

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: KIE224C

Kit expiry date: 12 November 2024

IA-2 Coated Wells:	Lot No. <u>IE221</u>	Expiry Date <u>19 DEC 2024</u>
IA-2-Biotin:	Lot No. <u>IEB151</u>	Expiry Date <u>25 NOV 2024</u>
Recon. Buffer for IA-2-Biotin:	Lot No. <u>IBB182</u>	Expiry Date <u>20 FEB 2025</u>
Streptavidin Peroxidase:	Lot No. <u>GEP569</u>	Expiry Date <u>05 JAN 2025</u>
Diluent for SA-POD:	Lot No. <u>PB174</u>	Expiry Date <u>12 FEB 2025</u>
Reaction Enhancer:	Lot No. <u>IES123</u>	Expiry Date <u>03 MAY 2025</u>
Peroxidase Substrate:	Lot No. <u>PTS183H</u>	Expiry Date <u>24 OCT 2026</u>
Stop Solution:	Lot No. <u>HESP125</u>	Expiry Date <u>31 MAY 2025</u>
Concentrated Wash Solution:	Lot No. <u>CW349</u>	Expiry Date <u>05 SEP 2025</u>
Calibrators:	Lot No. <u>IEC224c</u>	Expiry Date <u>12 NOV 2024</u>
Controls:	Lot No. <u>IENC224c / IEPC224c</u>	Expiry Date <u>12 NOV 2024</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	0.036	0.001
15	0.201	0.058
60	0.559	0.162
200	2.430	0.700
400	>4	1.373
4000	>4	2.396

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	1.301	0.375	122.0	120.9	125 ± 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:	<u>Rebecca Coles</u>
Signature:	<u><i>R. Coles</i></u>
Position:	<u>Senior Scientist</u>
Date:	<u>23/24 October 2023</u>
Authorised by:	<u><i>DR G Flood</i></u>
Signature:	<u><i>G Flood</i></u>
Position:	<u>HEAD OF QC</u>
Date:	<u>13TH NOV 2023</u>