

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

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

Kit lot number: KZTE169A Kit expiry date: 05 July 2027

Reagent Lot Numbers:

Coated Wells: <u>ZTE194</u>	Expiry date: <u>02 September 2027</u>
ZnT8-Biotin: <u>ZTB108a</u>	Expiry date: <u>05 July 2027</u>
Recon. Buffer for ZnT8-Biotin: <u>ZBB76</u>	Expiry date: <u>26 August 2027</u>
Streptavidin Peroxidase: <u>GEP787</u>	Expiry date: <u>30 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>CW501</u>	Expiry date: <u>09 September 2028</u>
Calibrators: <u>ZTEC120</u>	Expiry date: <u>26 September 2027</u>
Controls: <u>ZTEN120/ ZTEPa120/ ZTEPb120</u>	Expiry date: <u>26 September 2027</u>

Curve and Controls:

Incubation temp: +21°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.050	0.016
20	0.133	0.041
75	0.627	0.184
500	2.615	0.757
2000	8.107	2.384
	(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	0.006	<10	<10	<10
Positive I	0.544	0.159	60.2	59.5	61±30
Positive II	1.083	0.314	197.7	200.5	198±99

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: 02 April 2026

Authorised by: DR G FLOOD

Signature: [Signature]

Position: HEAD OF QC

Date: 3RD JULY 2026