

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

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

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Prepared by: **G FLOOD**

Approved by: **L CARR**

Kit lot number: **FKIE156**

Kit expiry date: **03 March 2025**

Kit manufacture date: **04 March 2024**

**Reagent Lot Numbers:**

IA-2 Coated Wells: **IE226**

Expiry date: **10 JUN 2025**

IA-2-Biotin: **IEB156**

Expiry date: **30 APR 2025**

Recon. Buffer for IA-2-Biotin: **IBB183**

Expiry date: **17 JUN 2025**

Streptavidin Peroxidase: **GEP610**

Expiry date: **15 JUL 2025**

Diluent for SA-POD: **PB179**

Expiry date: **13 NOV 2025**

Reaction Enhancer: **IES124**

Expiry date: **16 AUG 2025**

Peroxidase Substrate: **PTS185M**

Expiry date: **27 APR 2027**

Stop Solution: **HESP128**

Expiry date: **02 NOV 2025**

Concentrated Wash Solution: **CW373**

Expiry date: **25 APR 2026**

Calibrators: **IC156**

Expiry date: **03 MAR 2025**

Controls: **INC156/IPC156**

Expiry date: **03 MAR 2025**

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

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.069	0.019
7.5	0.152	0.044
35	0.419	0.120
120	1.825	0.524
350	>4	1.524
4000	>4	2.476

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	1.847	0.532	121.1	121.2	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: **Rebecca Coles**

Authorised by: **Dr G Flood**

Signature: **R. Coles**

Signature: **[Signature]**

Position: **Senior Scientist**

Position: **Head of Quality Control**

Date: **23 January 2024**

Date: **29<sup>th</sup> FEB 2024**