

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

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Prepared by: **G FLOOD**
Approved by: **L CARR**

Kit lot number: FKIE171 Kit expiry date: 13 October 2025

Kit manufacture date: 14 October 2024

Reagent Lot Numbers:

IA-2 Coated Wells: <u>IE236</u>	Expiry date: <u>18 FEB 2026</u>
IA-2-Biotin: <u>IEB164</u>	Expiry date: <u>06 FEB 2026</u>
Recon. Buffer for IA-2-Biotin: <u>IBB185</u>	Expiry date: <u>10 DEC 2025</u>
Streptavidin Peroxidase: <u>GEP665</u>	Expiry date: <u>15 MAR 2026</u>
Diluent for SA-POD: <u>PB181</u>	Expiry date: <u>09 APR 2026</u>
Reaction Enhancer: <u>IES129</u>	Expiry date: <u>10 JUN 2026</u>
Peroxidase Substrate: <u>PTS185N</u>	Expiry date: <u>27 APR 2027</u>
Stop Solution: <u>HESP133</u>	Expiry date: <u>19 JUN 2026</u>
Concentrated Wash Solution: <u>CW391</u>	Expiry date: <u>14 SEP 2026</u>
Calibrators: <u>IC171</u>	Expiry date: <u>13 OCT 2025</u>
Controls: <u>INC171/IPC171</u>	Expiry date: <u>13 OCT 2025</u>

Curve and Controls: Incubation temp: +21 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.068	0.021
7.5	0.148	0.045
35	0.394	0.115
120	1.855	0.537
350	>4	1.767
4000	>4	2.668

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	1.841	0.532	119.4	119.3	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>Rebecca Coles</u>	Authorised by: <u>DR G Flood</u>
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Position: <u>Senior Scientist</u>	Position: <u>Head of Quality Control</u>
Date: <u>02 October 2024</u>	Date: <u>14th OCT 2024</u>