

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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Approved by: **A SALVAGE**

Kit lot number: 2KIE107 Kit expiry date: 22 August 2022

Kit manufacture date: 23 August 2021

Reagent Lot Numbers:

IA-2 Coated Wells: <u>IE196E</u>	Expiry date: <u>21 DEC 2022</u>
IA-2-Biotin: <u>IEB134</u>	Expiry date: <u>22 DEC 2022</u>
Recon. Buffer for IA-2-Biotin: <u>IBB175</u>	Expiry date: <u>05 JAN 2023</u>
Streptavidin Peroxidase: <u>GEP441</u>	Expiry date: <u>17 FEB 2023</u>
Diluent for SA-POD: <u>PB166</u>	Expiry date: <u>01 JUN 2023</u>
Reaction Enhancer: <u>IES110</u>	Expiry date: <u>11 MAY 2023</u>
Peroxidase Substrate: <u>PTS175M</u>	Expiry date: <u>13 APR 2023</u>
Stop Solution: <u>HESP112</u>	Expiry date: <u>22 JUN 2023</u>
Concentrated Wash Solution: <u>CW291</u>	Expiry date: <u>26 JAN 2024</u>
Calibrators: <u>IC107</u>	Expiry date: <u>22 AUG 2022</u>
Controls: <u>INC107 / IPC107</u>	Expiry date: <u>22 AUG 2022</u>

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	0.018	0.001
7.5	0.093	0.025
35	0.394	0.121
120	2.033	0.638
350	>4	1.842
4000	>4	2.780

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	0.628	118.8	118.6	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: Emily Callard-Langdon
Signature: *pp R Coles*
Position: Scientist
Date: 18/19 August 2021

Authorised by: *DR G Flood*
Signature: *[Signature]*
Position: Head of Quality Control
Date: 22nd AUG 2021