Monobind Inc.
The World Resource for Diagnostic Products

CERTIFICATE OF ANALYSIS

QUALITY CONTROL RELEASE

Product: Rapid Thyrotropin (TSH-Rapid) Test System

Purpose: FINAL CHECK Kit Type: AccuBind® ELISA Microwells

REF 6025-300
LOT EIA-60K1C3
2024-11-21
2023-03-29

Components	Lot Number	Exp Date
Calibrators A-F	60"A-F"1J2	2025-10-12
Enzyme Reagent	60Q1J2	2025-10-07
Substrate A	SA3K2	2024-11-21
Substrate B	SB3K2	2024-11-21
Stop Solution	SSH1I2	2025-09-30
Wash Solution	CW1A3	2026-01-25
Microplate	EIA-CV1K2	2025-11-07

Results

I.D.	A1*	QC Test	Results	Specifications	Actions
"A" 0.0 µIU/ml	0.005	Abs(A)	0.005	<0.05	Pass
"B" 0.5 µIU/ml	0.017	Abs(B-A)	0.012	>0.01	Pass
"C" 2.5 µIU/ml	0.130	Abs(C/B)	7.65	>2.5	Pass
"D" 10.0 µIU/ml	0.499	Abs(D/C)	3.84	>2.5	Pass
"E" 30.0 µIU/ml	1.227	Abs(E/D)	2.46	>2	Pass
"F" 100.0 µIU/ml	2.825	Abs(F/E)	2.30	>2	Pass
100% of "F"	2.825	Abs(F)	2.825	>2	Pass

A1* = Absorbance of Individual Calibrators

Controls

Control Type	Lot Num	Results	Specifications	Actions
Monobind QSure Multi-Ligand	MLA1F2	0.66 µIU/ml	0.63 ± 0.21	Pass
	MLB1F2	4.64 µIU/ml	5.23 ± 1.72	Pass
	MLC1F2	32.05 µIU/ml	31.54 ± 10.41	Pass
BioRad Lyphocheck IA Plus	40421	0.51 µIU/ml	0.48 ± 0.16	Pass
	40422	4.85 µIU/ml	5.96 ± 1.97	Pass
	40423	34.41 µIU/ml	36.40 ± 12.01	Pass
BioRad Lyphocheck IA Plus	40431	0.52 µIU/ml	0.49 ± 0.16	Pass
	40432	5.12 µIU/ml	5.53 ± 1.82	Pass
	40433	33.81 µIU/ml	32.85 ± 10.84	Pass
	n/a	n/a	n/a	n/a
	n/a	n/a	n/a	n/a
	n/a	n/a	n/a	n/a

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 licensed tests in accordance with standard EN 136

QC Reference: QCR6025-23-08 **Date: 2023-03-29**

QC Approval: Sima Izadi **Sima Izadi**

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