Monobind Inc.
The World Resource for Diagnostic Products

CERTIFICATE OF ANALYSIS

QUALITY CONTROL RELEASE

Product: PTH Whole and Intact ELISA Accubind Microwells

REF 10025-300
LOT EIA-100K1L2
2024-11-17
2022-12-28

Purpose: FINAL CHECK

Kit Type: AccuBind® ELISA Microwells

Components	Lot Number	Exp Date
CALIBRATORS	90(A-F) 1F2	2025-06-16
PTH ENZYME REAGENT 3RD GEN	100Q 1K1	2024-11-17
PTH ENZYME REAGENT 2ND GEN	90Q 1H2	2025-08-18
SUBSTRATE	SN 2H2	2025-08-17
STOP SOLUTION	SS 1H2	2025-08-25
WASH SOLUTION	CW 1J2	2025-10-03
MICROPLATE	90X 2F2	2025-06-22
CONTROL	90(M-N) 1F2	2025-06-16

Results

PTH ENZYME REAGENT 3RD GEN	A1*	QC Test	Results	Specifications	Actions
"A" 0.0 pg/ml	0.012	Abs(A)	0.01	<0.06	Pass
"B" 15 pg/ml	0.054	Abs(B/A)	4.50	>1.5	Pass
"C" 75 pg/ml	0.215	Abs(C/B)	3.98	>2.0	Pass
"D" 150 pg/ml	0.422	Abs(D/C)	1.96	>1.6	Pass
"E" 500 pg/ml	1.234	Abs(E/D)	2.92	>2.6	Pass
"F" 1000 pg/ml	2.200	Abs(F/E)	1.78	>1.4	Pass
100% A"F"	2.200	Abs(F)	2.20	>1.8	Pass

* A1 = Absorbance of Individual Calibrators

Controls

Control Type	Lot Num	Results		Specifications	Actions
Monobind	90M1F2	54.87	pg/ml	46.0 ± 15.18	Pass
PTH Control	90N1F2	238.06	pg/ml	250.0 ± 82.5	Pass
Bio-Rad	88711	40.50	pg/ml	47.54 ± 15.69	Pass
Lyphochek Specialty IA	88712	520.37	pg/ml	558.64 ± 184.35	Pass
	88713	1047.10	pg/ml	1512.0 ± 571.5	Pass

Results

PTH ENZYME REAGENT 2ND GEN	A1*	QC Test	Results	Specifications	Actions
"A" 0.0 pg/ml	0.060	Abs(A)	0.06	<0.06	Pass
"B" 15 pg/ml	0.113	Abs(B/A)	1.88	>1.5	Pass
"C" 75 pg/ml	0.249	Abs(C/B)	2.20	>2.0	Pass
"D" 150 pg/ml	0.402	Abs(D/C)	1.61	>1.6	Pass
"E" 500 pg/ml	1.096	Abs(E/D)	2.73	>2.6	Pass
"F" 1000 pg/ml	2.039	Abs(F/E)	1.86	>1.4	Pass
"F" 100%	2.039	Abs(F)	2.04	>1.8	Pass

* A1 = Absorbance of Individual Calibrators

Controls

Control Type	Lot Num	Results		Specifications	Actions
Monobind	90M1F2	42.39	pg/ml	46.0 ± 15.2	Pass
PTH Control	90N1F2	200.80	pg/ml	250.0 ± 82.5	Pass
Bio-Rad	88731	38.20	pg/ml	52.72± 17.4	Pass
Lyphochek Specialty IA	88732	674.42	pg/ml	731.89± 250	Pass
	88733	1255.00	pg/ml	1500 ± 500	Pass

All individual units of human origin have been tested for the presence of HBs antigen and antibodies to HIV I & II and HCV, and were found to be nonreactive by license tests in accordance with standard EN 13641

QC Reference: QCR-10025-22-12-29-04

DATE : 2022-12-29

QC Approval:

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