

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

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Page 1 of 1

Prepared by: G FLOOD
Approved by: A SALVAGE

Kit lot number: 2KIE99 Kit expiry date: 30 MAY 2022

Kit manufacture date: 31 MAY 2021

Reagent Lot Numbers:

IA-2 Coated Wells: <u>IE193</u>	Expiry date: <u>28 SEP 2022</u>
IA-2-Biotin: <u>IEB132</u>	Expiry date: <u>22 SEP 2022</u>
Recon. Buffer for IA-2-Biotin: <u>IBB174</u>	Expiry date: <u>24 SEP 2022</u>
Streptavidin Peroxidase: <u>GEP427</u>	Expiry date: <u>17 NOV 2022</u>
Diluent for SA-POD: <u>PB164</u>	Expiry date: <u>01 MAR 2023</u>
Reaction Enhancer: <u>IES110</u>	Expiry date: <u>11 MAY 2023</u>
Peroxidase Substrate: <u>PTS175C</u>	Expiry date: <u>13 APR 2023</u>
Stop Solution: <u>HESP110</u>	Expiry date: <u>01 MAR 2023</u>
Concentrated Wash Solution: <u>CW273</u>	Expiry date: <u>24 AUG 2023</u>
Calibrators: <u>IC99</u>	Expiry date: <u>30 MAY 2022</u>
Controls: <u>INC99 / IPC99</u>	Expiry date: <u>30 MAY 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	0.033	0.004
7.5	0.126	0.034
35	0.497	0.151
120	1.949	0.608
350	>4	1.870
4000	>4	2.784

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	2.080	0.655	125.1	126.3	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: 18/19 May 2021

Authorised by: DR G Flood
Signature: [Signature]
Position: Head of Quality Control
Date: 26th MAY 2021