

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

Kit lot number: **KZTE100B** Kit expiry date: **13th March 2023**

Reagent Lot Numbers:

Coated Wells: <u> ZTE110 </u>	Expiry date: <u> 09 July 2023 </u>
ZnT8-Biotin: <u> ZTB61a </u>	Expiry date: <u> 13 March 2023 </u>
Recon. Buffer for ZnT8-Biotin: <u> ZBB55 </u>	Expiry date: <u> 15 August 2023 </u>
Streptavidin Peroxidase: <u> GEP460 </u>	Expiry date: <u> 09 July 2023 </u>
Diluent for SA-POD: <u> PB168 </u>	Expiry date: <u> 23 August 2023 </u>
Peroxidase Substrate: <u> PTS177J </u>	Expiry date: <u> 03 May 2024 </u>
Stop Solution: <u> HESP114 </u>	Expiry date: <u> 21 September 2023 </u>
Concentrated Wash Solution: <u> CW303 </u>	Expiry date: <u> 03 May 2024 </u>
Calibrators: <u> ZTEC53 </u>	Expiry date: <u> 19 June 2023 </u>
Controls: <u> ZTEN53 / ZTEPa53A / ZTEPb53 </u>	Expiry date: <u> 19 June 2023 </u>

Curve and Controls:

Incubation temp: **+21°C**

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.063	0.018
20	0.141	0.042
75	0.510	0.159
500	2.683	0.843
2000	6.882	2.024
	(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	0.005	0.000	<10	<10	<10
Positive I	0.397	0.126	56.6	58.8	55±25
Positive II	1.023	0.323	168.0	161.5	160±70

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: **24 February 2022**

Authorised by: **DR G FLOOD**
 Signature: **[Signature]**
 Position: **HEAD OF QC**
 Date: **11th MAR 2022**