

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

Document: **wi/qcrs/0.28a**
Revision: **3**
Date: **21 September 2018**
Page **1 of 1**

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Approved by: **A SALVAGE**

Kit lot number: 2KIE88B Kit expiry date: 20 SEPTEMBER 2021

Kit manufacture date: 21 SEPTEMBER 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>HESP105</u> | Expiry date: <u>13 MAY 2022</u> |
| Concentrated Wash Solution: <u>CW249</u> | Expiry date: <u>27 OCT 2022</u> |
| Calibrators: <u>IC88b</u> | Expiry date: <u>20 SEP 2021</u> |
| Controls: <u>INC88b / IPC88b</u> | Expiry date: <u>20 SEP 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 | 0.027 | 0.016 |
| 7.5 | 0.173 | 0.055 |
| 35 | 0.542 | 0.166 |
| 120 | 2.224 | 0.695 |
| 350 | >4 | 1.758 |
| 4000 | >4 | 2.825 |

| 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 | 2.412 | 0.716 | 128.1 | 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: A. E. COLLINS
Signature: *AEC*
Position: SECTION LEADER
Date: 01/02 SEPTEMBER 2020

Authorised by: *DR G FLOOD*
Signature: *A Salvage*
Position: Head of Quality Control
Date: 4TH SEP 2020