

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

Document: **wi/qcrs/0.38**

Revision: **3**

Date: **04 SEPTEMBER 2018**

Page **1 of 1**

Prepared by: **G FLOOD**

Approved by: **S STEPHENSON**

Kit lot number: KZTE115 Kit expiry date: 09<sup>th</sup> April 2024

**Reagent Lot Numbers:**

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

**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: 5<sup>TH</sup> APR 2023