

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

Document: **wi/qcrs/0.28b**
 Revision: **0**
 Date: **20 September 2022**
 Page **1 of 1**

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

Kit lot number: FKIE154 Kit expiry date: 21 January 2025

Kit manufacture date: 22 January 2024

Reagent Lot Numbers:

IA-2 Coated Wells: <u>IE225</u>	Expiry date: <u>22 APR 2025</u>
IA-2-Biotin: <u>IEB156</u>	Expiry date: <u>30 APR 2025</u>
Recon. Buffer for IA-2-Biotin: <u>IBB182</u>	Expiry date: <u>20 FEB 2025</u>
Streptavidin Peroxidase: <u>GEP599</u>	Expiry date: <u>20 MAY 2025</u>
Diluent for SA-POD: <u>PB177</u>	Expiry date: <u>10 AUG 2025</u>
Reaction Enhancer: <u>IES124</u>	Expiry date: <u>16 AUG 2025</u>
Peroxidase Substrate: <u>PTS185Ga</u>	Expiry date: <u>27 ^{APR} JUL 2027</u>
Stop Solution: <u>HESP127</u>	Expiry date: <u>20 SEP 2025</u>
Concentrated Wash Solution: <u>CW371</u>	Expiry date: <u>24 MAR 2026</u>
Calibrators: <u>IC154A</u>	Expiry date: <u>21 JAN 2025</u>
Controls: <u>INC154A/IPC154A</u>	Expiry date: <u>21 JAN 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	0.020
7.5	0.182	0.053
35	0.442	0.127
120	1.878	0.540
350	>4	1.679
4000	>4	2.892

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	1.987	0.572	124.8	124.8	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: Rebecca Coles
 Signature: *R. Coles*
 Position: Senior Scientist
 Date: 08 January 2024

Authorised by: SARAH NUTE
 Signature: *SNUTE*
 Position: Head of Quality Control
 Date: 23 JAN 2024