

Prepared by: **G Flood**
Approved by: **A Salvage**

Kit lot number: KIE192

Kit expiry date: 13 DECEMBER 2021

IA-2 Coated Wells:	Lot No. <u>IE185</u>	Expiry Date <u>02 JAN 2022</u>
IA-2-Biotin:	Lot No. <u>IEB127</u>	Expiry Date <u>14 MAR 2022</u>
Recon. Buffer for IA-2-Biotin:	Lot No. <u>IBB172</u>	Expiry Date <u>14 MAR 2022</u>
Streptavidin Peroxidase:	Lot No. <u>GEP401</u>	Expiry Date <u>01 SEP 2022</u>
Diluent for SA-POD:	Lot No. <u>PB160</u>	Expiry Date <u>19 AUG 2022</u>
Reaction Enhancer:	Lot No. <u>IES105</u>	Expiry Date <u>01 SEP 2022</u>
Peroxidase Substrate:	Lot No. <u>PTS173F</u>	Expiry Date <u>19 NOV 2022</u>
Stop Solution:	Lot No. <u>HESP107</u>	Expiry Date <u>15 SEP 2022</u>
Concentrated Wash Solution:	Lot No. <u>CW256</u>	Expiry Date <u>13 JAN 2023</u>
Calibrators:	Lot No. <u>IEC192</u>	Expiry Date <u>13 DEC 2021</u>
Controls:	Lot No. <u>IENC192 / IEPC192</u>	Expiry Date <u>13 DEC 2021</u>

Calibrator Curve and Controls: Incubation temp: +4 °C OVERNIGHT +20 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.059	0.032
15	0.212	0.072
60	0.665	0.206
200	2.595	0.779
400	>4	1.600
4000	>4	2.689

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	1.620	0.483	139.8	137.4	¹²⁰ ~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:	<u>A. E. COLLINS</u>
Signature:	<u><i>A. Collins</i></u>
Position:	<u>SECTION LEADER</u>
Date:	<u>09/10 DECEMBER 2020</u>
Authorised by:	<u>DR G FLOOD</u>
Signature:	<u><i>G Flood</i></u>
Position:	<u>HEAD OF QC</u>
Date:	<u>14TH DEC 2020</u>