

Title:

Quality Control Record Sheet

IA-2 Ab ELISA Version 2 Kit QC Data

Document: **wilqcrs/0.28a**Revision: **3**Date: **21 September 2018**Page **1 of 1**

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 Approved by: **A SALVAGE**

Kit lot number: **2KIE132**Kit expiry date: **30 October 2023**Kit manufacture date: **31 October 2022**

Reagent Lot Numbers:

IA-2 Coated Wells: **IE212**Expiry date: **04 MAR 2024**IA-2-Biotin: **IEB145**Expiry date: **16 FEB 2024**Recon. Buffer for IA-2-Biotin: **IBB178**Expiry date: **09 DEC 2023**Streptavidin Peroxidase: **GEP517**Expiry date: **06 APR 2024**Diluent for SA-POD: **PB171**Expiry date: **16 MAY 2024**Reaction Enhancer: **IES118**Expiry date: **19 MAY 2024**Peroxidase Substrate: **PTS181A**Expiry date: **21 APR 2026**Stop Solution: **HESP119**Expiry date: **05 JUL 2024**Concentrated Wash Solution: **CW326**Expiry date: **22 DEC 2024**Calibrators: **IC132**Expiry date: **30 OCT 2023**Controls: **INC132 / IPC132**Expiry date: **30 OCT 2023**

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	0.028	0.007
7.5	0.110	0.034
35	0.375	0.117
120	1.670	0.526
350	>4	1.545
4000	>4	2.401

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	2.004	0.632	135.6	137.1	140 ± 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: **Fiona Ryrie**Authorised by: **DR G Flood**Signature: **Fiona Ryrie**Signature: **G Flood**Position: **Scientist**Position: **Head of Quality Control**Date: **10/11 October 2022**Date: **21st OCT 2022**