

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: **KIE193**

Kit expiry date: **07 February 2022**

IA-2 Coated Wells:	Lot No. <u> IE189B </u>	Expiry Date <u> 14 JUN 2022 </u>
IA-2-Biotin:	Lot No. <u> IEB128A </u>	Expiry Date <u> 17 MAY 2022 </u>
Recon. Buffer for IA-2-Biotin:	Lot No. <u> IBB172 </u>	Expiry Date <u> 14 MAR 2022 </u>
Streptavidin Peroxidase:	Lot No. <u> GEP402 </u>	Expiry Date <u> 26 JUL 2022 </u>
Diluent for SA-POD:	Lot No. <u> PB161 </u>	Expiry Date <u> 18 OCT 2022 </u>
Reaction Enhancer:	Lot No. <u> IES105 </u>	Expiry Date <u> 01 SEP 2022 </u>
Peroxidase Substrate:	Lot No. <u> PTS173J </u>	Expiry Date <u> 19 NOV 2022 </u>
Stop Solution:	Lot No. <u> HESP105 </u>	Expiry Date <u> 12 MAY 2022 </u>
Concentrated Wash Solution:	Lot No. <u> CW263 </u>	Expiry Date <u> 18 MAY 2023 </u>
Calibrators:	Lot No. <u> IEC193 </u>	Expiry Date <u> 07 FEB 2022 </u>
Controls:	Lot No. <u> IENC193 / IEPC193 </u>	Expiry Date <u> 07 FEB 2022 </u>

Calibrator Curve and Controls:

Incubation temp: **+4 °C OVERNIGHT** **+20 °C**

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.049	0.027
15	0.271	0.089
60	0.735	0.224
200	2.915	0.869
400	>4	1.527
4000	>4	2.686

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	1.747	0.520	124.3	123.2	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:

 Rebecca Coles

Signature:

 R. Coles

Position:

 Senior Scientist

Date:

 03/04 February 2021

Authorised by:

 DR G Flood

Signature:

 G Flood

Position:

 HEAD OF QC

Date:

 9TH FEB 2021