

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

Document: **wi/qcrs/0.38a**
 Revision: **0**
 Date: **18 JANUARY 2019**
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Prepared by: **G FLOOD**
 Approved by: **J CLARK**

Kit lot number: FZTE171

Kit expiry date: 26 January 2026

Reagent Lot Numbers:

Coated Wells: ZTE171

Expiry date: 25 May 2026

ZnT8-Biotin: ZTB89c

Expiry date: 26 January 2026

Recon. Buffer for ZnT8-Biotin: ZBB69

Expiry date: 11 March 2026

Streptavidin Peroxidase: GEP682

Expiry date: 16 June 2026

Diluent for SA-POD: PB181

Expiry date: 09 April 2026

Peroxidase Substrate: PTS189J

Expiry date: 09 May 2028

Stop Solution: HESP136

Expiry date: 28 October 2026

Concentrated Wash Solution: CW378

Expiry date: 14 June 2026

Calibrators: ZTEC91

Expiry date: 25 May 2026

Controls: ZTEN91 / FZTEPa/b91

Expiry date: 25 May 2026

Curve and Controls:

Incubation temp: +21°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.071	0.021
20	0.127	0.037
75	0.598	0.174
500	2.937	0.850
2000	8.361	2.458
(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	0.027	0.007	<10	<10	<10
Positive I	0.497	0.144	60.0	59.5	57±28
Positive II	1.264	0.367	202.8	205.8	215±107

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: pp Sinead Stephenson
 Signature: [Signature]
 Position: Lab Technician
 Date: 16 January 2025

Authorised by: DR G Flood
 Signature: [Signature]
 Position: HEAD OF QC
 Date: 29TH JAN 2025