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**

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Approved by: A SALVAGE

Kit lot number: 2KIE97 Kit expiry date: 04 April 2022

Kit manufacture date: 05 April 2021

Reagent Lot Numbers:

IA-2 Coated Wells:	IE192	Expiry date:	31 AUG 2022
IA-2-Biotin:	IEB131	Expiry date:	23 AUG 2022
Recon. Buffer for IA-2-Biotin:	IBB173A	Expiry date:	21 JUL 2022
Streptavidin Peroxidase:	GEP417	Expiry date:	17 SEP 2022
Diluent for SA-POD:	PB162	Expiry date:	07 DEC 2022
Reaction Enhancer:	IES109	Expiry date:	20 JAN 2023
Peroxidase Substrate:	PTS175C	Expiry date:	13 APR 2023
Stop Solution:	HESP108	Expiry date:	08 NOV 2022
Concentrated Wash Solution:	CW273	Expiry date:	24 AUG 2023
Calibrators:	IC97	Expiry date:	04 APR 2022
Controls:	INC97 / IPC97	Expiry date:	04 APR 2022

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	0.026	0.002
7.5	0.101	0.027
35	0.358	0.108
120	1.313	0.409
350	>4	1.482
4000	>4	2.421

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	1.270	0.397	117.8	118.0	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:	OR G Flood
Signature:	Fiona Ryrie	Signature:	
Position:	Scientist	Position:	Head of Quality Control
Date:	08/09 April 2021	Date:	12TH APR 2021