

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

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Approved by: **J CLARK**

Kit lot number: FZTE161A Kit expiry date: 14 October 2025

Reagent Lot Numbers:

Coated Wells: <u>ZTE161</u>	Expiry date: <u>05 February 2026</u>
ZnT8-Biotin: <u>ZTB86d</u>	Expiry date: <u>17 November 2025</u>
Recon. Buffer for ZnT8-Biotin: <u>ZBB68</u>	Expiry date: <u>14 October 2025</u>
Streptavidin Peroxidase: <u>GEP659</u>	Expiry date: <u>18 February 2026</u>
Diluent for SA-POD: <u>PB181</u>	Expiry date: <u>09 April 2026</u>
Peroxidase Substrate: <u>PTS189B</u>	Expiry date: <u>09 May 2028</u>
Stop Solution: <u>HESP133</u>	Expiry date: <u>19 June 2026</u>
Concentrated Wash Solution: <u>CW399</u>	Expiry date: <u>30 November 2026</u>
Calibrators: <u>ZTEC83</u>	Expiry date: <u>14 February 2026</u>
Controls: <u>ZTEN83 / FZTEPa/b83</u>	Expiry date: <u>14 February 2026</u>

Curve and Controls:

Incubation temp: +21°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.059	0.018
20	0.124	0.036
75	0.452	0.131
500	2.797	0.810
2000	7.846	2.308
	(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	0.406	0.117	66.4	65.7	62±30
Positive II	1.014	0.294	180.5	183.1	176±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: AP Sinead Stephenson
Signature: [Signature]
Position: Lab Technician
Date: 19 September 2024

Authorised by: DR G FLOOD
Signature: [Signature]
Position: HEAD OF QC
Date: 18TH NOV 2024