



MULTI LIGAND CONTROL- TRI LEVEL
LOT# MC(A-C)1A7

PRODUCT CODE: ML-300
EXP: 01-12

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 Outdated material should be discarded as biohazardous component.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

EXPECTED RANGE OF VALUES FOR MULTI-LIGAND CONTROL - TRI LEVEL				
MASTER LOT MC(A-C)1A7				
Analyte	A	B	C	Method
	Range	Range	Range	
Allergy				
IgE in IU/ml	43.2 ± 14.26 42.9 ± 14.15	163.3 ± 37.05 169.4 ± 48.81	318.7 ± 52.65 308.3 ± 82.23	MB ACCUBIND ELISA MB ACCULITE CLIA
Anemia				
Ferritin in ng/ml	10.2 ± 6.90 9.81 ± 6.99	114.2 ± 32.22 111.6 ± 28.11	346.0 ± 94.59 354.5 ± 112.29	MB ACCUBIND ELISA MB ACCULITE CLIA
Cancer Markers				
AFP in ng/ml	12.3 ± 4.05 12.1 ± 3.98	98.0 ± 32.33 97.9 ± 33.09	168.1 ± 55.46 174.6 ± 60.99	MB ACCUBIND ELISA MB ACCULITE CLIA
CEA in ng/ml	2.24 ± 1.05 1.27 ± .42	15.7 ± 6.51 13.9 ± 5.79	32.4 ± 10.69 29.5 ± 9.81	MB ACCUBIND ELISA MB ACCULITE CLIA
fPSA in ng/ml	0.30 ± .18 0.26 ± .21	2.52 ± .83 2.56 ± .84	> 10.0 > 10.0	MB ACCUBIND ELISA MB ACCULITE CLIA
PSA in ng/ml	0.80 ± .24 0.47 ± .24	3.59 ± 1.18 3.51 ± 1.20	20.5 ± 6.75 21.9 ± 7.22	MB ACCUBIND ELISA MB ACCULITE CLIA
Cardiac Markers				
Dig in ng/ml	0.60 ± .27	1.48 ± .49	2.76 ± .91	MB ACCUBIND ELISA
Diabetes				
C-Peptide in ng/ml	1.08 ± .36 0.96 ± .36	3.11 ± 1.03 3.12 ± 1.03	5.81 ± 1.92 6.05 ± 2.00	MB ACCUBIND ELISA MB ACCULITE CLIA
Insulin in µU/ml	8.78 ± 2.90 8.14 ± 2.69	42.3 ± 13.94 41.2 ± 13.58	122.5 ± 40.42 126.0 ± 41.57	MB ACCUBIND ELISA MB ACCULITE CLIA
Rapid Insulin in µU/ml	8.78 ± 2.90	42.3 ± 13.94	122.5 ± 40.42	MB ACCUBIND ELISA
Fertility				
FSH in mIU/ml	15.4 ± 5.07 15.3 ± 5.05	25.1 ± 8.29 26.2 ± 8.65	77.8 ± 25.68 82.3 ± 27.15	MB ACCUBIND ELISA MB ACCULITE CLIA
hCG in mIU/ml	5.22 ± 1.72 4.36 ± 1.83	52.2 ± 17.22 49.5 ± 16.34	211.8 ± 69.88 207.0 ± 68.30	MB ACCUBIND ELISA MB ACCULITE CLIA
LH in mIU/ml	1.84 ± .69 1.49 ± .81	18.4 ± 6.08 18.3 ± 6.03	56.0 ± 18.46 57.5 ± 18.98	MB ACCUBIND ELISA MB ACCULITE CLIA
PRL in ng/ml	3.71 ± 1.22 3.51 ± 1.16	11.9 ± 3.92 11.7 ± 3.86	39.8 ± 13.13 41.1 ± 13.57	MB ACCUBIND ELISA MB ACCULITE CLIA
PRL-seq in ng/ml	4.07 ± 1.35 4.07 ± 1.09	12.7 ± 4.18 12.7 ± 4.08	41.5 ± 18.06 36.4 ± 12.01	MB ACCUBIND ELISA MB ACCULITE CLIA
Rapid HCG in mIU/ml	4.35 ± 5	40.6 ± 5	190.0 ± 50	MB ACCUBIND ELISA
Growth Deficiency				
hGH in µU/ml	2.90 ± 1.05 3.00 ± 1.02	8.86 ± 2.92 8.76 ± 2.89	23.6 ± 7.79 22.7 ± 7.49	MB ACCUBIND ELISA MB ACCULITE CLIA
Steroids				
Cortisol in µg/dl	3.24 ± 1.41 3.52 ± 1.35	19.7 ± 7.32 20.2 ± 6.65	32.9 ± 11.28 32.7 ± 10.77	MB ACCUBIND ELISA MB ACCULITE CLIA
DHEA-S in µg/ml	< 1.00 < 1.00	1.43 ± 0.57 1.43 ± 0.57	4.46 ± 1.68 4.46 ± 1.68	MB ACCUBIND ELISA MB ACCULITE CLIA
E2 in pg/ml	66.9 ± 22.03 74.7 ± 24.65	365.0 ± 120.44 391.8 ± 129.29	1230.2 ± 405.98 1352.6 ± 446.34	MB ACCUBIND ELISA MB ACCULITE CLIA
uE3 in ng/ml	0.97 ± .32 0.97 ± .32	2.87 ± .95 2.87 ± .95	4.98 ± 1.64 4.98 ± 1.64	MB ACCUBIND ELISA MB ACCULITE CLIA
Progesterone in ng/ml	1.72 ± .57 1.95 ± .64	10.8 ± 3.57 10.9 ± 3.61	33.3 ± 14.22 33.7 ± 11.11	MB ACCUBIND ELISA MB ACCULITE CLIA
Testosterone in ng/ml	0.84 ± 0.3 0.84 ± 0.28	8.73 ± 2.88 8.73 ± 2.88	13.4 ± 4.42 13.4 ± 4.42	MB ACCUBIND ELISA MB ACCULITE CLIA
Thyroid				
ft3 in pg/ml	2.23 ± .75 2.20 ± .78	4.09 ± 1.35 3.99 ± 1.32	11.2 ± 3.87 9.92 ± 3.27	MB ACCUBIND ELISA MB ACCULITE CLIA
ft4 in ng/dl	0.35 ± .21 0.33 ± .27	1.24 ± .41 1.23 ± .41	4.07 ± 1.34 3.99 ± 1.32	MB ACCUBIND ELISA MB ACCULITE CLIA
T3 in ng/ml	0.95 ± .31 0.93 ± .31	1.49 ± .49 1.46 ± .48	3.24 ± 1.07 3.04 ± 1.00	MB ACCUBIND ELISA MB ACCULITE CLIA
T3-Uptake in %U	26.3 ± 8.67 26.1 ± 8.60	34.5 ± 11.38 34.2 ± 11.27	45.7 ± 15.09 45.4 ± 14.99	MB ACCUBIND ELISA MB ACCULITE CLIA
T4 in µg/dl	3.45 ± 1.14 3.44 ± 1.14	8.28 ± 2.73 8.29 ± 2.74	18.2 ± 6.00 17.5 ± 5.78	MB ACCUBIND ELISA MB ACCULITE CLIA
TSH in µU/ml	0.46 ± .24 0.41 ± .24	7.64 ± 2.52 8.08 ± 2.67	16.4 ± 5.40 16.9 ± 5.57	MB ACCUBIND ELISA MB ACCULITE CLIA

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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