

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

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Approved by: S STEPHENSON

Kit lot number: KZTE94B Kit expiry date: 29 August 2022

Reagent Lot Numbers:

Coated Wells: ZTE104 Expiry date: 05 January 2023
ZnT8-Biotin: ZTB56 Expiry date: 29 August 2022
Recon. Buffer for ZnT8-Biotin: ZBB52 Expiry date: 15 February 2023
Streptavidin Peroxidase: GEP432 Expiry date: 21 December 2022
Diluent for SA-POD: PB166 Expiry date: 01 June 2023
Peroxidase Substrate: PTS175N Expiry date: 13 April 2023
Stop Solution: HESP112 Expiry date: 22 June 2023
Concentrated Wash Solution: CW274 Expiry date: 08 September 2023
Calibrators: ZTEC49 Expiry date: 14 December 2022
Controls: ZTEN49 / ZTEPa49 / ZTEPb49 Expiry date: 14 December 2022

Curve and Controls:

Incubation temp: +20°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.050	0.014
20	0.121	0.036
75	0.621	0.195
500	2.544	0.800
2000	6.872	2.021
	(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	0.009	0.000	<10	<10	<10
Positive I	0.536	0.171	62.1	64.1	55±22
Positive II	1.195	0.378	201.4	192.3	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
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Date: 17 August 2021

Authorised by: DR G FLOOD
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Position: HEAD OF QC
Date: 26th AUG 2021