

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

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Approved by: S STEPHENSON

Kit lot number: KZTE97B Kit expiry date: 21<sup>st</sup> November 2022

**Reagent Lot Numbers:**

Coated Wells: <u>ZTE107</u>	Expiry date: <u>03 April 2023</u>
ZnT8-Biotin: <u>ZTB59</u>	Expiry date: <u>21 November 2022</u>
Recon. Buffer for ZnT8-Biotin: <u>ZBB53</u>	Expiry date: <u>05 April 2023</u>
Streptavidin Peroxidase: <u>GEP454</u>	Expiry date: <u>08<sup>th</sup> May 2023</u>
Diluent for SA-POD: <u>PB168</u>	Expiry date: <u>23 August 2023</u>
Peroxidase Substrate: <u>PTS177E</u>	Expiry date: <u>03 May 2024</u>
Stop Solution: <u>HESP114</u>	Expiry date: <u>21 September 2023</u>
Concentrated Wash Solution: <u>CW297</u>	Expiry date: <u>25 February 2024</u>
Calibrators: <u>ZTEC51</u>	Expiry date: <u>23 March 2023</u>
Controls: <u>ZTEN51 / ZTEPa51 / ZTEPb51</u>	Expiry date: <u>23 March 2023</u>

**Curve and Controls:**

Incubation temp: +21°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.063	0.017
20	0.133	0.039
75	0.719	0.223
500	2.801	0.880
2000	7.810	2.297
	(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	0.013	0.001	<10	<10	<10
Positive I	0.579	0.181	56.8	58.1	58±23
Positive II	1.269	0.397	192.2	181.1	195±85

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  
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Position: Senior Scientist  
Date: 09 November 2021

Authorised by: DR G Flood  
Signature: G Flood  
Position: HEAD OF QC  
Date: 16<sup>th</sup> NOV 2021