

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

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Revision: **7**
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Prepared by: **G Flood**
Approved by: **A Salvage**

Kit lot number: KIE192A

Kit expiry date: 02 JANUARY 2022

IA-2 Coated Wells:	Lot No. <u>IE185</u>	Expiry Date <u>02 JAN 2022</u>
IA-2-Biotin:	Lot No. <u>IEB128</u>	Expiry Date <u>18 MAY 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>GEP401a</u>	Expiry Date <u>01 JUN 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>IEC192a</u>	Expiry Date <u>10 JAN 2022</u>
Controls:	Lot No. <u>IENC192a / IEPC192a</u>	Expiry Date <u>10 JAN 2022</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	0.055	0.028
15	0.203	0.063
60	0.646	0.196
200	2.554	0.756
400	>4	1.407
4000	>4	2.701

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	1.510	0.447	125.7	124.9	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>
Signature:	<u>pp <i>J. Bradbury</i></u>
Position:	<u> SECTION LEADER </u>
Date:	<u> 21/22 DECEMBER 2020 </u>
Authorised by:	<u> DR G FLOOD </u>
Signature:	<u> <i>A Salvage</i></u>
Position:	<u> HEAD OF QC </u>
Date:	<u> 4TH JAN 2021 </u>