

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

Document: **wi/qcrs/0.28b**

Revision: **0**

Date: **20 September 2022**

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Prepared by: **G FLOOD**

Approved by: **L CARR**

Kit lot number: **FKIE201**

Kit expiry date: **07 December 2026**

Kit manufacture date: **08 December 2025**

Reagent Lot Numbers:

IA-2 Coated Wells: **IE253** Expiry date: **28 MAR 2027**

IA-2-Biotin: **IEB180** Expiry date: **31 MAR 2027**

Recon. Buffer for IA-2-Biotin: **IBB190** Expiry date: **05 FEB 2027**

Streptavidin Peroxidase: **GEP750** Expiry date: **21 APR 2027**

Diluent for SA-POD: **PB188** Expiry date: **20 AUG 2027**

Reaction Enhancer: **IES134** Expiry date: **07 SEP 2027**

Peroxidase Substrate: **PTS189M** Expiry date: **09 MAY 2028**

Stop Solution: **HESP142** Expiry date: **02 JUL 2027**

Concentrated Wash Solution: **CW454** Expiry date: **08 JAN 2028**

Calibrators: **IC201** Expiry date: **07 DEC 2026**

Controls: **INC201/IPC201** Expiry date: **07 DEC 2026**

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

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.038	0.012
7.5	0.116	0.035
35	0.293	0.085
120	1.570	0.454
350	>4	1.354
4000	>4	2.576

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	1.766	0.511	130.8	130.6	130 ± 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: **pp S. Stephenson**

Position: **Principal Scientist**

Date: **18 November 2025**

Authorised by: **DR G FLOOD**

Signature: **[Signature]**

Position: **Head of Quality Control**

Date: **11TH DEC 2025**