

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

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 Revision: **0**
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Prepared by: **G FLOOD**
 Approved by: **L CARR**

Kit lot number: FKIE150 Kit expiry date: 15 October 2024

Kit manufacture date: 16 October 2023

Reagent Lot Numbers:

IA-2 Coated Wells: <u>IE223</u>	Expiry date: <u>06 FEB 2025</u>
IA-2-Biotin: <u>IEB151</u>	Expiry date: <u>25 NOV 2024</u>
Recon. Buffer for IA-2-Biotin: <u>IBB182</u>	Expiry date: <u>20 FEB 2025</u>
Streptavidin Peroxidase: <u>GEP589</u>	Expiry date: <u>28 MAR 2025</u>
Diluent for SA-POD: <u>PB174</u>	Expiry date: <u>12 FEB 2025</u>
Reaction Enhancer: <u>IES124</u>	Expiry date: <u>16 AUG 2025</u>
Peroxidase Substrate: <u>PTS183F</u>	Expiry date: <u>24 OCT 2026</u>
Stop Solution: <u>HESP123</u>	Expiry date: <u>12 JAN 2025</u>
Concentrated Wash Solution: <u>CW353</u>	Expiry date: <u>01 NOV 2025</u>
Calibrators: <u>IC150</u>	Expiry date: <u>15 OCT 2024</u>
Controls: <u>INC150/IPC150</u>	Expiry date: <u>15 OCT 2024</u>

Curve and Controls: Incubation temp: +21 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.069	0.015
7.5	0.170	0.047
35	0.397	0.120
120	1.831	0.571
350	>4	1.554
4000	>4	2.738

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	1.800	0.567	118.5	119.3	115 ± 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 Ryrie</u>	Authorised by: <u>J. Bradbury</u>
Signature: <u><i>Fiona Ryrie</i></u>	Signature: <u><i>J. Bradbury</i></u>
Position: <u>Scientist</u>	Position: <u>pp Head of Quality Control</u>
Date: <u>05 October 2023</u>	Date: <u>17 October 2023</u>