

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

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Page: **1 of 1**

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

Kit lot number: KIE238

Kit expiry date: 12 January 2026

IA-2 Coated Wells:	Lot No. <u>IE238</u>	Expiry Date <u>06 APR 2026</u>
IA-2-Biotin:	Lot No. <u>IEB167</u>	Expiry Date <u>29 APR 2026</u>
Recon. Buffer for IA-2-Biotin:	Lot No. <u>IBB186</u>	Expiry Date <u>18 MAR 2026</u>
Streptavidin Peroxidase:	Lot No. <u>GEP679</u>	Expiry Date <u>02 JUN 2026</u>
Diluent for SA-POD:	Lot No. <u>PB183</u>	Expiry Date <u>16 SEP 2026</u>
Reaction Enhancer:	Lot No. <u>IES130</u>	Expiry Date <u>03 OCT 2026</u>
Peroxidase Substrate:	Lot No. <u>PTS189C</u>	Expiry Date <u>09 MAY 2028</u>
Stop Solution:	Lot No. <u>HESP135</u>	Expiry Date <u>23 SEP 2026</u>
Concentrated Wash Solution:	Lot No. <u>CW410</u>	Expiry Date <u>20 FEB 2027</u>
Calibrators:	Lot No. <u>IEC238</u>	Expiry Date <u>12 JAN 2026</u>
Controls:	Lot No. <u>IEC238 / IEPC238</u>	Expiry Date <u>12 JAN 2026</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	0.058	0.017
15	0.181	0.034 53 _{ns}
60	0.482	0.140
200	2.352	0.679
400	>4	1.484
4000	>4	2.658

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	1.252	0.362	128.5	129.8	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: Fiona Ryrie

Signature: *Fiona Ryrie*

Position: Scientist

Date: 18 December 2024

Authorised by: DR G FLOOD

Signature: *G Flood*

Position: HEAD OF QC

Date: 13TH JAN 2025