

Title:

Quality Control Record Sheet

Fast ZnT8 Ab ELISA Kit QC Data

Document: **wi/qcrs/0.38a**Revision: **0**Date: **18 JANUARY 2019**Page **1 of 1**Prepared by: **G FLOOD**Approved by: **J CLARK**Kit lot number: **FZTE196**Kit expiry date: **02 August 2027**

Reagent Lot Numbers:

Coated Wells: **ZTE196**Expiry date: **06 October 2027**ZnT8-Biotin: **ZTB113a**Expiry date: **02 August 2027**Recon. Buffer for ZnT8-Biotin: **ZBB77**Expiry date: **21 November 2027**Streptavidin Peroxidase: **GEP808**Expiry date: **24 December 2027**Diluent for SA-POD: **PB192**Expiry date: **30 April 2028**Peroxidase Substrate: **PTS197K**Expiry date: **13 October 2029**Stop Solution: **HESP149**Expiry date: **30 April 2028**Concentrated Wash Solution: **CW511**Expiry date: **20 November 2028**Calibrators: **ZTEC125**Expiry date: **18 December 2027**Controls: **ZTEN125 / FZTEPa/b125**Expiry date: **18 December 2027**

Curve and Controls:

Incubation temp: **+21°C**

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.075	0.022
20	0.151	0.045
75	0.483	0.141
500	2.644	0.768
2000	8.057	2.370
(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	0.026	0.008	<10	<10	<10
Positive I	0.415	0.121	60.2	59.3	59±29
Positive II	0.934	0.271	182.9	184.7	180±90

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: **Principal Scientist**Date: **21 July 2026**Authorised by: **DR G flood**Signature: **[Signature]**Position: **HEAD OF QC**Date: **31st JULY 2026**