

Prepared by: G FLOOD  
Approved by: S STEPHENSON

Kit lot number:           KZTE90B                Kit expiry date:           14<sup>th</sup> March 2022          

**Reagent Lot Numbers:**

Coated Wells: <u>          ZTE100          </u>	Expiry date: <u>          07 June 2022          </u>
ZnT8-Biotin: <u>          ZTB51b          </u>	Expiry date: <u>          14 March 2022          </u>
Recon. Buffer for ZnT8-Biotin: <u>          ZBB49          </u>	Expiry date: <u>          15 August 2022          </u>
Streptavidin Peroxidase: <u>          GEP405          </u>	Expiry date: <u>          14 June 2022          </u>
Diluent for SA-POD: <u>          PB162          </u>	Expiry date: <u>          07 December 2022          </u>
Peroxidase Substrate: <u>          PTS173L          </u>	Expiry date: <u>          19 November 2022          </u>
Stop Solution: <u>          HESP108          </u>	Expiry date: <u>          08 November 2022          </u>
Concentrated Wash Solution: <u>          CW263          </u>	Expiry date: <u>          18 May 2023          </u>
Calibrators: <u>          ZTEC48          </u>	Expiry date: <u>          21 August 2022          </u>
Controls: <u>          ZTEN48 / ZTEPa48 / ZTEPb48          </u>	Expiry date: <u>          21 August 2022          </u>

**Curve and Controls:**

Incubation temp:           +20°C          

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.056	0.017
20	0.134	0.041
75	0.756	0.236
500	2.893	0.907
2000	7.891	2.321
	(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	0.010	0.002	<10	<10	<10
Positive I	0.555	0.174	51.7	52.8	54±21
Positive II	1.339	0.419	192.1	181.2	185±75

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:           Becky Coles            
Signature:           R Coles            
Position:           Senior Scientist            
Date:           24 February 2021          

Authorised by:           DR G Flood            
Signature:           G Flood            
Position:           HEAD OF QC            
Date:           9<sup>th</sup> MAR 2021