

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

Document: **wi/qcrs/0.28b**

Revision: **0**

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Approved by: **L CARR**

Kit lot number: FKIE156A

Kit expiry date: 31 March 2025

Kit manufacture date: 01 April 2024

Reagent Lot Numbers:

IA-2 Coated Wells: <u>IE226</u>	Expiry date: <u>10 JUN 2025</u>
IA-2-Biotin: <u>IEB156</u>	Expiry date: <u>30 APR 2025</u>
Recon. Buffer for IA-2-Biotin: <u>IBB183</u>	Expiry date: <u>17 JUN 2025</u>
Streptavidin Peroxidase: <u>GEP610</u>	Expiry date: <u>15 JUL 2025</u>
Diluent for SA-POD: <u>PB179</u>	Expiry date: <u>13 NOV 2025</u>
Reaction Enhancer: <u>IES124</u>	Expiry date: <u>16 AUG 2025</u>
Peroxidase Substrate: <u>PTS185M</u>	Expiry date: <u>27 APR 2027</u>
Stop Solution: <u>HESP128</u>	Expiry date: <u>02 NOV 2025</u>
Concentrated Wash Solution: <u>CW373</u>	Expiry date: <u>25 APR 2026</u>
Calibrators: <u>IC156a</u>	Expiry date: <u>31 MAR 2025</u>
Controls: <u>INC156a/IPC156a</u>	Expiry date: <u>31 MAR 2025</u>

Curve and Controls: Incubation temp: +21 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.069	0.019
7.5	0.152	0.044
35	0.419	0.120
120	1.825	0.524
350	>4	1.524
4000	>4	2.476

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	1.847	0.532	121.1	121.2	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: Rebecca Coles
 Signature: R Coles
 Position: Senior Scientist
 Date: 23 January 2024

Authorised by: DR G Flood
 Signature: G Flood
 Position: Head of Quality Control
 Date: 27th MAR 2024