

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

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

Kit lot number: KIE190

Kit expiry date: 13 OCT 2021

IA-2 Coated Wells:	Lot No. <u>IE184</u>	Expiry Date <u>22 DEC 2021</u>
IA-2-Biotin:	Lot No. <u>IEB126</u>	Expiry Date <u>08 JAN 2022</u>
Recon. Buffer for IA-2-Biotin:	Lot No. <u>IBB171</u>	Expiry Date <u>13 OCT 2021</u>
Streptavidin Peroxidase:	Lot No. <u>GEP390</u>	Expiry Date <u>27 MAR 2022</u>
Diluent for SA-POD:	Lot No. <u>PB159</u>	Expiry Date <u>30 JUN 2022</u>
Reaction Enhancer:	Lot No. <u>IES103</u>	Expiry Date <u>23 APR 2022</u>
Peroxidase Substrate:	Lot No. <u>PTS173A</u>	Expiry Date <u>19 NOV 2022</u>
Stop Solution:	Lot No. <u>HESP106</u>	Expiry Date <u>02 JUN 2022</u>
Concentrated Wash Solution:	Lot No. <u>CW249</u>	Expiry Date <u>27 OCT 2022</u>
Calibrators:	Lot No. <u>IEC190</u>	Expiry Date <u>18 OCT 2021</u>
Controls:	Lot No. <u>IENC190 / IEPC190</u>	Expiry Date <u>18 OCT 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	0.048	0.034
15	0.216	0.073
60	0.758	0.237
200	2.960	0.927
400	>4	1.658
4000	>4	2.693

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	1.901	0.571	136.6	127.5	130 ± 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: A. E. COLLINS
Signature: *A.E. Collins*
Position: SECTION LEADER
Date: 14 /15 OCT 2020

Authorised by: *DR G Flood*
Signature: *G Flood*
Position: HEAD OF QC
Date: 19TH OCT 2020