

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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Prepared by: **G FLOOD**
Approved by: **A SALVAGE**

Kit lot number: 2KIE172B Kit expiry date: 02 February 2026

Kit manufacture date: 03 February 2025

Reagent Lot Numbers:

IA-2 Coated Wells: <u>IE238</u>	Expiry date: <u>06 APR 2026</u>
IA-2-Biotin: <u>IEB165</u>	Expiry date: <u>03 MAR 2026</u>
Recon. Buffer for IA-2-Biotin: <u>IBB186</u>	Expiry date: <u>18 MAR 2026</u>
Streptavidin Peroxidase: <u>GEP673</u>	Expiry date: <u>21 APR 2026</u>
Diluent for SA-POD: <u>PB181</u>	Expiry date: <u>09 APR 2026</u>
Reaction Enhancer: <u>IES130</u>	Expiry date: <u>03 OCT 2026</u>
Peroxidase Substrate: <u>PTS187L</u>	Expiry date: <u>30 NOV 2027</u>
Stop Solution: <u>HESP134</u>	Expiry date: <u>19 AUG 2026</u>
Concentrated Wash Solution: <u>CW406</u>	Expiry date: <u>30 JAN 2027</u>
Calibrators: <u>IC172b</u>	Expiry date: <u>02 FEB 2026</u>
Controls: <u>INC172b / IPC172b</u>	Expiry date: <u>02 FEB 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	0.060	0.017
7.5	0.116	0.033
35	0.439	0.127
120	1.990	0.574
350	>4	1.647
4000	>4	2.499

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	2.138	0.616	126.8	126.4	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: Rebecca Coles
Signature: R. Coles
Position: Principal Scientist
Date: 22 October 2024

Authorised by: DR G FLOOD
Signature: G Flood
Position: Head of Quality Control
Date: 20 FEB 2025