

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

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Approved by: S STEPHENSON

Kit lot number: KZTE88 Kit expiry date: 22nd November 2021

Reagent Lot Numbers:

Coated Wells: <u>ZTE98</u>	Expiry date: <u>04 April 2022</u>
ZnT8-Biotin: <u>ZTB51</u>	Expiry date: <u>22 November 2021</u>
Recon. Buffer for ZnT8-Biotin: <u>ZBB46</u>	Expiry date: <u>02 February 2022</u>
Streptavidin Peroxidase: <u>GEP396</u>	Expiry date: <u>04 May 2022</u>
Diluent for SA-POD: <u>PB160</u>	Expiry date: <u>19 August 2022</u>
Peroxidase Substrate: <u>PTS173E</u>	Expiry date: <u>19 November 2022</u>
Stop Solution: <u>HESP106</u>	Expiry date: <u>02 June 2022</u>
Concentrated Wash Solution: <u>CW255</u>	Expiry date: <u>29 December 2022</u>
Calibrators: <u>ZTEC45</u>	Expiry date: <u>19 April 2022</u>
Controls: <u>ZTEN45 / ZTEPa45 / ZTEPb45</u>	Expiry date: <u>19 April 2022</u>

Curve and Controls:

Incubation temp: +23°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.067	0.022
20	0.161	0.052
75	0.661	0.212
500	2.747	0.878
2000	7.939	2.335
	(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	0.005	<10	<10	<10
Positive I	0.575	0.184	61.2	62.1	59±23
Positive II	1.094	0.350	174.3	161.0	170±65

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: p.p. R. Coles
Position: Lab Technician
Date: 13 November 2020

Authorised by: DR G FLOOD
Signature: G Flood
Position: HEAD OF QC
Date: 23RD Nov 2020