

Title:

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

Document: wi/qcrs/0.28a

Revision: 3

Date: 21 September 2018

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Prepared by: G FLOOD

Approved by: A SALVAGE

Kit lot number: 2KIE195

Kit expiry date: 12 October 2026

Kit manufacture date: 13 October 2025

Reagent Lot Numbers:

IA-2 Coated Wells: IE251

Expiry date: 10 FEB 2027

IA-2-Biotin: IEB175

Expiry date: 10 DEC 2026

Recon. Buffer for IA-2-Biotin: IBB190

Expiry date: 05 FEB 2027

Streptavidin Peroxidase: GEP739

Expiry date: 15 MAR 2027

Diluent for SA-POD: PB187

Expiry date: 17 JUN 2027

Reaction Enhancer: IES133

Expiry date: 22 MAY 2027

Peroxidase Substrate: PTS189Q

Expiry date: 09 MAY 2028

Stop Solution: HESP139

Expiry date: 09 MAR 2027

Concentrated Wash Solution: CW452

Expiry date: 02 JAN 2028

Calibrators: IC195

Expiry date: 12 OCT 2026

Controls: INC195 / IPC195

Expiry date: 12 OCT 2026

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	0.036	0.010
7.5	0.151	0.044
35	0.439	0.125
120	2.016	0.581
350	>4	1.711
4000	>4	2.555

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	2.008	0.578	119.6	119.6	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

Authorised by: DR G FLOOD

Signature: pp S Stephenson

Signature: [Signature]

Position: Principal Scientist

Position: Head of Quality Control

Date: 24/25 September 2025

Date: 9TH OCT 2025