

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: **2KIE154**

Kit expiry date: **10 December 2024**

Kit manufacture date: **11 December 2023**

Reagent Lot Numbers:

IA-2 Coated Wells: **IE225**

Expiry date: **22 APR 2025**

IA-2-Biotin: **IEB156**

Expiry date: **30 APR 2025**

Recon. Buffer for IA-2-Biotin: **IBB182**

Expiry date: **20 FEB 2025**

Streptavidin Peroxidase: **GEP599**

Expiry date: **20 MAY 2025**

Diluent for SA-POD: **PB177**

Expiry date: **10 AUG 2025**

Reaction Enhancer: **IES124**

Expiry date: **16 AUG 2025**

Peroxidase Substrate: **PTS185G**

Expiry date: **24 JUL 2027**

Stop Solution: **HESP127**

Expiry date: **20 SEP 2025**

Concentrated Wash Solution: **CW371**

Expiry date: **24 MAR 2026**

Calibrators: **IC154**

Expiry date: **10 DEC 2024**

Controls: **INC154 / IPC154**

Expiry date: **10 DEC 2024**

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	0.008	0.001
7.5	0.142	0.041
35	0.466	0.135
120	2.088	0.601
350	>4	1.648
4000	>4	2.735

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	2.268	0.652	128.2	128.0	125± 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: **R. Coles**

Signature: **G Flood**

Position: **Senior Scientist**

Position: **Head of Quality Control**

Date: **21/22 November 2023**

Date: **11TH DEC 2023**