

Prepared by: G FLOOD
Approved by: A SALVAGE

Kit lot number: 2KIE94A Kit expiry date: 10 JANUARY 2022

Kit manufacture date: 11 JANUARY 2021

Reagent Lot Numbers:

IA-2 Coated Wells: <u>IE187</u>	Expiry date: <u>11 APR 2022</u>
IA-2-Biotin: <u>IEB127</u>	Expiry date: <u>14 MAR 2022</u>
Recon. Buffer for IA-2-Biotin: <u>IBB172</u>	Expiry date: <u>14 MAR 2022</u>
Streptavidin Peroxidase: <u>GEP398</u>	Expiry date: <u>04 MAY 2022</u>
Diluent for SA-POD: <u>PB161</u>	Expiry date: <u>18 OCT 2022</u>
Reaction Enhancer: <u>IES105</u>	Expiry date: <u>01 SEP 2022</u>
Peroxidase Substrate: <u>PTS173J</u>	Expiry date: <u>19 NOV 2022</u>
Stop Solution: <u>HESP108</u>	Expiry date: <u>08 NOV 2022</u>
Concentrated Wash Solution: <u>CW261</u>	Expiry date: <u>11 APR 2023</u>
Calibrators: <u>IC94a</u>	Expiry date: <u>10 JAN 2022</u>
Controls: <u>INC94a / IPC94a</u>	Expiry date: <u>10 JAN 2022</u>

Curve and Controls: Incubation temp: +4 °C OVERNIGHT +21 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.031	0.023
7.5	0.136	0.050
35	0.451	0.143
120	1.683	0.506
350	>4	1.618
4000	>4	2.602

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	1.714	0.510	121.4	120.6	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: <u>A. E. COLLINS</u>	Authorised by: <u>OR G Flood</u>
Signature: <u>pp JBradbury</u>	Signature: <u>J Flood</u>
Position: <u>SECTION LEADER</u>	Position: <u>Head of Quality Control</u>
Date: <u>07/08 DECEMBER 2020</u>	Date: <u>8TH JAN 2021</u>