

Title:

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

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Revision: 3

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Approved by: A SALVAGE

Kit lot number: 2KIE160A Kit expiry date: 26 May 2025

Kit manufacture date: 27 May 2024

Reagent Lot Numbers:

IA-2 Coated Wells:	IE230	Expiry date:	18 SEP 2025
IA-2-Biotin:	IEB160	Expiry date:	05 SEP 2025
Recon. Buffer for IA-2-Biotin:	IBB184	Expiry date:	18 SEP 2025
Streptavidin Peroxidase:	GEP630	Expiry date:	08 OCT 2025
Diluent for SA-POD:	PB177	Expiry date:	10 AUG 2025
Reaction Enhancer:	IES126	Expiry date:	15 JAN 2026
Peroxidase Substrate:	PTS185S	Expiry date:	27 APR 2027
Stop Solution:	HESP130	Expiry date:	08 FEB 2026
Concentrated Wash Solution:	CW379	Expiry date:	17 JUN 2026
Calibrators:	IC160a	Expiry date:	26 MAY 2025
Controls:	INC160a / IPC160a	Expiry date:	26 MAY 2025

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	0.039	0.012
7.5	0.133	0.039
35	0.462	0.135
120	2.311	0.667
350	>4	1.707
4000	>4	2.496

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	2.115	0.613	111.4	111.8	110± 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
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Position: Senior Scientist
Date: 17/18 April 2024

Authorised by: DR G Flood
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Position: Head of Quality Control
Date: 23RD MAY 2024