

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

Kit lot number: FKIE141 Kit expiry date: 11 June 2024

Kit manufacture date: 12 June 2023

Reagent Lot Numbers:

IA-2 Coated Wells: <u>IE219</u>	Expiry date: <u>23 OCT 2024</u>
IA-2-Biotin: <u>IEB150</u>	Expiry date: <u>21 SEP 2024</u>
Recon. Buffer for IA-2-Biotin: <u>IBB180</u>	Expiry date: <u>08 AUG 2024</u>
Streptavidin Peroxidase: <u>GEP537</u>	Expiry date: <u>17 JUL 2024</u>
Diluent for SA-POD: <u>PB174</u>	Expiry date: <u>12 FEB 2025</u>
Reaction Enhancer: <u>IES123</u>	Expiry date: <u>03 MAY 2025</u>
Peroxidase Substrate: <u>PTS183F</u>	Expiry date: <u>24 OCT 2026</u>
Stop Solution: <u>HESP124</u>	Expiry date: <u>02 APR 2025</u>
Concentrated Wash Solution: <u>CW353</u>	Expiry date: <u>01 NOV 2025</u>
Calibrators: <u>IC141</u>	Expiry date: <u>11 JUN 2024</u>
Controls: <u>INC141/IPC141</u>	Expiry date: <u>11 JUN 2024</u>

Curve and Controls: Incubation temp: +21 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.030	0.000
7.5	0.138	0.033
35	0.370	0.107
120	1.613	0.498
350	>4	1.553
4000	>4	2.705

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	1.715	0.537	124.8	126.3	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: 06 June 2023

Authorised by: DR G Flood
Signature: G Flood
Position: Head of Quality Control
Date: 12TH JUN 2023