

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

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Approved by: S STEPHENSON

Kit lot number: KZTE136B Kit expiry date: 28th July 2025

Reagent Lot Numbers:

Coated Wells: <u>ZTE151</u>	Expiry date: <u>08 October 2025</u>
ZnT8-Biotin: <u>ZTB84b</u>	Expiry date: <u>28 July 2025</u>
Recon. Buffer for ZnT8-Biotin: <u>ZBB68</u>	Expiry date: <u>14 October 2025</u>
Streptavidin Peroxidase: <u>GEP633</u>	Expiry date: <u>23 October 2025</u>
Diluent for SA-POD: <u>PB180</u>	Expiry date: <u>18 January 2026</u>
Peroxidase Substrate: <u>PTS187J</u>	Expiry date: <u>30 November 2027</u>
Stop Solution: <u>HESP131</u>	Expiry date: <u>11 March 2026</u>
Concentrated Wash Solution: <u>CW391</u>	Expiry date: <u>14 September 2026</u>
Calibrators: <u>ZTEC77</u>	Expiry date: <u>22 October 2025</u>
Controls: <u>ZTEN77/ ZTEPa77/ ZTEPb77</u>	Expiry date: <u>22 October 2025</u>

Curve and Controls:

Incubation temp: +21°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.059	0.017
20	0.130	0.038
75	0.651	0.189
500	2.857	0.824
2000	7.857	2.311
(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	0.017	0.005	<10	<10	<10
Positive I	0.542	0.156	59.7	59.0	60±27
Positive II	1.166	0.336	175.6	177.6	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: Rebecca Coles

Signature: PP S Stephenson

Position: Senior Scientist

Date: 01 May 2024

Authorised by: DR G Flood

Signature: S Flood

Position: HEAD OF QC

Date: 26th JULY 2024