Title:

## Quality Control Record Sheet Fast ZnT8 Ab ELISA Kit QC Data

Prepared by: G FLOOD Approved by: J CLARK

**Curve and Controls:** 

Document: Revision:

wi/qcrs/0.38a

Date:

**18 JANUARY 2019** 

+21°C

Page

Incubation temp:

1 of 1

Kit lot number: FZTE	130	Kit expiry date:	18 June 2024
Reagent Lot Numbers:			
Coated Wells:	ZTE130	Expiry date:	01 November 2024
ZnT8-Biotin:	ZTB72a	Expiry date:	18 June 2024
Recon. Buffer for ZnT8-Biotin: _	ZBB62	Expiry date:	26 September 2024
Streptavidin Peroxidase:	GEP557	Expiry date:	24 November 2024
Diluent for SA-POD:	PB174	Expiry date:	12 February 2025
Peroxidase Substrate:	PTS183C	Expiry date:	24 October 2026
Stop Solution:	HESP124	Expiry date:	02 April 2025
Concentrated Wash Solution: _	CW319	Expiry date:	25 November 2024
Calibrators:	ZTEC66	Expiry date:	14 November 2024
Controls: ZTEN66 / FZTEPa/b66		Expiry date:	14 November 2024

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.069	0.019
20	0.135	0.039
75	0.578	0.168
500	2.707	0.788
2000	7.885	2.319
	(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	0.007	0.002	<10	<10	<10
Positive I	0.443	0.129	53.4	53.1	55±24
Positive II	1.067	0.312	183.8	186.6	165±75

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 perfo	ormed by: Sinead Stephenson	Authorised by: S'ARAH NUTE	
Signature:_	5 Stephenson	Signature: SENULE	
Position:	Lab Technician	Position: PO HEAD OF QC	
Date:	02 June 2023	Date: 15 JUNE 2023	