

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: 2KIE103 Kit expiry date: 01 August 2022

Kit manufacture date: 02 August 2021

Reagent Lot Numbers:

IA-2 Coated Wells: <u>IE197</u>	Expiry date: <u>28 DEC 2022</u>
IA-2-Biotin: <u>IEB131</u>	Expiry date: <u>23 AUG 2022</u>
Recon. Buffer for IA-2-Biotin: <u>IBB175</u>	Expiry date: <u>05 JAN 2023</u>
Streptavidin Peroxidase: <u>GEP427</u>	Expiry date: <u>17 NOV 2022</u>
Diluent for SA-POD: <u>PB165</u>	Expiry date: <u>03 MAY 2023</u>
Reaction Enhancer: <u>IES110</u>	Expiry date: <u>11 MAY 2023</u>
Peroxidase Substrate: <u>PTS175F</u>	Expiry date: <u>13 APR 2023</u>
Stop Solution: <u>HESP112</u>	Expiry date: <u>22 JUN 2023</u>
Concentrated Wash Solution: <u>CW257</u>	Expiry date: <u>16 JAN 2023</u>
Calibrators: <u>IC103</u>	Expiry date: <u>01 AUG 2022</u>
Controls: <u>INC103 / IPC103</u>	Expiry date: <u>01 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	0.027	0.003
7.5	0.100	0.028
35	0.327	0.099
120	1.675	0.524
350	>4	1.740 ^{LT}
4000	>4	2.922

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	1.475	0.466	111.5	111.7	110 ± 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: 02/03 August 2021

Authorised by: DR G FLOOD
Signature: *G Flood*
Position: Head of Quality Control
Date: 4TH AUG 2021