

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

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

Kit lot number: 2KIE136 Kit expiry date: 16 February 2024

Kit manufacture date: 20 February 2023

Reagent Lot Numbers:

IA-2 Coated Wells: <u>IE215</u>	Expiry date: <u>05 JUN 2024</u>
IA-2-Biotin: <u>IEB145</u>	Expiry date: <u>16 FEB 2024</u>
Recon. Buffer for IA-2-Biotin: <u>IBB179</u>	Expiry date: <u>24 APR 2024</u>
Streptavidin Peroxidase: <u>GEP541</u>	Expiry date: <u>30 JUL 2024</u>
Diluent for SA-POD: <u>PB173</u>	Expiry date: <u>09 NOV 2024</u>
Reaction Enhancer: <u>IES119</u>	Expiry date: <u>28 JUL 2024</u>
Peroxidase Substrate: <u>PTS181K</u>	Expiry date: <u>21 APR 2026</u>
Stop Solution: <u>HESP122</u>	Expiry date: <u>14 DEC 2024</u>
Concentrated Wash Solution: <u>CW340</u>	Expiry date: <u>31 MAY 2025</u>
Calibrators: <u>IC136</u>	Expiry date: <u>19 FEB 2024</u>
Controls: <u>INC136/ IPC136</u>	Expiry date: <u>19 FEB 2024</u>

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	0.032	0.008
7.5	0.132	0.040
35	0.380	0.119
120	1.861	0.587
350	>4	1.648
4000	>4	2.703

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	1.825	0.576	118.4	118.3	115± 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: 02/03 February 2023

Authorised by: *DR G Flood*
Signature: *S. Salvage*
Position: Head of Quality Control
Date: 21st FEB 2023