

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

Document: **wi/qcrs/0.28a**
Revision: **3**
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Approved by: **A SALVAGE**

Kit lot number: 2KIE164 Kit expiry date: 21 July 2025

Kit manufacture date: 22 July 2024

Reagent Lot Numbers:

IA-2 Coated Wells: <u>IE232</u>	Expiry date: <u>12 NOV 2025</u>
IA-2-Biotin: <u>IEB161</u>	Expiry date: <u>31 OCT 2025</u>
Recon. Buffer for IA-2-Biotin: <u>IBB184</u>	Expiry date: <u>18 SEP 2025</u>
Streptavidin Peroxidase: <u>GEP636</u>	Expiry date: <u>06 NOV 2025</u>
Diluent for SA-POD: <u>PB180</u>	Expiry date: <u>18 JAN 2026</u>
Reaction Enhancer: <u>IES129</u>	Expiry date: <u>10 JUN 2026</u>
Peroxidase Substrate: <u>PTS187F</u>	Expiry date: <u>30 NOV 2027</u>
Stop Solution: <u>HESP131</u>	Expiry date: <u>11 MAR 2026</u>
Concentrated Wash Solution: <u>CW388</u>	Expiry date: <u>31 AUG 2026</u>
Calibrators: <u>IC164</u>	Expiry date: <u>21 JUL 2025</u>
Controls: <u>INC164 / IPC164</u>	Expiry date: <u>21 JUL 2025</u>

Curve and Controls: Incubation temp: +4 °C OVERNIGHT +22 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.029	0.008
7.5	0.115	0.032
35	0.469	0.135
120	2.003	0.578
350	>4	1.707
4000	>4	2.762

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	2.247	0.648	130.7	130.2	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
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Date: 24/25 June 2024

Authorised by: *DR G FLOOD*
Signature: *G Flood*
Position: Head of Quality Control
Date: 11th July 2024