

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

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Approved by: **J CLARK**

Kit lot number: **FZTE171B** Kit expiry date: **09 March 2026**

Reagent Lot Numbers:

Coated Wells: ZTE171	Expiry date: 25 May 2026
ZnT8-Biotin: ZTB90b	Expiry date: 09 March 2026
Recon. Buffer for ZnT8-Biotin: ZBB70	Expiry date: 13 July 2026
Streptavidin Peroxidase: GEP684	Expiry date: 07 July 2026
Diluent for SA-POD: PB184	Expiry date: 26 November 2026
Peroxidase Substrate: PTS189	Expiry date: 09 May 2028
Stop Solution: HESP137	Expiry date: 27 November 2026
Concentrated Wash Solution: CW419	Expiry date: 20 May 2027
Calibrators: ZTEC93	Expiry date: 22 July 2026
Controls: ZTEN93 / FZTEPa/b93	Expiry date: 22 July 2026

Curve and Controls:

Incubation temp: **+21°C**

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.067	0.020
20	0.130	0.038
75	0.529	0.156
500	2.724	0.791
2000	7.585	2.231
(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	0.026	0.008	<10	<10	<10
Positive I	0.529	0.154	74.9	73.9	76±38
Positive II	1.176	0.341	203.5	204.8	196±98

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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Position: **Principal Scientist**
Date: **04 February 2025**

Authorised by: **DR G FLOOD**
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Position: **HEAD OF QC**
Date: **10th MAR 2025**