

Title: **Quality Control Record Sheet
ZnT8 Ab ELISA Kit QC Data**

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Approved by: S STEPHENSON

Kit lot number: KZTE99A Kit expiry date: 13th February 2023

Reagent Lot Numbers:

| | |
|--|---|
| Coated Wells: <u> ZTE109 </u> | Expiry date: <u> 22 May 2023 </u> |
| ZnT8-Biotin: <u> ZTB60b </u> | Expiry date: <u> 13 February 2023 </u> |
| Recon. Buffer for ZnT8-Biotin: <u> ZBB54 </u> | Expiry date: <u> 23 May 2023 </u> |
| Streptavidin Peroxidase: <u> GEP460 </u> | Expiry date: <u> 09 July 2023 </u> |
| Diluent for SA-POD: <u> PB169 </u> | Expiry date: <u> 19 October 2023 </u> |
| Peroxidase Substrate: <u> PTS177J </u> | Expiry date: <u> 03 May 2024 </u> |
| Stop Solution: <u> HESP114 </u> | Expiry date: <u> 21 September 2023 </u> |
| Concentrated Wash Solution: <u> CW300 </u> | Expiry date: <u> 07 April 2024 </u> |
| Calibrators: <u> ZTEC53 </u> | Expiry date: <u> 19 June 2023 </u> |
| Controls: <u> ZTEN53 / ZTEPa53A / ZTEPb53 </u> | Expiry date: <u> 19 June 2023 </u> |

Curve and Controls: Incubation temp: +21°C

| Calibrator Concentration (units per mL) | Absorbance at 450 nm | Absorbance at 405 nm |
|--|------------------------------|-------------------------|
| 10 | 0.070 | 0.015 |
| 20 | 0.149 | 0.041 |
| 75 | 0.626 | 0.192 |
| 500 | 2.492 | 0.784 |
| 2000 | 6.402 | 1.883 |
| | (derived from Abs at 405 nm) | |

| 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) |
|-------------|-------------------------|-------------------------|--|--|-------------------------|
| Negative | -0.002 | -0.007 | <10 | <10 | <10 |
| Positive I | 0.440 | 0.140 | 49.0 | 52.1 | 55±25 |
| Positive II | 0.974 | 0.306 | 147.2 | 141.7 | 160±70 |

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: Sinead Stephenson
Signature: S Stephenson
Position: Lab Technician
Date: 13 January 2022

Authorised by: DR G Flood
Signature: G Flood
Position: HEAD OF QC
Date: 11th FEB 2022