

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

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Approved by: **A SALVAGE**

Kit lot number: 2KIE141 Kit expiry date: 11 June 2024

Kit manufacture date: 12 June 2023

**Reagent Lot Numbers:**

IA-2 Coated Wells: <u>IE219</u>	Expiry date: <u>23 OCT 2024</u>
IA-2-Biotin: <u>IEB150</u>	Expiry date: <u>21 SEP 2024</u>
Recon. Buffer for IA-2-Biotin: <u>IBB180</u>	Expiry date: <u>08 AUG 2024</u>
Streptavidin Peroxidase: <u>GEP559</u>	Expiry date: <u>14 NOV 2024</u>
Diluent for SA-POD: <u>PB174</u>	Expiry date: <u>12 FEB 2025</u>
Reaction Enhancer: <u>IES123</u>	Expiry date: <u>03 MAY 2025</u>
Peroxidase Substrate: <u>PTS183F</u>	Expiry date: <u>24 OCT 2026</u>
Stop Solution: <u>HESP124</u>	Expiry date: <u>02 APR 2025</u>
Concentrated Wash Solution: <u>CW353</u>	Expiry date: <u>01 NOV 2025</u>
Calibrators: <u>IC141</u>	Expiry date: <u>11 JUN 2024</u>
Controls: <u>INC141/ IPC141</u>	Expiry date: <u>11 JUN 2024</u>

**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	0.025	0.003
7.5	0.127	0.036
35	0.360	0.110
120	1.670	0.523
350	>4	1.582
4000	>4	2.633

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 I	1.591	0.500	116.3	116.4	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: <u>Fiona Rylie</u>	Authorised by: <u>DR G Flood</u>
Signature: <u>Fiona Rylie</u>	Signature: <u>[Signature]</u>
Position: <u>Scientist</u>	Position: <u>Head of Quality Control</u>
Date: <u>25/26 May 2023</u>	Date: <u>9<sup>th</sup> JUN 2023</u>