

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

Kit lot number:                     KZTE89                          Kit expiry date:                     17<sup>th</sup> January 2022                    

**Reagent Lot Numbers:**

Coated Wells:	<u>                    ZTE99                    </u>	Expiry date:	<u>                    09 May 2022                    </u>
ZnT8-Biotin:	<u>                    ZTB52                    </u>	Expiry date:	<u>                    17 January 2022                    </u>
Recon. Buffer for ZnT8-Biotin:	<u>                    ZBB48                    </u>	Expiry date:	<u>                    23 May 2022                    </u>
Streptavidin Peroxidase:	<u>                    GEP405                    </u>	Expiry date:	<u>                    14 June 2022                    </u>
Diluent for SA-POD:	<u>                    PB161                    </u>	Expiry date:	<u>                    18 October 2022                    </u>
Peroxidase Substrate:	<u>                    PTS173G                    </u>	Expiry date:	<u>                    19 November 2022                    </u>
Stop Solution:	<u>                    HESP107                    </u>	Expiry date:	<u>                    15 September 2022                    </u>
Concentrated Wash Solution:	<u>                    CW260                    </u>	Expiry date:	<u>                    21 March 2023                    </u>
Calibrators:	<u>                    ZTEC47                    </u>	Expiry date:	<u>                    13 June 2022                    </u>
Controls:	<u>                    ZTEN47 / ZTEPa47 / ZTEPb47                    </u>	Expiry date:	<u>                    13 June 2022                    </u>

**Curve and Controls:**      Incubation temp:                     +20°C                    

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.064	0.020
20	0.177	0.055
75	0.797	0.250
500	2.834	0.890
2000	7.324	2.154
	(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	0.006	0.001	<10	<10	<10
Positive I	0.690	0.217	61.3	62.1	56±22
Positive II	1.439	0.452	203.7	193.0	195±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:                     Sinead Stephenson                      
Signature:                     pp. R. Coles                      
Position:                     Lab Technician                      
Date:                     14 January 2021                    

Authorised by:                     DR G Flood                      
Signature:                     G Flood                      
Position:                     HEAD OF QC                      
Date:                     19<sup>TH</sup> JAN 2021