

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

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Approved by: **J CLARK**

Kit lot number: FZTE155 Kit expiry date: ³⁰02 June 2025

Reagent Lot Numbers:

Coated Wells: <u>ZTE155</u>	Expiry date: <u>20 November 2025</u>
ZnT8-Biotin: <u>ZTB84a</u>	Expiry date: <u>30 June 2025</u>
Recon. Buffer for ZnT8-Biotin: <u>ZBB67</u>	Expiry date: <u>14 August 2025</u>
Streptavidin Peroxidase: <u>GEP637</u>	Expiry date: <u>16 November 2025</u>
Diluent for SA-POD: <u>PB177</u>	Expiry date: <u>10 August 2025</u>
Peroxidase Substrate: <u>PTS185P</u>	Expiry date: <u>27 April 2027</u>
Stop Solution: <u>HESP127</u>	Expiry date: <u>20 September 2025</u>
Concentrated Wash Solution: <u>CW378</u>	Expiry date: <u>14 June 2026</u>
Calibrators: <u>ZTEC78</u>	Expiry date: <u>16 November 2025</u>
Controls: <u>ZTEN78 / FZTEPa/b78</u>	Expiry date: <u>16 November 2025</u>

Curve and Controls:

Incubation temp: +21°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.065	0.019
20	0.137	0.040
75	0.497	0.144
500	2.716	0.787
2000	8.163	2.401
(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	0.024	0.008	<10	<10	<10
Positive I	0.378	0.109	52.5	51.7	55±27
Positive II	0.893	0.259	165.7	167.8	177±88

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
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Date: 06 June 2024

Authorised by: DR G Flood
Signature: G Flood
Position: HEAD OF QC
Date: 1ST JULY 2024