

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

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

Revision: **0**

Date: **20 September 2022**

Page **1 of 1**

Prepared by: **G FLOOD**

Approved by: **L CARR**

Kit lot number: **FKIE183**

Kit expiry date: **27 April 2026**

Kit manufacture date: **28 April 2025**

Reagent Lot Numbers:

IA-2 Coated Wells: **IE243**

Expiry date: **16 AUG 2026**

IA-2-Biotin: **IEB170**

Expiry date: **28 JUL 2026**

Recon. Buffer for IA-2-Biotin: **IBB188**

Expiry date: **19 AUG 2026**

Streptavidin Peroxidase: **GEP700**

Expiry date: **16 SEP 2026**

Diluent for SA-POD: **PB183**

Expiry date: **16 SEP 2026**

Reaction Enhancer: **IES131**

Expiry date: **28 JAN 2027**

Peroxidase Substrate: **PTS191**

Expiry date: **11 NOV 2028**

Stop Solution: **HESP135**

Expiry date: **23 SEP 2026**

Concentrated Wash Solution: **CW404**

Expiry date: **16 JAN 2027**

Calibrators: **IC183**

Expiry date: **27 APR 2026**

Controls: **INC183/IPC183**

Expiry date: **27 APR 2026**

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

| Calibrator Concentration (units per mL) | Absorbance at 450 nm | Absorbance at 405 nm |
|--|-------------------------|-------------------------|
| Negative control | 0.088 | 0.026 |
| 7.5 | 0.150 | 0.044 |
| 35 | 0.395 | 0.114 |
| 120 | 1.893 | 0.549 |
| 350 | >4 | 1.882 |
| 4000 | >4 | 2.782 |

| 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 | 2.045 | 0.591 | 125.8 | 125.4 | 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 Rebecca Coles**

Authorised by: **DR G Flood**

Signature: **[Signature]**

Signature: **[Signature]**

Position: **Principal Scientist**

Position: **Head of Quality Control**

Date: **07 April 2025**

Date: **27th APR 2025**