

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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Approved by: **A SALVAGE**

Kit lot number: 2KIE130A Kit expiry date: 18 September 2023

Kit manufacture date: 19 September 2022

Reagent Lot Numbers:

IA-2 Coated Wells: <u>IE210</u>	Expiry date: <u>11 JAN 2024</u>
IA-2-Biotin: <u>IEB144</u>	Expiry date: <u>19 JAN 2024</u>
Recon. Buffer for IA-2-Biotin: <u>IBB178</u>	Expiry date: <u>09 DEC 2023</u>
Streptavidin Peroxidase: <u>GEP507</u>	Expiry date: <u>09 FEB 2024</u>
Diluent for SA-POD: <u>PB171</u>	Expiry date: <u>16 MAY 2024</u>
Reaction Enhancer: <u>IES118</u>	Expiry date: <u>19 MAY 2024</u>
Peroxidase Substrate: <u>PTS179P</u>	Expiry date: <u>30 SEP 2024</u>
Stop Solution: <u>HESP118</u>	Expiry date: <u>16 MAY 2024</u>
Concentrated Wash Solution: <u>CW321</u>	Expiry date: <u>22 DEC 2024</u>
Calibrators: <u>IC130a</u>	Expiry date: <u>18 SEP 2023</u>
Controls: <u>INC130a / IPC130a</u>	Expiry date: <u>18 SEP 2023</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	0.027	0.009
7.5	0.110	0.035
35	0.397	0.129
120	1.848	0.585
350	>4	1.544
4000	>4	2.475

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	1.949	0.622	124.9	126.3	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: pp Fiona Ryrie
Signature: R. Coles
Position: Scientist
Date: 09/10 August 2022

Authorised by: OR G Flood
Signature: [Signature]
Position: Head of Quality Control
Date: 15TH SEP 2022