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-60K2A3
2024-09-16
2023-01-03

Components	Lot Number	Exp Date
Calibrators A-F	60"A-F"1E2	2025-05-03
Enzyme Reagent	60Q1J1	2024-10-13
Substrate A	SA2I2	2024-09-16
Substrate B	SB2I2	2024-09-16
Stop Solution	SSH1H2	2025-08-08
Wash Solution	CW1J2	2025-10-03
Microplate	EIA-CV1I2	2025-09-06

Results

I.D.	A1*	QC Test	Results	Specifications	Actions
"A" 0.0 µIU/ml	0.028	Abs(A)	0.028	<0.05	Pass
"B" 0.5 µIU/ml	0.049	Abs(B-A)	0.021	>0.01	Pass
"C" 2.5 µIU/ml	0.132	Abs(C/B)	2.69	>2.5	Pass
"D" 10.0 µIU/ml	0.391	Abs(D/C)	2.96	>2.5	Pass
"E" 30.0 µIU/ml	0.967	Abs(E/D)	2.47	>2	Pass
"F" 100.0 µIU/ml	2.388	Abs(F/E)	2.47	>2	Pass
100% of "F"	2.388	Abs(F)	2.388	>2	Pass

A1* = Absorbance of Individual Calibrators

Controls

Control Type	Lot Num	Results	Specifications	Actions
Monobind QSure Multi-Ligand	MLA1F2	0.69 µIU/ml	0.63 ± 0.21	Pass
	MLB1F2	4.2 µIU/ml	5.23 ± 1.72	Pass
	MLC1F2	30.78 µIU/ml	31.54 ± 10.41	Pass
BioRad Lyphocheck IA Plus	40431	0.44 µIU/ml	0.49 ± 0.16	Pass
	40432	5.11 µIU/ml	5.53 ± 1.82	Pass
	40433	32.13 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
	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: QCR6025-23-02 **Date: 2023-01-04**

QC Approval: **Janet Varona**

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