

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

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Prepared by: **G FLOOD**  
Approved by: **A SALVAGE**

Kit lot number: 2KIE161A Kit expiry date: 21 July 2025

Kit manufacture date: 22 July 2024

**Reagent Lot Numbers:**

IA-2 Coated Wells:	<u>IE231</u>	Expiry date:	<u>21 OCT 2025</u>
IA-2-Biotin:	<u>IEB160</u>	Expiry date:	<u>05 SEP 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>PTS187</u>	Expiry date:	<u>30 NOV 2027</u>
Stop Solution:	<u>HESP130</u>	Expiry date:	<u>08 FEB 2026</u>
Concentrated Wash Solution:	<u>CW384</u>	Expiry date:	<u>28 JUL 2026</u>
Calibrators:	<u>IC161a</u>	Expiry date:	<u>21 JUL 2025</u>
Controls:	<u>INC161a / IPC161a</u>	Expiry date:	<u>21 JUL 2025</u>

**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	0.055	0.016
7.5	0.140	0.041
35	0.473	0.137
120	2.130	0.618
350	>4	1.720
4000	>4	2.700

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	2.265	0.655	125.9	125.5	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: Rebecca Coles  
Signature: R. Coles  
Position: Senior Scientist  
Date: 21/22 May 2024

Authorised by: DR G Flood  
Signature: G Flood  
Position: Head of Quality Control  
Date: 22<sup>nd</sup> JULY 2024