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-60K1D3
2025-01-11
2023-04-28

Components	Lot Number	Exp Date
Calibrators A-F	60"A-F"1J2	2025-10-12
Enzyme Reagent	60Q1J2	2025-10-07
Substrate A	SA1A3	2025-01-11
Substrate B	SB1A3	2025-01-11
Stop Solution	SSH1I2	2025-09-30
Wash Solution	CW1A3	2026-01-25
Microplate	EIA-CV1L2	2025-12-05

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	0.019	Abs(B-A)	0.014	>0.01	Pass
"C" 2.5 µIU/ml	0.129	Abs(C/B)	6.79	>2.5	Pass
"D" 10.0 µIU/ml	0.505	Abs(D/C)	3.91	>2.5	Pass
"E" 30.0 µIU/ml	1.225	Abs(E/D)	2.43	>2	Pass
"F" 100.0 µIU/ml	2.882	Abs(F/E)	2.35	>2	Pass
100% of "F"	2.882	Abs(F)	2.882	>2	Pass

A1* = Absorbance of Individual Calibrators

Controls

Control Type	Lot Num	Results	Specifications	Actions
Monobind QSure Multi-Ligand	MLA1F2	0.62 µIU/ml	0.63 ± 0.21	Pass
	MLB1F2	4.68 µIU/ml	5.23 ± 1.72	Pass
	MLC1F2	32.19 µIU/ml	31.54 ± 10.41	Pass
BioRad Lyphocheck IA Plus	40421	0.47 µIU/ml	0.48 ± 0.16	Pass
	40422	4.89 µIU/ml	5.96 ± 1.97	Pass
	40423	34.61 µIU/ml	36.40 ± 12.01	Pass
BioRad Lyphocheck IA Plus	40431	0.48 µIU/ml	0.49 ± 0.16	Pass
	40432	5.16 µIU/ml	5.53 ± 1.82	Pass
	40433	34 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 license tests in accordance with standard EN 13641

QC Reference: QCR6025-23-09 **Date: 2023-05-01**

QC Approval: **Janet Varona**

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