

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

Document: **WI/QCRS/0.28a**  
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Prepared by: **G FLOOD**  
Approved by: **A SALVAGE**

Kit lot number: 2KIE181A  
Kit manufacture date: 26 May 2025

Kit expiry date: 25 May 2026

**Reagent Lot Numbers:**

IA-2 Coated Wells: IE242  
IA-2-Biotin: IEB171  
Recon. Buffer for IA-2-Biotin: IBB188  
Streptavidin Peroxidase: GEP700  
Diluent for SA-POD: PB184  
Reaction Enhancer: IES131  
Peroxidase Substrate: PTS191  
Stop Solution: HESP138  
Concentrated Wash Solution: CW424  
Calibrators: IC181a  
Controls: INC181a / IPC181a

Expiry date: 26 JUL 2026  
Expiry date: 18 AUG 2026  
Expiry date: 19 AUG 2026  
Expiry date: 16 SEP 2026  
Expiry date: 26 NOV 2026  
Expiry date: 28 JAN 2027  
Expiry date: 11 NOV 2028  
Expiry date: 02 FEB 2027  
Expiry date: 06 JUL 2027  
Expiry date: 25 MAY 2026  
Expiry date: 25 MAY 2026

**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	0.049	0.013
7.5	0.126	0.036
35	0.378	0.109
120	1.858	0.537
350	>4	1.644
4000	>4	2.743

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	1.780	0.514	116.5	116.5	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: pp Rebecca Coles  
Signature: Bradbury  
Position: Principal Scientist  
Date: 18/19 March 2025

Authorised by: DR G Flood  
Signature: S. Ward  
Position: Head of Quality Control  
Date: 27<sup>th</sup> MAY 2025