Monobind Inc.
The World Resource for Diagnostic Products

CERTIFICATE OF ANALYSIS
QUALITY CONTROL RELEASE

Product: Rubella IgG Test System

REF 6325-300
LOT EIA-63K1E3
2025-10-26
2023-05-04

Purpose: FINAL CHECK Kit Type: AccuBind® ELISA Microwells

Components	Lot Number	Exp Date
Negative Control	63NC1K2	2025-11-08
Cut-Off Control	63CC1K2	2025-11-08
Positive Control	63PC1K2	2025-11-08
Enzyme Reagent	63Q1K2	2025-11-07
Substrate	SC1K2	2025-11-01
Stop Solution	SS1A3	2026-01-20
Wash Solution	CW1A3	2026-01-25
Serum Diluent	CU1K2	2025-11-04
Microplate	EIA-63X1J2	2025-10-26

Results

I.D.	A1*	QC Test	Results	Specifications	Actions
"N" Negative Control	0.241	Abs(N)	0.241	<0.4	Pass
"C" Cut-Off Control	0.754	Abs(C/N)	3.13	>1.8	Pass
"P" Positive Control	2.868	Abs(P/C)	3.80	>1.5	Pass
100% of "P"	2.868	Abs(P)	2.868	>1.8	Pass
Cut-Off Factor		Factor	1	0.8 > Factor < 1.6	Pass

A1* = Absorbance of Individual Controls

Controls

Control Type	Lot Num	Results	Specifications	Actions
Monobind Off the Clot Control	63101A22	8.4	7.5 ± 1.5	Pass
	63201A22	16.69	15.0 ± 3.0	Pass
	63301A22	38.14	34.2 ± 6.8	Pass
Monobind Off the Clot Control	63401A22	5.02	4.6 ± 0.9	Pass
	63501A22	11.31	11.0 ± 2.2	Pass
	63601A22	25.52	23.2 ± 4.6	Pass
Monobind Off the Clot Control	63701A22	7.77	7.0 ± 1.4	Pass
	63801A22	22.76	19.0 ± 3.8	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

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 13641

QC Reference: QCR6325-23-01 **Date: 2023-05-05**

QC Approval: Sima Izadi **Sima Izadi**

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