

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

Document: **wi/qcrs/0.28**
Revision: **7**
Date: **10/10/14**
Page **1 of 1**

Prepared by: **G Flood**
Approved by: **A Salvage**

Kit lot number: KIE196

Kit expiry date: 04 April 2022

IA-2 Coated Wells:	Lot No. <u>IE189</u>	Expiry Date <u>14 JUN 2022</u>
IA-2-Biotin:	Lot No. <u>IEB129A</u>	Expiry Date <u>25 JUL 2022</u>
Recon. Buffer for IA-2-Biotin:	Lot No. <u>IBB173A</u>	Expiry Date <u>21 JUL 2022</u>
Streptavidin Peroxidase:	Lot No. <u>GEP403</u>	Expiry Date <u>15 AUG 2022</u>
Diluent for SA-POD:	Lot No. <u>PB164</u>	Expiry Date <u>01 MAR 2023</u>
Reaction Enhancer:	Lot No. <u>IES109</u>	Expiry Date <u>20 JAN 2023</u>
Peroxidase Substrate:	Lot No. <u>PTS173N</u>	Expiry Date <u>19 NOV 2022</u>
Stop Solution:	Lot No. <u>HESP108</u>	Expiry Date <u>08 NOV 2022</u>
Concentrated Wash Solution:	Lot No. <u>CW266</u>	Expiry Date <u>06 JUL 2023</u>
Calibrators:	Lot No. <u>IEC196</u>	Expiry Date <u>04 APR 2022</u>
Controls:	Lot No. <u>IENC196 / IEPC196</u>	Expiry Date <u>04 APR 2022</u>

Calibrator 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	0.011
15	0.224	0.070
60	0.579	0.183
200	2.360	0.745
400	>4	1.537
4000	>4	2.750

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	1.313	0.415	132.6	127.5	135 ± 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

Signature:

Fiona Ryrie

Position:

Scientist

Date:

06/07 April 2021

Authorised by:

DR G Flood

Signature:

G Flood

Position:

HEAD OF QC

Date:

12TH APR 2021