

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**

Page **1 of 1**

Prepared by: **G FLOOD**
Approved by: **A SALVAGE**

Kit lot number: 2KIE139

Kit expiry date: 07 May 2024

Kit manufacture date: 08 May 2023

Reagent Lot Numbers:

IA-2 Coated Wells: <u>IE218</u>	Expiry date: <u>26 SEP 2024</u>
IA-2-Biotin: <u>IEB148</u>	Expiry date: <u>18 JUN 2024</u>
Recon. Buffer for IA-2-Biotin: <u>IBB180</u>	Expiry date: <u>08 AUG 2024</u>
Streptavidin Peroxidase: <u>GEP543</u>	Expiry date: <u>13 AUG 2024</u>
Diluent for SA-POD: <u>PB172</u>	Expiry date: <u>23 AUG 2024</u>
Reaction Enhancer: <u>IES118</u>	Expiry date: <u>19 MAY 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>CW311</u>	Expiry date: <u>17 AUG 2025</u>
Calibrators: <u>IC139</u>	Expiry date: <u>07 MAY 2024</u>
Controls: <u>INC139/ IPC139</u>	Expiry date: <u>07 MAY 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	0.045	0.013
7.5	0.156	0.046
35	0.439	0.134
120	2.015	0.586
350	>4	1.567
4000	>4	2.427

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	2.091	0.608	123.6	123.5	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: 18/19 April 2023

Authorised by: DR G Flood
Signature: [Signature]
Position: Head of Quality Control
Date: 9th MAY 2023