

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: 2KIE138

Kit expiry date: 09 April 2024

Kit manufacture date: 10 April 2023

Reagent Lot Numbers:

IA-2 Coated Wells: <u>IE217</u>	Expiry date: <u>26 AUG 2024</u>
IA-2-Biotin: <u>IEB149</u>	Expiry date: <u>31 JUL 2024</u>
Recon. Buffer for IA-2-Biotin: <u>IBB180</u>	Expiry date: <u>08 AUG 2024</u>
Streptavidin Peroxidase: <u>GEP547</u>	Expiry date: <u>14 SEP 2024</u>
Diluent for SA-POD: <u>PB174</u>	Expiry date: <u>12 FEB 2025</u>
Reaction Enhancer: <u>IES119</u>	Expiry date: <u>28 JUL 2024</u>
Peroxidase Substrate: <u>PTS183B</u>	Expiry date: <u>24 OCT 2026</u>
Stop Solution: <u>HESP123</u>	Expiry date: <u>12 JAN 2025</u>
Concentrated Wash Solution: <u>CW348</u>	Expiry date: <u>02 AUG 2025</u>
Calibrators: <u>IC138</u>	Expiry date: <u>09 APR 2024</u>
Controls: <u>INC138/ IPC138</u>	Expiry date: <u>09 APR 2024</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	0.035	0.012
7.5	0.133	0.039
35	0.368	0.113
120	1.852	0.582
350	>4	1.562
4000	>4	2.329

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	1.903	0.596	122.3	122.3	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: Senior Scientist
Date: 21/22 March 2023

Authorised by: DR G FLOOD
Signature: G Flood
Position: Head of Quality Control
Date: 5TH APR 2023