

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

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Page **1 of 1**

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

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

Reagent Lot Numbers:

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

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**
Signature: **pp S Stephenson**
Position: **Senior Scientist**
Date: **17 August 2021**

Authorised by: **DR G Flood**
Signature: **G Flood**
Position: **HEAD OF QC**
Date: **26th AUG 2021**