Title:

Quality Control Record Sheet IA-2 Ab ELISA Kit QC Data

KIE223

Document: Revision:

wi/gcrs/0.28

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Prepared by: G Flood

Kit lot number:

Approved by: A Salvage

Kit expiry date: 11 June 2024

IA-2 Coated Wells: Lot No. IE218 Expiry Date 26 SEP 2024

IA-2-Biotin: Lot No. IEB150 Expiry Date 21 SEP 2024

Recon. Buffer for IA-2-Biotin: Lot No. IBB180 Expiry Date 08 AUG 2024

Streptavidin Peroxidase: Lot No. GEP558 Expiry Date 14 NOV 2024

Diluent for SA-POD: Lot No. PB174 Expiry Date 12 FEB 2025

Lot No. IES119 Reaction Enhancer: Expiry Date 28 JUL 2024

Peroxidase Substrate: Lot No. PTS183F Expiry Date 24 OCT 2026

Stop Solution: Lot No. HESP124 Expiry Date 02 APR 2025

Concentrated Wash Solution: Lot No. CW349 Expiry Date <u>05 SEP 2025</u>

Calibrators: Lot No. IEC223 Expiry Date 11 JUN 2024

Controls: Lot No. IENC223 / IEPC223 Expiry Date 11 JUN 2024

Calibrator Curve and Controls: Incubation temp: +4 °C OVERNIGHT +21 °C

Calibrator Concentration	Absorbance at	Absorbance at
(units per mL)	450 nm	405 nm
Negative control	0.077	0.022
15	0.202	0.060
60	0.655	0.205
200	2.538	0.799
400	>4	1.572
4000	>4	2.626

Control	Absorbance at 450 nm	Absorbance at 405 nm	Concentration at 450 nm (units per mL)	Concentration at 405 nm (units per mL)	Range (units per mL)
Positive	1.359	0.433	124.2	120.3	125 ± 40

Materials of human origin used in the manufacture of this product have been tested and found nonreactive for HIV1 and 2 and HCV antibodies and HBsAg at the time of testing.

Assay performed by:	Rebecca Coles		
Signature:	P. Coles		

Position: Senior Scientist

Date: 24/25 May 2023

Authorised by:

Signature:

Position: Date: