

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

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Page **1 of 1**

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Approved by: **A SALVAGE**

Kit lot number: 2KIE94 Kit expiry date: 13 DECEMBER 2021

Kit manufacture date: 14 DECEMBER 2020

**Reagent Lot Numbers:**

IA-2 Coated Wells: <u>IE187</u>	Expiry date: <u>11 APR 2022</u>
IA-2-Biotin: <u>IEB127</u>	Expiry date: <u>14 MAR 2022</u>
Recon. Buffer for IA-2-Biotin: <u>IBB172</u>	Expiry date: <u>14 MAR 2022</u>
Streptavidin Peroxidase: <u>GEP398</u>	Expiry date: <u>04 MAY 2022</u>
Diluent for SA-POD: <u>PB161</u>	Expiry date: <u>18 OCT 2022</u>
Reaction Enhancer: <u>IES105</u>	Expiry date: <u>01 SEP 2022</u>
Peroxidase Substrate: <u>PTS173J</u>	Expiry date: <u>19 NOV 2022</u>
Stop Solution: <u>HESP108</u>	Expiry date: <u>08 NOV 2022</u>
Concentrated Wash Solution: <u>CW261</u>	Expiry date: <u>11 APR 2023</u>
Calibrators: <u>IC94</u>	Expiry date: <u>13 DEC 2021</u>
Controls: <u>INC94 / IPC94</u>	Expiry date: <u>13 DEC 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	0.031	0.023
7.5	0.136	0.050
35	0.451	0.143
120	1.683	0.506
350	>4	1.618
4000	>4	2.602

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	1.714	0.510	121.4	120.6	120± 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: 07/08 DECEMBER 2020

Authorised by: *G Flood*  
Signature: *G Flood*  
Position: Head of Quality Control  
Date: 11<sup>th</sup> DEC 2020