

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: FZTE158A

Kit expiry date: 25 August 2025

Reagent Lot Numbers:

Coated Wells: ZTE158

Expiry date: 17 December 2025

ZnT8-Biotin: ZTB85b

Expiry date: 25 August 2025

Recon. Buffer for ZnT8-Biotin: ZBB68

Expiry date: 14 October 2025

Streptavidin Peroxidase: GEP648

Expiry date: 02 January 2026

Diluent for SA-POD: PB181

Expiry date: 09 April 2026

Peroxidase Substrate: PTS185H

Expiry date: 27 April 2027

Stop Solution: HESP132

Expiry date: 29 April 2026

Concentrated Wash Solution: CW372

Expiry date: 16 April 2026

Calibrators: ZTEC80

Expiry date: 02 January 2026

Controls: ZTEN80 / FZTEPa/b80

Expiry date: 02 January 2026

Curve and Controls:

Incubation temp: +21°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.058	0.014
20	0.136	0.036
75	0.554	0.158
500	2.883	0.839
2000	7.619	2.241
	(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	0.001	<10	<10	<10
Positive I	0.455	0.128	60.0	59.4	55±27
Positive II	1.108	0.317	171.9	171.0	173±86

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: *RColes*

Position: Senior Scientist

Date: 23 July 2024

Authorised by: *DR G Flood*

Signature: *G Flood*

Position: HEAD OF QC

Date: 22nd AUG 2024