

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

Document: **wi/qcrs/0.28a**  
 Revision: **3**  
 Date: **21 September 2018**  
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Prepared by: **G FLOOD**  
 Approved by: **A SALVAGE**

Kit lot number: 2KIE147A Kit expiry date: 15 October 2024

Kit manufacture date: 16 October 2023

**Reagent Lot Numbers:**

IA-2 Coated Wells: <u>IE222</u>	Expiry date: <u>16 JAN 2025</u>
IA-2-Biotin: <u>IEB153</u>	Expiry date: <u>17 FEB 2025</u>
Recon. Buffer for IA-2-Biotin: <u>IBB182</u>	Expiry date: <u>20 FEB 2025</u>
Streptavidin Peroxidase: <u>GEP580</u>	Expiry date: <u>28 FEB 2025</u>
Diluent for SA-POD: <u>PB175</u>	Expiry date: <u>30 MAY 2025</u>
Reaction Enhancer: <u>IES123</u>	Expiry date: <u>03 MAY 2025</u>
Peroxidase Substrate: <u>PTS183N</u>	Expiry date: <u>24 OCT 2026</u>
Stop Solution: <u>HESP126</u>	Expiry date: <u>18 JUL 2025</u>
Concentrated Wash Solution: <u>CW360</u>	Expiry date: <u>22 DEC 2025</u>
Calibrators: <u>IC147a</u>	Expiry date: <u>15 OCT 2024</u>
Controls: <u>INC147a / IPC147a</u>	Expiry date: <u>15 OCT 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	0.010	0.000
7.5	0.145	0.042
35	0.439	0.135
120	1.991	0.624
350	>4	1.677
4000	>4	2.601

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	1.881	0.592	115.1	115.0	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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 Position: Scientist  
 Date: 30/31 August 2023

Authorised by: *DR G Flood*  
 Signature: *G Flood*  
 Position: Head of Quality Control  
 Date: 12<sup>th</sup> OCT 2023