

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

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Approved by: J CLARK

Kit lot number: FZTE171 Kit expiry date: 26 January 2026

Reagent Lot Numbers:

Coated Wells: <u>ZTE171</u>	Expiry date: <u>25 May 2026</u>
ZnT8-Biotin: <u>ZTB89c</u>	Expiry date: <u>26 January 2026</u>
Recon. Buffer for ZnT8-Biotin: <u>ZBB69</u>	Expiry date: <u>11 March 2026</u>
Streptavidin Peroxidase: <u>GEP682</u>	Expiry date: <u>16 June 2026</u>
Diluent for SA-POD: <u>PB181</u>	Expiry date: <u>09 April 2026</u>
Peroxidase Substrate: <u>PTS189J</u>	Expiry date: <u>09 May 2028</u>
Stop Solution: <u>HESP136</u>	Expiry date: <u>28 October 2026</u>
Concentrated Wash Solution: <u>CW378</u>	Expiry date: <u>14 June 2026</u>
Calibrators: <u>ZTEC91</u>	Expiry date: <u>25 May 2026</u>
Controls: <u>ZTEN91 / FZTEPa/b91</u>	Expiry date: <u>25 May 2026</u>

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: m 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