

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

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 Approved by: L CARR

Kit lot number: FKIE134D

Kit expiry date: 05 March 2024

Kit manufacture date: 06 March 2023

Reagent Lot Numbers:

IA-2 Coated Wells: <u>IE214</u>	Expiry date: <u>13 MAY 2024</u>
IA-2-Biotin: <u>IEB146</u>	Expiry date: <u>02 APR 2024</u>
Recon. Buffer for IA-2-Biotin: <u>IBB179</u>	Expiry date: <u>24 APR 2024</u>
Streptavidin Peroxidase: <u>GEP528</u>	Expiry date: <u>22 MAY 2024</u>
Diluent for SA-POD: <u>PB172</u>	Expiry date: <u>23 AUG 2024</u>
Reaction Enhancer: <u>IES118</u>	Expiry date: <u>19 MAY 2024</u>
Peroxidase Substrate: <u>PTS181F</u>	Expiry date: <u>21 APR 2026</u>
Stop Solution: <u>HESP121</u>	Expiry date: <u>11 OCT 2024</u>
Concentrated Wash Solution: <u>CW335</u>	Expiry date: <u>12 APR 2025</u>
Calibrators: <u>IC134c/IC134Ac</u>	Expiry date: <u>05 MAR 2024</u>
Controls: <u>INC134c/IPC134c</u>	Expiry date: <u>05 MAR 2024</u>

Curve and Controls: Incubation temp: +20 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.049	0.004
7.5	0.168	0.043
35	0.342 0.642	0.099
120	1.585	0.491
350	>4	1.506
4000	>4	2.634

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	1.627	0.509	122.0	123.1	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: 09 March 2023

Authorised by: DR G Flood
 Signature: [Signature]
 Position: Head of Quality Control
 Date: 16th MAR 2023