

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

Document: **wi/qcrs/0.28**

Revision: **7**

Date: **10/10/14**

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Prepared by: **G Flood**
Approved by: **A Salvage**

Kit lot number: KIE246

Kit expiry date: 12 October 2026

IA-2 Coated Wells:	Lot No. <u>IE249</u>	Expiry Date <u>31 DEC 2026</u>
IA-2-Biotin:	Lot No. <u>IEB175</u>	Expiry Date <u>10 DEC 2026</u>
Recon. Buffer for IA-2-Biotin:	Lot No. <u>IBB190</u>	Expiry Date <u>05 FEB 2027</u>
Streptavidin Peroxidase:	Lot No. <u>GEP723</u>	Expiry Date <u>01 JAN 2027</u>
Diluent for SA-POD:	Lot No. <u>PB186</u>	Expiry Date <u>09 APR 2027</u>
Reaction Enhancer:	Lot No. <u>IES133</u>	Expiry Date <u>22 MAY 2027</u>
Peroxidase Substrate:	Lot No. <u>PTS189C</u>	Expiry Date <u>09 MAY 2028</u>
Stop Solution:	Lot No. <u>HESP140</u>	Expiry Date <u>07 APR 2027</u>
Concentrated Wash Solution:	Lot No. <u>CW446</u>	Expiry Date <u>08 DEC 2027</u>
Calibrators:	Lot No. <u>IEC246</u>	Expiry Date <u>12 OCT 2026</u>
Controls:	Lot No. <u>IENC246 / IEPC246</u>	Expiry Date <u>12 OCT 2026</u>

Calibrator Curve and Controls:

Incubation temp: +4 °C OVERNIGHT +22 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.073	0.022
15	0.269	0.078
60	0.709	0.206
200	2.662	0.769
400	>4	1.430
4000	>4	2.374

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	1.537	0.445	121.1	122.5	115 ± 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:

17/18 September 2025

Authorised by:

DR G Flood

Signature:

G Flood

Position:

HEAD OF QC

Date:

9TH OCT 2025