

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

Document: **wi/qcrs/0.38**

Revision: **3**

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

Kit lot number: KZTE142A Kit expiry date: 17 November 2025

Reagent Lot Numbers:

Coated Wells: <u>ZTE165</u>	Expiry date: <u>07 April 2026</u>
ZnT8-Biotin: <u>ZTB87b</u>	Expiry date: <u>17 November 2025</u>
Recon. Buffer for ZnT8-Biotin: <u>ZBB69</u>	Expiry date: <u>11 March 2026</u>
Streptavidin Peroxidase: <u>GEP667</u>	Expiry date: <u>25 March 2026</u>
Diluent for SA-POD: <u>PB182</u>	Expiry date: <u>27 June 2026</u>
Peroxidase Substrate: <u>PTS189F</u>	Expiry date: <u>09 May 2028</u>
Stop Solution: <u>HESP134</u>	Expiry date: <u>19 August 2026</u>
Concentrated Wash Solution: <u>CW402</u>	Expiry date: <u>02 January 2027</u>
Calibrators: <u>ZTEC84A</u>	Expiry date: <u>16 March 2026</u>
Controls: <u>ZTEN84A/ ZTEPa84A/ ZTEPb84A</u>	Expiry date: <u>16 March 2026</u>

Curve and Controls:

Incubation temp: +21°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.049	0.015
20	0.134	0.039
75	0.635	0.184
500	2.846	0.826
2000	7.531	2.215
	(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	0.012	0.004	<10	<10	<10
Positive I	0.518	0.150	58.6	58.5	58±28
Positive II	1.119	0.328	163.9	168.4	177±88

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: Principal Scientist

Date: 23 October 2024

Authorised by: DR G FLOOD

Signature: G Flood

Position: HEAD OF QC

Date: 18TH NOV 2024