

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: FKIE163 Kit expiry date: 23 June 2025

Kit manufacture date: 24 June 2024

**Reagent Lot Numbers:**

IA-2 Coated Wells: <u>IE229</u>	Expiry date: <u>25 AUG 2025</u>
IA-2-Biotin: <u>IEB161</u>	Expiry date: <u>31 OCT 2025</u>
Recon. Buffer for IA-2-Biotin: <u>IBB184</u>	Expiry date: <u>18 SEP 2025</u>
Streptavidin Peroxidase: <u>GEP636</u>	Expiry date: <u>06 NOV 2025</u>
Diluent for SA-POD: <u>PB180</u>	Expiry date: <u>18 JAN 2026</u>
Reaction Enhancer: <u>IES126</u>	Expiry date: <u>15 JAN 2026</u>
Peroxidase Substrate: <u>PTS185M</u>	Expiry date: <u>27 APR 2027</u>
Stop Solution: <u>HESP130</u>	Expiry date: <u>08 FEB 2026</u>
Concentrated Wash Solution: <u>CW388</u>	Expiry date: <u>31 AUG 2026</u>
Calibrators: <u>IC163</u>	Expiry date: <u>23 JUN 2025</u>
Controls: <u>INC163/IPC163</u>	Expiry date: <u>23 JUN 2025</u>

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

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.079	0.022
7.5	0.150	0.043
35	0.376	0.109
120	1.747	0.506
350	>4	1.537
4000	>4	2.343

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	1.723	0.497	118.8	118.6	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  
Signature: R. Coles  
Position: Senior Scientist  
Date: 19 June 2024

Authorised by: DR G Flood  
Signature: G Flood  
Position: Head of Quality Control  
Date: 20<sup>th</sup> Jun 2024