

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

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Approved by: L CARR

Kit lot number: FKIE130A

Kit expiry date: 18 September 2023

Kit manufacture date: 19 September 2022

Reagent Lot Numbers:

IA-2 Coated Wells: <u>IE210</u>	Expiry date: <u>11 JAN 2024</u>
IA-2-Biotin: <u>IEB144</u>	Expiry date: <u>19 JAN 2024</u>
Recon. Buffer for IA-2-Biotin: <u>IBB178</u>	Expiry date: <u>09 DEC 2023</u>
Streptavidin Peroxidase: <u>GEP507</u>	Expiry date: <u>09 FEB 2024</u>
Diluent for SA-POD: <u>PB171</u>	Expiry date: <u>16 MAY 2024</u>
Reaction Enhancer: <u>IES118</u>	Expiry date: <u>19 MAY 2024</u>
Peroxidase Substrate: <u>PTS179P</u>	Expiry date: <u>30 SEP 2024</u>
Stop Solution: <u>HESP118</u>	Expiry date: <u>16 MAY 2024</u>
Concentrated Wash Solution: <u>CW321</u>	Expiry date: <u>22 DEC 2024</u>
Calibrators: <u>IC130a</u>	Expiry date: <u>18 SEP 2023</u>
Controls: <u>INC130a/ IPC130a</u>	Expiry date: <u>18 SEP 2023</u>

Curve and Controls: Incubation temp: +21 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.072	0.019
7.5	0.176	0.053
35	0.473	0.146
120	2.035	0.637
350	>4	1.697
4000	>4	2.711

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	2.244	0.704	129.2	130.1	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: Fiona Ryrie
Signature: Fiona Ryrie
Position: Scientist
Date: 14/15 August 2022

Authorised by: DR G Flood
Signature: [Signature]
Position: Head of Quality Control
Date: 20th SEP 2022