Title:

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

Document: Revision:

wi/qcrs/0.28

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Prepared by: Approved by:

Controls:

G Flood A Salvage

Kit lot number: KIE222

Kit expiry date: ___ 13 May 2024

Expiry Date 14 MAY 2024

Expiry Date 14 MAY 2024

IA-2 Coated Wells: Lot No. IE218 Expiry Date 26 SEP 2024 IA-2-Biotin Lot No. IEB147 Expiry Date 13 MAY 2024 Recon. Buffer for IA-2-Biotin: Lot No. IBB180 Expiry Date 08 AUG 2024 Streptavidin Peroxidase: Lot No. GEP541 Expiry Date 30 JUL 2024 Diluent for SA-POD: Lot No. PB172 Expiry Date 23 AUG 2024 Reaction Enhancer: Lot No. IES118 Expiry Date 19 MAY 2024 Peroxidase Substrate: Lot No. PTS181F Expiry Date 21 APR 2026 Stop Solution: Lot No. HESP121 Expiry Date 11 OCT 2024 Concentrated Wash Solution: Lot No. CW311 Expiry Date 17 AUG 2024 Calibrators:

Lot No. IENC222 / IEPC222

Lot No. IEC222

Calibrator Curve and Controls:

Incubation temp: +4 °C OVERNIGHT

The state of the s	incubation temp. +4 C OVERNIGHT +22 °C		
Calibrator Concentration	Absorbance at	Absorbance at 405 nm	
(units per mL)	450 nm		
Negative control	0.068	0.019	
15	0.182	0.056	
60	0.692	0.214	
200	2.566	0.801	
400	>4	1.454	
4000	>4	2.721	

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	1.280	0.399	108.7	104.8	110 ± 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		
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Position:	Senior Scientist		
Date:	24/25 April 2023		
Authorised by:	DR G FLOOD		
Signature:	5 Mul		
Position:	MEAD OF QC		
Date:	15TH MAY 2023		