

Title: **Quality Control Record Sheet**
IA-2 Ab ELISA Version 2 Kit QC Data

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Approved by: A SALVAGE

Kit lot number: 2KIE109 Kit expiry date: 19 September 2022

Kit manufacture date: 20 September 2021

Reagent Lot Numbers:

IA-2 Coated Wells: <u>IE197E</u>	Expiry date: <u>23 JAN 2023</u>
IA-2-Biotin: <u>IEB135</u>	Expiry date: <u>13 JAN 2023</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>CW294</u>	Expiry date: <u>09 FEB 2024</u>
Calibrators: <u>IC109</u>	Expiry date: <u>19 SEP 2022</u>
Controls: <u>INC109 / IPC109</u>	Expiry date: <u>19 SEP 2022</u>

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	0.021	0.002
7.5	0.098	0.026
35	0.377	0.113
120	1.840	0.571
350	>4	1.890
4000	>4	2.849

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	1.948	0.611	124.0	125.1	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
Signature: R. Coles
Position: Senior Scientist
Date: 13/14 September 2021

Authorised by: DR G Flood
Signature: G Flood
Position: Head of Quality Control
Date: 21st SEP 2021