

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

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Revision: **3**

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

Kit lot number: KZTE108 Kit expiry date: 25th September 2023

Reagent Lot Numbers:

Coated Wells: <u>ZTE118</u>	Expiry date: <u>15 February 2024</u>
ZnT8-Biotin: <u>ZTB67b</u>	Expiry date: <u>25 September 2023</u>
Recon. Buffer for ZnT8-Biotin: <u>ZBB58</u>	Expiry date: <u>08 February 2024</u>
Streptavidin Peroxidase: <u>GEP513</u>	Expiry date: <u>12 March 2024</u>
Diluent for SA-POD: <u>PB172</u>	Expiry date: <u>23 August 2024</u>
Peroxidase Substrate: <u>PTS179Q</u>	Expiry date: <u>30 September 2024</u>
Stop Solution: <u>HESP120</u>	Expiry date: <u>23 August 2024</u>
Concentrated Wash Solution: <u>CW312</u>	Expiry date: <u>13 September 2024</u>
Calibrators: <u>ZTEC58A</u>	Expiry date: <u>15 February 2024</u>
Controls: <u>ZTEN58A/ ZTEPa58A/ ZTEPb58A</u>	Expiry date: <u>15 February 2024</u>

Curve and Controls:

Incubation temp: +22°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.059	0.014
20	0.150	0.042
75	0.671	0.206
500	2.851	0.892
2000	6.273	1.845
	(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	0.004	0.000	<10	<10	<10
Positive I	0.568	0.176	62.5	63.9	59±26
Positive II	1.403	0.437	187.4	180.6	180±80

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: 13 September 2022

Authorised by: DR G flood

Signature: [Signature]

Position: HEAD OF QC

Date: 29th SEP 2022