

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

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Approved by: **A SALVAGE**

Kit lot number: 2KIE167A Kit expiry date: 15 September 2025

Kit manufacture date: 16 September 2024

Reagent Lot Numbers:

IA-2 Coated Wells:	<u>IE234</u>	Expiry date:	<u>16 DEC 2025</u>
IA-2-Biotin:	<u>IEB162</u>	Expiry date:	<u>14 NOV 2025</u>
Recon. Buffer for IA-2-Biotin:	<u>IBB185</u>	Expiry date:	<u>10 DEC 2025</u>
Streptavidin Peroxidase:	<u>GEP651</u>	Expiry date:	<u>15 JAN 2026</u>
Diluent for SA-POD:	<u>PB181</u>	Expiry date:	<u>09 APR 2026</u>
Reaction Enhancer:	<u>IES129</u>	Expiry date:	<u>10 JUN 2026</u>
Peroxidase Substrate:	<u>PTS189</u>	Expiry date:	<u>09 MAY 2028</u>
Stop Solution:	<u>HESP132</u>	Expiry date:	<u>29 APR 2026</u>
Concentrated Wash Solution:	<u>CW397</u>	Expiry date:	<u>28 NOV 2026</u>
Calibrators:	<u>IC167a</u>	Expiry date:	<u>15 SEP 2025</u>
Controls:	<u>INC167a / IPC167a</u>	Expiry date:	<u>15 SEP 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	0.032	0.008
7.5	0.096	0.027
35	0.358	0.103
120	1.760	0.508
350	>4	1.657
4000	>4	2.866

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	1.757	0.507	119.9	119.8	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: pp Fiona Ryrie
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Position: Scientist
Date: 01 August 2024

Authorised by: DR G Flood
Signature: [Signature]
Position: Head of Quality Control
Date: 13th SEP 2024