

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

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 Revision: **3**
 Date: **04 SEPTEMBER 2018**
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Prepared by: **G FLOOD**
 Approved by: **S STEPHENSON**

Kit lot number: KZTE165A Kit expiry date: 08 February 2027

Reagent Lot Numbers:

Coated Wells: <u> ZTE189 </u>	Expiry date: <u> 15 June 2027 </u>
ZnT8-Biotin: <u> ZTB101a </u>	Expiry date: <u> 08 February 2027 </u>
Recon. Buffer for ZnT8-Biotin: <u> ZBB75 </u>	Expiry date: <u> 15 June 2027 </u>
Streptavidin Peroxidase: <u> GEP768 </u>	Expiry date: <u> 12 July 2027 </u>
Diluent for SA-POD: <u> PB190 </u>	Expiry date: <u> 10 December 2027 </u>
Peroxidase Substrate: <u> PTS193E </u>	Expiry date: <u> 28 January 2029 </u>
Stop Solution: <u> HESP146 </u>	Expiry date: <u> 10 December 2027 </u>
Concentrated Wash Solution: <u> CW483 </u>	Expiry date: <u> 03 June 2028 </u>
Calibrators: <u> ZTEC114 </u>	Expiry date: <u> 05 July 2027 </u>
Controls: <u> ZTEN114/ ZTEPa114/ ZTEPb114 </u>	Expiry date: <u> 05 July 2027 </u>

Curve and Controls:

Incubation temp: +21°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.055	0.017
20	0.137	0.041
75	0.624	0.182
500	2.621	0.758
2000	7.551	2.221
(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	0.014	0.005	<10	<10	<10
Positive I	0.574	0.167	66.5	66.0	62±31
Positive II	1.045	0.303	173.9	177.0	179±89

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: Principal Scientist
 Date: 13 January 2026

Authorised by: DR G FLOOD
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 Position: HEAD OF QC
 Date: 6TH FEB 2026