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-60K1H3
2025-04-21
2023-08-29

Components	Lot Number	Exp Date
Calibrators A-F	60"A-F"1G3	2026-07-17
Enzyme Reagent	60Q1C3	2026-03-29
Substrate A	SA1D3	2025-04-21
Substrate B	SB1D3	2025-04-21
Stop Solution	SSH1C3	2026-03-31
Wash Solution	CW1D3	2026-04-28
Microplate	EIA-CV2C3	2026-03-20

Results

I.D.	A1*	QC Test	Results	Specifications	Actions
"A" 0.0 µIU/ml	0.020	Abs(A)	0.020	<0.05	Pass
"B" 0.5 µIU/ml	0.046	Abs(B-A)	0.026	>0.01	Pass
"C" 2.5 µIU/ml	0.136	Abs(C/B)	2.96	>2.5	Pass
"D" 10.0 µIU/ml	0.468	Abs(D/C)	3.44	>2.5	Pass
"E" 30.0 µIU/ml	1.143	Abs(E/D)	2.44	>2	Pass
"F" 100.0 µIU/ml	2.724	Abs(F/E)	2.38	>2	Pass
100% of "F"	2.724	Abs(F)	2.724	>2	Pass

A1* = Absorbance of Individual Calibrators

Controls

Control Type	Lot Num	Results	Specifications	Actions
Monobind QSure Multi-Ligand	MLA1D3	0.769 µIU/ml	0.87 ± 0.29	Pass
	MLB1D3	6.902 µIU/ml	6.45 ± 2.13	Pass
	MLC1D3	35.354 µIU/ml	34.26 ± 11.31	Pass
BioRad Lyphocheck IA Plus	40421	0.375 µIU/ml	0.48 ± 0.16	Pass
	40422	6.024 µIU/ml	5.96 ± 1.97	Pass
	40423	38.173 µIU/ml	36.40 ± 12.01	Pass
BioRad Lyphocheck IA Plus	40431	0.489 µIU/ml	0.49 ± 0.16	Pass
	40432	5.022 µIU/ml	5.53 ± 1.82	Pass
	40433	36.506 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: QCR6025-23-14 **Date: 2023-08-29**

QC Approval: OBREGON **Chealsea Obregon**

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