

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: 2KIE157

Kit expiry date: 07 April 2025

Kit manufacture date: 08 April 2024

Reagent Lot Numbers:

IA-2 Coated Wells: IE227

Expiry date: 07 JUL 2025

IA-2-Biotin: IEB158

Expiry date: 09 JUL 2025

Recon. Buffer for IA-2-Biotin: IBB183

Expiry date: 17 JUN 2025

Streptavidin Peroxidase: GEP613

Expiry date: 24 JUL 2025

Diluent for SA-POD: PB179

Expiry date: 13 NOV 2025

Reaction Enhancer: IES124

Expiry date: 16 AUG 2025

Peroxidase Substrate: PTS187

Expiry date: 30 NOV 2027

Stop Solution: HESP129

Expiry date: 10 DEC 2025

Concentrated Wash Solution: CW376

Expiry date: 23 MAY 2026

Calibrators: IC157

Expiry date: 07 APR 2025

Controls: INC157 / IPC157

Expiry date: 07 APR 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	0.041	0.011
7.5	0.114	0.032
35	0.347	0.099
120	1.797	0.520
350	>4	1.787
4000	>4	2.713

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	1.793	0.518	119.8	119.8	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: Sinead Stephenson

Authorised by: DR G Flood

Signature: S. Stephenson

Signature: [Signature]

Position: Lab Technician

Position: Head of Quality Control

Date: 03/04 April 2024

Date: 5th APR 2024