

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

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Prepared by: **G Flood**
Approved by: **A Salvage**

Kit lot number: KIE234A

Kit expiry date: 15 September 2025

IA-2 Coated Wells:	Lot No. <u>IE233</u>	Expiry Date <u>19 NOV 2025</u>
IA-2-Biotin:	Lot No. <u>IEB162</u>	Expiry Date <u>14 NOV 2025</u>
Recon. Buffer for IA-2-Biotin:	Lot No. <u>IBB185</u>	Expiry Date <u>10 DEC 2025</u>
Streptavidin Peroxidase:	Lot No. <u>GEP651</u>	Expiry Date <u>15 JAN 2026</u>
Diluent for SA-POD:	Lot No. <u>PB181</u>	Expiry Date <u>09 APR 2026</u>
Reaction Enhancer:	Lot No. <u>IES129</u>	Expiry Date <u>10 JUN 2026</u>
Peroxidase Substrate:	Lot No. <u>PTS187H</u>	Expiry Date <u>30 NOV 2027</u>
Stop Solution:	Lot No. <u>HESP132</u>	Expiry Date <u>29 APR 2026</u>
Concentrated Wash Solution:	Lot No. <u>CW364</u>	Expiry Date <u>10 FEB 2026</u>
Calibrators:	Lot No. <u>IEC234a</u>	Expiry Date <u>15 SEP 2025</u>
Controls:	Lot No. <u>IENC234a / IEPC234a</u>	Expiry Date <u>15 SEP 2025</u>

Calibrator Curve and Controls:

Incubation temp: +4 °C OVERNIGHT +22 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.075	0.023
15	0.233	0.069
60	0.545	0.159
200	2.446	0.707
400	>4	1.363
4000	>4	2.684

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	1.344	0.389	121.5	122.8	120 ± 40

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

Assay performed by:

 Fiona Ryrie

Signature:

 RColes

Position:

 Scientist

Date:

 30/31 July 2024

Authorised by:

 DR G Flood

Signature:

 G Flood

Position:

 HEAD OF QC

Date:

 13TH SEP 2024