

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

Document: **wi/qcrs/0.38a**

Revision: **0**

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Prepared by: **G FLOOD**

Approved by: **J CLARK**

Kit lot number: **FZTE184**

Kit expiry date: **16 November 2026**

Reagent Lot Numbers:

Coated Wells: **ZTE184**

Expiry date: **25 February 2027**

ZnT8-Biotin: **ZTB100**

Expiry date: **16 November 2026**

Recon. Buffer for ZnT8-Biotin: **ZBB73**

Expiry date: **29 December 2026**

Streptavidin Peroxidase: **GEP736**

Expiry date: **01 March 2027**

Diluent for SA-POD: **PB188**

Expiry date: **20 August 2027**

Peroxidase Substrate: **PTS193E**

Expiry date: **28 January 2029**

Stop Solution: **HESP143**

Expiry date: **06 August 2027**

Concentrated Wash Solution: **CW464**

Expiry date: **29 February 2028**

Calibrators: **ZTEC108A**

Expiry date: **22 March 2027**

Controls: **ZTEN108A / FZTEPa/b108A**

Expiry date: **22 March 2027**

Curve and Controls:

Incubation temp: **+21°C**

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.054	0.015
20	0.138	0.040
75	0.592	0.171
500	2.521	0.729
2000	7.811	2.297
(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	0.016	0.006	<10	<10	<10
Positive I	0.505	0.146	58.8	58.5	70±35
Positive II	0.941	0.272	174.2	177.7	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: **Rebecca Coles**

Signature: **R. Coles**

Position: **Principal Scientist**

Date: **30 September 2025**

Authorised by: **DR G Flood**

Signature: **G Flood**

Position: **HEAD OF QC**

Date: **13th NOV 2025**