 ± 2.63	MB ACCULITE CLIA
fT4 in ng/dl	0.52 ± 0.17	1.28 ± 0.42	4.06 ± 1.34	MB ACCUBIND ELISA
	0.54 ± 0.18	1.19 ± 0.39	3.83 ± 1.26	MB ACCULITE CLIA
T3-Uptake in %U	32.35 ± 1.86	30.65 ± 1.86	46.15 ± 1.85	MB ACCUBIND ELISA
	31.55 ± 2.42	30.88 ± 2.34	46.55 ± 2.70	MB ACCULITE CLIA
Rapid TSH in µlU/ml	0.59 ± 0.20	4.17 ± 1.37	19.63 ± 6.48	MB ACCUBIND ELISA
	0.31 ± 0.12	4.05 ± 1.34	21.0 ± 6.93	MB ACCULITE CLIA
TSH-RC in µlU/ml	0.56 ± 0.18	4.61 ± 1.52	21.88 ± 7.22	MB ACCUBIND ELISA
Thyroid VAST				
(TSH) in µlU/ml	0.37 ± 0.12	4.18 ± 1.38	22.95 ± 7.57	MB ACCUBIND ELISA
	0.31 ± 0.10	4.32 ± 1.43	24.24 ± 8.00	MB ACCULITE CLIA
Strep T3 in ng/ml	0.51 ± 0.17	1.46 ± 0.48	3.15 ± 1.04	MB ACCUBIND ELISA
	0.47 ± 0.16	1.32 ± 0.43	3.14 ± 1.04	MB ACCULITE CLIA
Strep T4 in µg/dl	3.27 ± 1.08	8.54 ± 2.82	17.19 ± 5.67	MB ACCUBIND ELISA
	2.98 ± 0.98	8.26 ± 2.73	16.29 ± 5.37	MB ACCULITE CLIA
Free Thyroid VAST				
(TSH) in µlU/ml	0.46 ± 0.15	4.64 ± 1.53	23.78 ± 7.85	MB ACCUBIND ELISA
	0.53 ± 0.17	4.87 ± 1.61	22.56 ± 7.44	MB ACCULITE CLIA
Strept fT3 in pg/ml	1.81 ± 0.60	3.42 ± 1.13	9.78 ± 4.20	MB ACCUBIND ELISA
	1.79 ± 0.59	3.87 ± 1.28	8.64 ± 2.85	MB ACCULITE CLIA
Strept fT4 in ng/dl	0.91 ± 0.30	1.25 ± 0.41	5.22 ± 1.72	MB ACCUBIND ELISA
	0.94 ± 0.31	1.26 ± 0.41	5.32 ± 1.75	MB ACCULITE CLIA