

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

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Prepared by: **G FLOOD**
Approved by: **A SALVAGE**

Kit lot number: 2KIE88 Kit expiry date: 26 JULY 2021
Kit manufacture date: 27 JULY 2020

Reagent Lot Numbers:

IA-2 Coated Wells: <u>IE183</u>	Expiry date: <u>26 OCT 2021</u>
IA-2-Biotin: <u>IEB125</u>	Expiry date: <u>28 NOV 2021</u>
Recon. Buffer for IA-2-Biotin: <u>IBB171</u>	Expiry date: <u>13 OCT 2021</u>
Streptavidin Peroxidase: <u>GEP378</u>	Expiry date: <u>01 JAN 2022</u>
Diluent for SA-POD: <u>PB158</u>	Expiry date: <u>05 MAY 2022</u>
Reaction Enhancer: <u>IES103</u>	Expiry date: <u>23 APR 2022</u>
Peroxidase Substrate: <u>PTS169H</u>	Expiry date: <u>17 FEB 2022</u>
Stop Solution: <u>HESP104</u>	Expiry date: <u>03 MAR 2022</u>
Concentrated Wash Solution: <u>CW249</u>	Expiry date: <u>27 OCT 2022</u>
Calibrators: <u>IC88</u>	Expiry date: <u>26 JUL 2021</u>
Controls: <u>INC88 / IPC88</u>	Expiry date: <u>26 JUL 2021</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	0.034	0.015
7.5	0.134	0.040
35	0.446	0.135
120	1.854	0.533
350	>4	1.520
4000	>4	2.856

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	2.007	0.592	127.7	126.8	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: A. E. COLLINS
Signature: A Collins
Position: SECTION LEADER
Date: 22/23 JULY 2020

Authorised by: DR G FLOOD
Signature: G Flood
Position: Head of Quality Control
Date: 24TH JULY 2020