

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: KZTE135 Kit expiry date: 02nd June 2025

Reagent Lot Numbers:

Coated Wells: <u>ZTE150</u>	Expiry date: <u>11 September 2025</u>
ZnT8-Biotin: <u>ZTB84</u>	Expiry date: <u>02 June 2025</u>
Recon. Buffer for ZnT8-Biotin: <u>ZBB68</u>	Expiry date: <u>14 October 2025</u>
Streptavidin Peroxidase: <u>GEP629</u>	Expiry date: <u>04 October 2025</u>
Diluent for SA-POD: <u>PB180</u>	Expiry date: <u>18 January 2026</u>
Peroxidase Substrate: <u>PTS187J</u>	Expiry date: <u>30 November 2027</u>
Stop Solution: <u>HESP131</u>	Expiry date: <u>11 March 2026</u>
Concentrated Wash Solution: <u>CW390</u>	Expiry date: <u>14 September 2026</u>
Calibrators: <u>ZTEC76</u>	Expiry date: <u>02 October 2025</u>
Controls: <u>ZTEN76/ ZTEPa76/ ZTEPb76</u>	Expiry date: <u>02 October 2025</u>

Curve and Controls:

Incubation temp: +21°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.060	0.018
20	0.145	0.043
75	0.689	0.200
500	2.829	0.819
2000	6.582	1.936
(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	0.010	0.003	<10	<10	<10
Positive I	0.546	0.159	57.8	57.4	60±27
Positive II	1.382	0.400	189.5	191.5	190±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: PP S. Stephenson

Position: Senior Scientist

Date: 24 April 2024

Authorised by: DR G. Flood

Signature: [Signature]

Position: HEAD OF QC

Date: 31st MAY 2024