

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

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Approved by: **S STEPHENSON**

Kit lot number: KZTE118 Kit expiry date: 2<sup>nd</sup> July 2024

**Reagent Lot Numbers:**

Coated Wells: <u>ZTE130</u>	Expiry date: <u>01 November 2024</u>
ZnT8-Biotin: <u>ZTB75b</u>	Expiry date: <u>02 July 2024</u>
Recon. Buffer for ZnT8-Biotin: <u>ZBB62</u>	Expiry date: <u>26 September 2024</u>
Streptavidin Peroxidase: <u>GEP565</u>	Expiry date: <u>01 December 2024</u>
Diluent for SA-POD: <u>PB174</u>	Expiry date: <u>12 February 2025</u>
Peroxidase Substrate: <u>PTS183</u>	Expiry date: <u>24 October 2026</u>
Stop Solution: <u>HESP124</u>	Expiry date: <u>02 April 2025</u>
Concentrated Wash Solution: <u>CW351</u>	Expiry date: <u>29 September 2025</u>
Calibrators: <u>ZTEC65A</u>	Expiry date: <u>17 October 2024</u>
Controls: <u>ZTEN65A/ ZTEPa65A/ ZTEPb65A</u>	Expiry date: <u>17 October 2024</u>

**Curve and Controls:**

Incubation temp: +21°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.075	0.022
20	0.164	0.050
75	0.702	0.218
500	2.837	0.889
2000	6.783	1.995
(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	0.598	0.190	61.8	63.8	60±27
Positive II	1.432	0.450	201.3	193.9	185±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: 08 June 2023

Authorised by: DR G Flood  
Signature: G Flood  
Position: HEAD OF QC  
Date: 29<sup>th</sup> JUN 2023