

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

Document: **wi/qcrs/0.28a**
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Prepared by: **G FLOOD**
Approved by: **A SALVAGE**

Kit lot number: 2KIE91 Kit expiry date: 13 OCTOBER 2021

Kit manufacture date: 19 OCTOBER 2020

Reagent Lot Numbers:

IA-2 Coated Wells: <u>IE182</u>	Expiry date: <u>20 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>GEP389</u>	Expiry date: <u>27 MAR 2022</u>
Diluent for SA-POD: <u>PB159</u>	Expiry date: <u>30 JUN 2022</u>
Reaction Enhancer: <u>IES103</u>	Expiry date: <u>23 APR 2022</u>
Peroxidase Substrate: <u>PTS171B</u>	Expiry date: <u>27 FEB 2022</u>
Stop Solution: <u>HESP105</u>	Expiry date: <u>13 MAY 2022</u>
Concentrated Wash Solution: <u>CW249</u>	Expiry date: <u>27 OCT 2022</u>
Calibrators: <u>IC91</u>	Expiry date: <u>18 OCT 2021</u>
Controls: <u>INC91 / IPC91</u>	Expiry date: <u>18 OCT 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	0.039	0.012
7.5	0.141	0.042
35	0.427	0.128
120	1.488	0.446
350	>4	1.430
4000	>4	2.790

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	1.535	0.459	122.5	122.4	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: pp R. ANANIEVA
Signature: J. Bradbury
Position: HEAD OF OPERATIONS
Date: 08/09 OCTOBER 2020

Authorised by: DR G FLOOD
Signature: [Signature]
Position: Head of Quality Control
Date: 12th OCT 2020