

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: KZTE113 Kit expiry date: 12th March 2024

Reagent Lot Numbers:

Coated Wells: <u> ZTE123 </u>	Expiry date: <u> 05 June 2024 </u>
ZnT8-Biotin: <u> ZTB72 </u>	Expiry date: <u> 12 March 2024 </u>
Recon. Buffer for ZnT8-Biotin: <u> ZBB60 </u>	Expiry date: <u> 12 July 2024 </u>
Streptavidin Peroxidase: <u> GEP531 </u>	Expiry date: <u> 06 June 2024 </u>
Diluent for SA-POD: <u> PB173 </u>	Expiry date: <u> 09 November 2024 </u>
Peroxidase Substrate: <u> PTS181J </u>	Expiry date: <u> 21 April 2026 </u>
Stop Solution: <u> HESP122 </u>	Expiry date: <u> 14 December 2024 </u>
Concentrated Wash Solution: <u> CW337 </u>	Expiry date: <u> 08 May 2025 </u>
Calibrators: <u> ZTEC62A </u>	Expiry date: <u> 11 July 2024 </u>
Controls: <u> ZTEN62A / ZTEPa62A / ZTEPb62A </u>	Expiry date: <u> 11 July 2024 </u>

Curve and Controls:

Incubation temp: +22°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.057	0.013
20	0.153	0.045
75	0.628	0.195
500	2.794	0.887
2000	6.106	1.796
	(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	0.002	0.000	<10	<10	<10
Positive I	0.468	0.152	55.0	58.7	56±25
Positive II	1.408	0.445	196.5	188.3	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: Rebecca Coles

Signature: R Coles

Position: Senior Scientist

Date: 14 February 2023

Authorised by: DR G FLOOD

Signature: S Flood

Position: HEAD OF QC

Date: 2ND MAR 2023