

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**

Page **1 of 1**

Prepared by: **G FLOOD**

Approved by: **A SALVAGE**

Kit lot number: 2KIE123

Kit expiry date: 01 May 2023

Kit manufacture date: 02 May 2022

Reagent Lot Numbers:

IA-2 Coated Wells: IE206

Expiry date: 31 AUG 2023

IA-2-Biotin: IEB140

Expiry date: 27 AUG 2023

Recon. Buffer for IA-2-Biotin: IBB177

Expiry date: 02 AUG 2023

Streptavidin Peroxidase: GEP484

Expiry date: 19 OCT 2023

Diluent for SA-POD: PB169

Expiry date: 19 OCT 2023

Reaction Enhancer: IES114

Expiry date: 11 APR 2024

Peroxidase Substrate: PTS179C

Expiry date: 30 SEP 2024

Stop Solution: HESP116

Expiry date: 10 JAN 2024

Concentrated Wash Solution: CW306

Expiry date: 07 JUN 2024

Calibrators: IC123

Expiry date: 01 MAY 2023

Controls: INC123 / IPC123

Expiry date: 01 MAY 2023

Curve and Controls: Incubation temp: +4 °C OVERNIGHT +20 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.036	0.005
7.5	0.112	0.029
35	0.387	0.115
120	2.048	0.636
350	>4	1.671
4000	>4	2.710

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	2.005	0.628	118.1	118.7	115 ± 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: *J. Salvage*

Position: Scientist

Position: Head of Quality Control

Date: 27/28 April 2022

Date: 29th APR 2022