

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

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Date: **18 JANUARY 2019**  
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Prepared by: **G FLOOD**  
Approved by: **J CLARK**

Kit lot number: **FZTE123**

Kit expiry date: **04 June 2024**

**Reagent Lot Numbers:**

Coated Wells: **ZTE123**

Expiry date: **05 June 2024**

ZnT8-Biotin: **ZTB73a**

Expiry date: **04 June 2024**

Recon. Buffer for ZnT8-Biotin: **ZBB60**

Expiry date: **12 July 2024**

Streptavidin Peroxidase: **GEP551**

Expiry date: **03 October 2024**

Diluent for SA-POD: **PB172**

Expiry date: **23 August 2024**

Peroxidase Substrate: **PTS181F**

Expiry date: **21 April 2026**

Stop Solution: **HESP120**

Expiry date: **23 August 2024**

Concentrated Wash Solution: **CW334**

Expiry date: **11 April 2025**

Calibrators: **ZTEC64**

Expiry date: **27 September 2024**

Controls: **ZTEN64 / FZTEPa/b64**

Expiry date: **27 September 2024**

**Curve and Controls:**

Incubation temp: **+21°C**

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.060	0.017
20	0.120	0.035
75	0.523	0.153
500	2.826	0.831
2000	7.201	2.118
(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	0.001	0.002	<10	<10	<10
Positive I	0.431	0.126	61.3	61.3	58±26
Positive II	1.107	0.325	172.8	172.7	185±85

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**

Authorised by: **DR G Flood**

Signature: **S. Stephenson**

Signature: **[Signature]**

Position: **Lab Technician**

Position: **HEAD OF QC**

Date: **24 May 2023**

Date: **2<sup>ND</sup> JUN 2023**