

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

Document: **wi/qcrs/0.28a**
Revision: **3**
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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: <u>IE192</u>	Expiry date: <u>31 AUG 2022</u>
IA-2-Biotin: <u>IEB131</u>	Expiry date: <u>23 AUG 2022</u>
Recon. Buffer for IA-2-Biotin: <u>IBB173A</u>	Expiry date: <u>21 JUL 2022</u>
Streptavidin Peroxidase: <u>GEP417</u>	Expiry date: <u>17 SEP 2022</u>
Diluent for SA-POD: <u>PB162</u>	Expiry date: <u>07 DEC 2022</u>
Reaction Enhancer: <u>IES109</u>	Expiry date: <u>20 JAN 2023</u>
Peroxidase Substrate: <u>PTS175C</u>	Expiry date: <u>13 APR 2023</u>
Stop Solution: <u>HESP108</u>	Expiry date: <u>08 NOV 2022</u>
Concentrated Wash Solution: <u>CW273</u>	Expiry date: <u>24 AUG 2023</u>
Calibrators: <u>IC97</u>	Expiry date: <u>04 APR 2022</u>
Controls: <u>INC97 / IPC97</u>	Expiry date: <u>04 APR 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	0.026	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
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Position: Scientist
Date: 08/09 April 2021

Authorised by: *DR G Flood*
Signature: *G Flood*
Position: Head of Quality Control
Date: 12th APR 2021