

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: **KIE227C**

Kit expiry date: **31 March 2025**

IA-2 Coated Wells:	Lot No. <u> IE225 </u>	Expiry Date <u> 22 APR 2025 </u>
IA-2-Biotin:	Lot No. <u> IEB155 </u>	Expiry Date <u> 08 APR 2025 </u>
Recon. Buffer for IA-2-Biotin:	Lot No. <u> IBB183 </u>	Expiry Date <u> 17 JUN 2025 </u>
Streptavidin Peroxidase:	Lot No. <u> GEP596 </u>	Expiry Date <u> 07 MAY 2025 </u>
Diluent for SA-POD:	Lot No. <u> PB175 </u>	Expiry Date <u> 30 MAY 2025 </u>
Reaction Enhancer:	Lot No. <u> IES124 </u>	Expiry Date <u> 16 AUG 2025 </u>
Peroxidase Substrate:	Lot No. <u> PTS183H </u>	Expiry Date <u> 24 OCT 2026 </u>
Stop Solution:	Lot No. <u> HESP127 </u>	Expiry Date <u> 20 SEP 2025 </u>
Concentrated Wash Solution:	Lot No. <u> CW360 </u>	Expiry Date <u> 22 DEC 2025 </u>
Calibrators:	Lot No. <u> IEC227c </u>	Expiry Date <u> 31 MAR 2025 </u>
Controls:	Lot No. <u> IENC227c / IEPC227c </u>	Expiry Date <u> 31 MAR 2025 </u>

Calibrator Curve and Controls:

Incubation temp: **+4 °C OVERNIGHT** **+21 °C**

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.078	0.023
15	0.225	0.065
60	0.554	0.160
200	2.501	0.720
400	>4	1.462
4000	>4	2.691

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	1.251	0.361	116.1	117.8	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:

 pp Fiona Pyrie

Signature:

 J Bradbury

Position:

 Scientist

Date:

 12/13 February 2024

Authorised by:

 DR G Flood

Signature:

 A Salvage

Position:

 HEAD OF QC

Date:

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