

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: KZTE147A Kit expiry date: 09 March 2026

**Reagent Lot Numbers:**

Coated Wells: <u>ZTE169</u>	Expiry date: <u>11 May 2026</u>
ZnT8-Biotin: <u>ZTB89d</u>	Expiry date: <u>09 March 2026</u>
Recon. Buffer for ZnT8-Biotin: <u>ZBB70</u>	Expiry date: <u>13 July 2026</u>
Streptavidin Peroxidase: <u>GEP672</u>	Expiry date: <u>16 April 2026</u>
Diluent for SA-POD: <u>PB183</u>	Expiry date: <u>16 September 2026</u>
Peroxidase Substrate: <u>PTS189C</u>	Expiry date: <u>09 May 2028</u>
Stop Solution: <u>HESP136</u>	Expiry date: <u>28 October 2026</u>
Concentrated Wash Solution: <u>CW411</u>	Expiry date: <u>22 March 2027</u>
Calibrators: <u>ZTEC89</u>	Expiry date: <u>02 June 2026</u>
Controls: <u>ZTEN89/ ZTEPa89/ ZTEPb89</u>	Expiry date: <u>02 June 2026</u>

**Curve and Controls:**

Incubation temp: +21°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.059	0.018
20	0.128	0.039
75	0.566	0.163
500	2.664	0.772
2000	7.565	2.225
(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	0.009	0.003	<10	<10	<10
Positive I	0.572	0.165	76.0	76.3	68±34
Positive II	1.151	0.333	200.9	204.1	193±96

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: pp Sinead Stephenson

Signature: R Cole

Position: Lab Technician

Date: 07 February 2025

Authorised by: DR G Flood

Signature: S Flood

Position: HEAD OF QC

Date: 10<sup>TH</sup> MAR 2025