

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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Approved by: **J CLARK**

Kit lot number: FZTE189A Kit expiry date: 08 February 2027

Reagent Lot Numbers:

Coated Wells: <u>ZTE189</u>	Expiry date: <u>15 June 2027</u>
ZnT8-Biotin: <u>ZTB102c</u>	Expiry date: <u>08 February 2027</u>
Recon. Buffer for ZnT8-Biotin: <u>ZBB74</u>	Expiry date: <u>05 April 2027</u>
Streptavidin Peroxidase: <u>GEP767</u>	Expiry date: <u>12 July 2027</u>
Diluent for SA-POD: <u>PB190</u>	Expiry date: <u>10 December 2027</u>
Peroxidase Substrate: <u>PTS193E</u>	Expiry date: <u>28 January 2029</u>
Stop Solution: <u>HESP146</u>	Expiry date: <u>10 December 2027</u>
Concentrated Wash Solution: <u>CW483</u>	Expiry date: <u>03 June 2028</u>
Calibrators: <u>ZTEC115</u>	Expiry date: <u>13 April 2027</u>
Controls: <u>ZTEN115 / FZTEPa/b115</u>	Expiry date: <u>13 April 2027</u>

Curve and Controls:

Incubation temp: +21°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.058	0.017
20	0.137	0.041
75	0.622	0.183
500	2.726	0.788
2000	7.710	2.268
	(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	0.009	<10	<10	<10
Positive I	0.484	0.141	54.1	53.3	53±26
Positive II	1.020	0.296	160.4	163.4	163±81

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: pp S Stephenson
Position: Principal Scientist
Date: 20 January 2026

Authorised by: DR G Flood
Signature: G Flood
Position: HEAD OF QC
Date: 6TH FEB 2026