

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

Document: **wi/qcrs/0.38**

Revision: **3**

Date: **04 SEPTEMBER 2018**

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

Kit lot number: KZTE115 Kit expiry date: 09th April 2024

Reagent Lot Numbers:

Coated Wells: ZTE126 Expiry date: 23 July 2024
 ZnT8-Biotin: ZTB74 Expiry date: 09 April 2024
 Recon. Buffer for ZnT8-Biotin: ZBB61 Expiry date: 15 August 2024
 Streptavidin Peroxidase: GEP536A Expiry date: 17 July 2024
 Diluent for SA-POD: PB174 Expiry date: 12 February 2025
 Peroxidase Substrate: PTS181P Expiry date: 21 April 2026
 Stop Solution: HESP123 Expiry date: 12 January 2025
 Concentrated Wash Solution: CW348 Expiry date: 02 August 2025
 Calibrators: ZTEC63 Expiry date: 31 August 2024
 Controls: ZTEN63 / ZTEPa63 / ZTEPb63 Expiry date: 31 August 2024

Curve and Controls:

Incubation temp: +21°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.056	0.012
20	0.135	0.038
75	0.670	0.205
500	2.758	0.863
2000	5.855	1.722
(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	0.000	0.000	<10	<10	<10
Positive I	0.562	0.181	62.3	66.1	64±29
Positive II	1.321	0.415	173.5	169.8	175±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: R Coles

Position: Senior Scientist

Date: 29 March 2023

Authorised by: DR G FLOOD

Signature: [Signature]

Position: HEAD OF QC

Date: 5th APR 2023