

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: 2KIE176 Kit expiry date: 12 January 2026

Kit manufacture date: 13 January 2025

Reagent Lot Numbers:

IA-2 Coated Wells:	<u>IE238</u>	Expiry date:	<u>06 APR 2026</u>
IA-2-Biotin:	<u>IEB166</u>	Expiry date:	<u>15 APR 2026</u>
Recon. Buffer for IA-2-Biotin:	<u>IBB186</u>	Expiry date:	<u>18 MAR 2026</u>
Streptavidin Peroxidase:	<u>GEP679</u>	Expiry date:	<u>02 JUN 2026</u>
Diluent for SA-POD:	<u>PB183</u>	Expiry date:	<u>16 SEP 2026</u>
Reaction Enhancer:	<u>IES130</u>	Expiry date:	<u>03 OCT 2026</u>
Peroxidase Substrate:	<u>PTS189</u>	Expiry date:	<u>09 MAY 2028</u>
Stop Solution:	<u>HESP136</u>	Expiry date:	<u>28 OCT 2026</u>
Concentrated Wash Solution:	<u>CW419</u>	Expiry date:	<u>20 MAY 2027</u>
Calibrators:	<u>IC176</u>	Expiry date:	<u>12 JAN 2026</u>
Controls:	<u>INC176 / IPC176</u>	Expiry date:	<u>12 JAN 2026</u>

Curve and Controls: Incubation temp: +4 °C OVERNIGHT +21 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.041	0.015
7.5	0.119	0.036
35	0.396	0.116
120	1.982	0.576
350	>4	1.816
4000	>4	2.784

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	2.099	0.608	124.7	124.3	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 Rebecca Coles
Signature: Fiona Lynch
Position: Principal Scientist
Date: 17/18 December 2024

Authorised by: DR G Flood
Signature: [Signature]
Position: Head of Quality Control
Date: 10th JAN 2025