

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

Document: **wi/qcrs/0.38**

Revision: **3**

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Prepared by: **G FLOOD**
Approved by: **S STEPHENSON**

Kit lot number: KZTE168 Kit expiry date: 12 April 2027

Reagent Lot Numbers:

Coated Wells: <u> ZTE192 </u>	Expiry date: <u> 02 August 2027 </u>
ZnT8-Biotin: <u> ZTB106 </u>	Expiry date: <u> 12 April 2027 </u>
Recon. Buffer for ZnT8-Biotin: <u> ZBB75 </u>	Expiry date: <u> 15 June 2027 </u>
Streptavidin Peroxidase: <u> GEP782 </u>	Expiry date: <u> 12 September 2027 </u>
Diluent for SA-POD: <u> PB191 </u>	Expiry date: <u> 05 March 2028 </u>
Peroxidase Substrate: <u> PTS197E </u>	Expiry date: <u> 13 October 2029 </u>
Stop Solution: <u> HESP148 </u>	Expiry date: <u> 08 February 2028 </u>
Concentrated Wash Solution: <u> CW496 </u>	Expiry date: <u> 08 September 2028 </u>
Calibrators: <u> ZTEC118 </u>	Expiry date: <u> 05 September 2027 </u>
Controls: <u> ZTEN118/ ZTEPa118/ ZTEPb118 </u>	Expiry date: <u> 05 September 2027 </u>

Curve and Controls:

Incubation temp: +21°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.068	0.021
20	0.132	0.039
75	0.648	0.189
500	2.598	0.754
2000	8.170	2.403
	(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	0.018	0.006	<10	<10	<10
Positive I	0.568	0.165	61.0	60.5	61±30
Positive II	1.075	0.312	196.1	198.6	201±100

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: 17 March 2026

Authorised by: DR G flood
Signature: [Signature]
Position: HEAD OF QC
Date: 8TH APR 2026