

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: FZTE147A

Kit expiry date: 05 May 2025

Reagent Lot Numbers:

Coated Wells: <u>ZTE147</u>	Expiry date: <u>11 June 2025</u>
ZnT8-Biotin: <u>ZTB82b</u>	Expiry date: <u>05 May 2025</u>
Recon. Buffer for ZnT8-Biotin: <u>ZBB66</u>	Expiry date: <u>11 June 2025</u>
Streptavidin Peroxidase: <u>GEP616</u>	Expiry date: <u>15 August 2025</u>
Diluent for SA-POD: <u>PB180</u>	Expiry date: <u>18 January 2026</u>
Peroxidase Substrate: <u>PTS187B</u>	Expiry date: <u>30 November 2027</u>
Stop Solution: <u>HESP130</u>	Expiry date: <u>08 February 2026</u>
Concentrated Wash Solution: <u>CW380</u>	Expiry date: <u>04 July 2026</u>
Calibrators: <u>ZTEC75</u>	Expiry date: <u>13 August 2025</u>
Controls: <u>ZTEN75 / FZTEPa/b75</u>	Expiry date: <u>13 August 2025</u>

Curve and Controls:

Incubation temp: +21°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.077	0.022
20	0.132	0.038
75	0.478	0.139
500	2.643	0.766
2000	6.817	2.005
(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	0.020	0.006	<10	<10	<10
Positive I	0.367	0.106	56.5	56.1	67±30
Positive II	1.073	0.310	183.6	184.8	200±90

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: Sinead Stephenson
 Signature: S. Stephenson
 Position: Lab Technician
 Date: 06 March 2024

Authorised by: DR G Flood
 Signature: G Flood
 Position: HEAD OF QC
 Date: 3RD MAY 2024