

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: KZTE139 Kit expiry date: 25th August 2025

Reagent Lot Numbers:

Coated Wells:	<u>ZTE157</u>	Expiry date:	<u>17 December 2025</u>
ZnT8-Biotin:	<u>ZTB86</u>	Expiry date:	<u>25 August 2025</u>
Recon. Buffer for ZnT8-Biotin:	<u>ZBB68</u>	Expiry date:	<u>14 October 2025</u>
Streptavidin Peroxidase:	<u>GEP650</u>	Expiry date:	<u>08 January 2026</u>
Diluent for SA-POD:	<u>PB181</u>	Expiry date:	<u>09 April 2026</u>
Peroxidase Substrate:	<u>PTS185N</u>	Expiry date:	<u>27 April 2027</u>
Stop Solution:	<u>HESP132</u>	Expiry date:	<u>29 April 2026</u>
Concentrated Wash Solution:	<u>CW378</u>	Expiry date:	<u>14 June 2026</u>
Calibrators:	<u>ZTEC81</u>	Expiry date:	<u>07 January 2026</u>
Controls:	<u>ZTEN81/ ZTEPa81/ ZTEPb81</u>	Expiry date:	<u>07 January 2026</u>

Curve and Controls:

Incubation temp: +21°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.070	0.020
20	0.153	0.043
75	0.666	0.192
500	2.624	0.759
2000	6.528	1.920
(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	0.006	0.001	<10	<10	<10
Positive I	0.538	0.154	57.5	57.2	55±27
Positive II	1.238	0.357	186.6	188.7	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: Sinead Stephenson

Signature: S. Stephenson

Position: Lab Technician

Date: 11 July 2024

Authorised by: DR G Flood

Signature: [Signature]

Position: HEAD OF QC

Date: 23RD AUG 2024