

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

Document: **wi/qcrs/0.28a**  
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Date: **21 September 2018**  
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Prepared by: G FLOOD  
Approved by: A SALVAGE

Kit lot number: 2KIE145B Kit expiry date: 17 September 2024

Kit manufacture date: 18 September 2023

**Reagent Lot Numbers:**


IA-2 Coated Wells: <u>IE220</u>	Expiry date: <u>29 NOV 2024</u>
IA-2-Biotin: <u>IEB152</u>	Expiry date: <u>13 DEC 2024</u>
Recon. Buffer for IA-2-Biotin: <u>IBB181</u>	Expiry date: <u>08 NOV 2024</u>
Streptavidin Peroxidase: <u>GEP569</u>	Expiry date: <u>05 JAN 2024<sup>5</sup></u>
Diluent for SA-POD: <u>PB174</u>	Expiry date: <u>12 FEB 2025</u>
Reaction Enhancer: <u>IES123</u>	Expiry date: <u>03 MAY 2025</u>
Peroxidase Substrate: <u>PTS183H</u>	Expiry date: <u>24 OCT 2026</u>
Stop Solution: <u>HESP124</u>	Expiry date: <u>02 APR 2025</u>
Concentrated Wash Solution: <u>CW355</u>	Expiry date: <u>15 NOV 2025</u>
Calibrators: <u>IC145b</u>	Expiry date: <u>17 SEP 2024</u>
Controls: <u>INC145b/ IPC145b</u>	Expiry date: <u>17 SEP 2024</u>

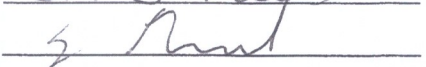
**Curve and Controls:** Incubation temp: +4 °C OVERNIGHT +21 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.001	0.000
7.5	0.132	0.031
35	0.389	0.113
120	1.983	0.617
350	>4	1.614
4000	>4	2.612

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	2.061	0.645	123.4	124.4	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: Jonathon Davies  
Signature:   
Position: Senior Scientist  
Date: 06/07 July 2023

Authorised by: DR G FLOOD  
Signature:   
Position: Head of Quality Control  
Date: 18<sup>th</sup> SEP 2023