

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

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Approved by: S STEPHENSON

Kit lot number: KZTE92 Kit expiry date: 06th June 2022

Reagent Lot Numbers:

Coated Wells: <u> ZTE102 </u>	Expiry date: <u> 22 September 2022 </u>
ZnT8-Biotin: <u> ZTB54 </u>	Expiry date: <u> 06 June 2022 </u>
Recon. Buffer for ZnT8-Biotin: <u> ZBB50 </u>	Expiry date: <u> 17 November 2022 </u>
Streptavidin Peroxidase: <u> GEP415A </u>	Expiry date: <u> 24 August 2022 </u>
Diluent for SA-POD: <u> PB165 </u>	Expiry date: <u> 03 May 2023 </u>
Peroxidase Substrate: <u> PTS175G </u>	Expiry date: <u> 13 April 2023 </u>
Stop Solution: <u> HESP110 </u>	Expiry date: <u> 01 March 2023 </u>
Concentrated Wash Solution: <u> CW269 </u>	Expiry date: <u> 21 July 2023 </u>
Calibrators: <u> ZTEC48 </u>	Expiry date: <u> 21 August 2022 </u>
Controls: <u> ZTEN48 / ZTEPa48 / ZTEPb48 </u>	Expiry date: <u> 21 August 2022 </u>

Curve and Controls:

Incubation temp: +20°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.053	0.015
20	0.116	0.034
75	0.638	0.201
500	2.756	0.872
2000	7.711	2.268
	(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	0.024	0.005	<10	<10	<10
Positive I	0.497	0.157	55.4	56.8	54±21
Positive II	1.301	0.439	213.1	217.7	185±75

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: Sinead Stephenson
Signature: S Stephenson
Position: Lab Technician
Date: 28 May 2021

Authorised by: DR G FLOOD
Signature: j Flood
Position: HEAD OF QC
Date: 3RD JUN 2021