

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

Document: **wi/qcrs/0.38a**

Revision: **0**

Date: **18 JANUARY 2019**

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Prepared by: **G FLOOD**

Approved by: **J CLARK**

Kit lot number: **FZTE115**

Kit expiry date: **31 July 2023**

Reagent Lot Numbers:

Coated Wells: **ZTE115**

Expiry date: **06 December 2023**

ZnT8-Biotin: **ZTB62^b**

Expiry date: **31 July 2023**

Recon. Buffer for ZnT8-Biotin: **ZBB55**

Expiry date: **15 August 2023**

Streptavidin Peroxidase: **GEP495A**

Expiry date: **06 December 2023**

Diluent for SA-POD: **PB169**

Expiry date: **19 October 2023**

Peroxidase Substrate: **PTS177R**

Expiry date: **03 May 2024**

Stop Solution: **HESP117**

Expiry date: **10 March 2024**

Concentrated Wash Solution: **CW299**

Expiry date: **20 March 2024**

Calibrators: **ZTEC55B**

Expiry date: **31 August 2023**

Controls: **ZTEN55B / FZTEPa/b55B**

Expiry date: **31 August 2023**

Curve and Controls:

Incubation temp: **+21°C**

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.059	0.015
20	0.108	0.031
75	0.527	0.163
500	2.645	0.824
2000	6.208	1.826
	(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	0.020	0.004	<10	<10	<10
Positive I	0.461	0.144	65.7	66.6	66±29
Positive II	1.128	0.352	174.2	168.6	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: **[Signature]**

Position: **Senior Scientist**

Date: **12 July 2022**

Authorised by: **DR G Flood**

Signature: **[Signature]**

Position: **HEAD OF QC**

Date: **12TH SEP 2022**