

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

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Approved by: S STEPHENSON

Kit lot number: KZTE89A Kit expiry date: 14th February 2022

Reagent Lot Numbers:

Coated Wells: <u>ZTE99</u>	Expiry date: <u>09 May 2022</u>
ZnT8-Biotin: <u>ZTB52a</u>	Expiry date: <u>14 February 2022</u>
Recon. Buffer for ZnT8-Biotin: <u>ZBB48</u>	Expiry date: <u>23 May 2022</u>
Streptavidin Peroxidase: <u>GEP405</u>	Expiry date: <u>14 June 2022</u>
Diluent for SA-POD: <u>PB161</u>	Expiry date: <u>18 October 2022</u>
Peroxidase Substrate: <u>PTS173G</u>	Expiry date: <u>19 November 2022</u>
Stop Solution: <u>HESP107</u>	Expiry date: <u>15 September 2022</u>
Concentrated Wash Solution: <u>CW260</u>	Expiry date: <u>21 March 2023</u>
Calibrators: <u>ZTEC47</u>	Expiry date: <u>13 June 2022</u>
Controls: <u>ZTEN47 / ZTEPa47 / ZTEPb47</u>	Expiry date: <u>13 June 2022</u>

Curve and Controls:

Incubation temp: +20°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.064	0.020
20	0.177	0.055
75	0.797	0.250
500	2.834	0.890
2000	7.324	2.154
	(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	0.006	0.001	<10	<10	<10
Positive I	0.690	0.217	61.3	62.1	56±22
Positive II	1.439	0.452	203.7	193.0	195±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: 14 January 2021

Authorised by: G Flood
Signature: G Flood
Position: HEAD OF QC
Date: 5th FEB 2021