

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

Kit lot number: KZTE146A Kit expiry date: 12 January 2026

Reagent Lot Numbers:

Coated Wells: <u> ZTE168 </u>	Expiry date: <u> 28 April 2026 </u>
ZnT8-Biotin: <u> ZTB89a </u>	Expiry date: <u> 12 January 2026 </u>
Recon. Buffer for ZnT8-Biotin: <u> ZBB69 </u>	Expiry date: <u> 11 March 2026 </u>
Streptavidin Peroxidase: <u> GEP675A </u>	Expiry date: <u> 11 May 2026 </u>
Diluent for SA-POD: <u> PB183 </u>	Expiry date: <u> 16 September 2026 </u>
Peroxidase Substrate: <u> PTS189F </u>	Expiry date: <u> 09 May 2028 </u>
Stop Solution: <u> HESP136 </u>	Expiry date: <u> 28 October 2026 </u>
Concentrated Wash Solution: <u> CW417 </u>	Expiry date: <u> 23 April 2027 </u>
Calibrators: <u> ZTEC88 </u>	Expiry date: <u> 10 May 2026 </u>
Controls: <u> ZTEN88/ ZTEPa88/ ZTEPb88</u>	Expiry date: <u> 10 May 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	0.122	0.035
75	0.619	0.179
500	2.507	0.725
2000	7.116	2.093
(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	0.013	0.005	<10	<10	<10
Positive I	0.471	0.136	53.0	52.7	58±29
Positive II	1.081	0.313	186.9	189.6	172±86

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: 29 November 2024

Authorised by: DR G Flood
 Signature: G Flood
 Position: HEAD OF QC
 Date: 10th JAN 2025