

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

Kit lot number:           KZTE112                Kit expiry date:           12<sup>th</sup> February 2024          

**Reagent Lot Numbers:**

Coated Wells: <u>          ZTE122          </u>	Expiry date: <u>          21 May 2024          </u>
ZnT8-Biotin: <u>          ZTB71          </u>	Expiry date: <u>          12 February 2024          </u>
Recon. Buffer for ZnT8-Biotin: <u>  ZBB60          </u>	Expiry date: <u>          12 July 2024          </u>
Streptavidin Peroxidase: <u>          GEP536          </u>	Expiry date: <u>          17 July 2024          </u>
Diluent for SA-POD: <u>          PB173          </u>	Expiry date: <u>          09 November 2024          </u>
Peroxidase Substrate: <u>          PTS181G          </u>	Expiry date: <u>          21 April 2026          </u>
Stop Solution: <u>          HESP121          </u>	Expiry date: <u>          11 October 2024          </u>
Concentrated Wash Solution: <u>  CW334          </u>	Expiry date: <u>          11 April 2025          </u>
Calibrators: <u>          ZTEC62          </u>	Expiry date: <u>          11 July 2024          </u>
Controls: <u>  ZTEN62 / ZTEPa62 / ZTEPb62          </u>	Expiry date: <u>          11 July 2024          </u>

**Curve and Controls:**      Incubation temp:           +22°C          

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.058	0.011
20	0.155	0.041
75	0.708	0.214
500	2.951	0.919
2000	5.797	1.705
	(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	0.000	0.000	<10	<10	<10
Positive I	0.628	0.192	66.3	67.8	65±29
Positive II	1.397	0.432	165.2	160.8	175±80

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:           R Coles            
Position:           Senior Scientist            
Date:           02 February 2023          

Authorised by:           DR G FLOOD            
Signature:           S Flood            
Position:           HEAD OF QC            
Date:           7<sup>th</sup> FEB 2023