

Prepared by: G FLOOD  
Approved by: S STEPHENSON

Kit lot number: KZTE94 Kit expiry date: 1st August 2022

**Reagent Lot Numbers:**

Coated Wells: <u>ZTE104</u>	Expiry date: <u>05 January 2023</u>
ZnT8-Biotin: <u>ZTB56</u>	Expiry date: <u>01 August 2022</u>
Recon. Buffer for ZnT8-Biotin: <u>ZBB50</u>	Expiry date: <u>17 November 2022</u>
Streptavidin Peroxidase: <u>GEP432</u>	Expiry date: <u>21 December 2022</u>
Diluent for SA-POD: <u>PB166</u>	Expiry date: <u>01 June 2023</u>
Peroxidase Substrate: <u>PTS175N</u>	Expiry date: <u>13 April 2023</u>
Stop Solution: <u>HESP112</u>	Expiry date: <u>22 June 2023</u>
Concentrated Wash Solution: <u>CW274</u>	Expiry date: <u>08 September 2023</u>
Calibrators: <u>ZTEC49</u>	Expiry date: <u>14 December 2022</u>
Controls: <u>ZTEN49 / ZTEPa49 / ZTEPb49</u>	Expiry date: <u>14 December 2022</u>

**Curve and Controls:**

Incubation temp: +20°C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
10	0.059	0.018
20	0.138	0.044
75	0.654	0.209
500	2.643	0.845
2000	7.133	2.098
(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	0.017	0.003	<10	<10	<10
Positive I	0.548	0.176	59.4	60.6	55±22
Positive II	1.205	0.388	192.6	181.4	180±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: pp Bradbury  
Position: Senior Scientist  
Date: 14 July 2021

Authorised by: DR G Flood  
Signature: J. Anand  
Position: HEAD OF QC  
Date: 27<sup>th</sup> JUL 2021