

Prepared by: **G Flood**
 Approved by: **F Ryrie**

Kit lot number: KZGIE83 Kit expiry date: 24th November 2025

Reagent Lot Numbers:

3 Screen Coated Wells: <u> ZGIE47 </u>	Expiry date: <u> 01 Mar 2026 </u>
3 Screen-Biotin: <u> ZGIB29e </u>	Expiry date: <u> 24 Nov 2025 </u>
Recon. Buffer for 3 Screen-Biotin: <u> 3BB30 </u>	Expiry date: <u> 28 Jan 2026 </u>
Streptavidin Peroxidase: <u> GEP658 </u>	Expiry date: <u> 13 Feb 2026 </u>
Diluent for SA-POD: <u> PB182 </u>	Expiry date: <u> 27 Jun 2026 </u>
Peroxidase Substrate: <u> PTS187T </u>	Expiry date: <u> 30 Nov 2027 </u>
Stop Solution: <u> HESP133 </u>	Expiry date: <u> 19 Jun 2026 </u>
Concentrated Wash Solution: <u> CW404 </u>	Expiry date: <u> 16 Jan 2027 </u>
Reference Preparation: <u> ZGIR46 </u>	Expiry date: <u> 28 Jan 2026 </u>
Calibrators: <u> ZGIC46 </u>	Expiry date: <u> 28 Jan 2026 </u>
Negative Control: <u> ZGIN46 </u>	Expiry date: <u> 28 Jan 2026 </u>
GAD Ab Positive Control: <u> 3SGP46 </u>	Expiry date: <u> 28 Jan 2026 </u>
IA-2 Ab Positive Control: <u> 3SIP46 </u>	Expiry date: <u> 28 Jan 2026 </u>
ZnT8 Ab Positive Control: <u> 3SZP46 </u>	Expiry date: <u> 28 Jan 2026 </u>

Curve and Controls: Incubation temp: 22 °C

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.070	0.020
Calibrator 15 units per mL	0.130	0.036
Calibrator 100 units per mL	0.519	0.150
Calibrator 400 units per mL	2.173	0.629
Calibrator 2000 units per mL	>4	2.149
Reference Preparation	0.532	0.154
Negative Control	0.031	0.009
GAD Ab Positive Control	1.224	0.355
IA-2 Ab Positive Control	0.492	0.143
ZnT8 Ab Positive Control	0.291	0.084

Control	Concentration at 450 nm (units per mL)	Concentration at 405 nm (units per mL)	Range (units per mL)	Index Value at 450 nm	Index Value at 405 nm	Range (Index value)
Negative	<5	<5	<5	<30	<30	<30
GAD Ab Positive	229.6	231.3	215±85	230.1	230.5	220±80
IA-2 Ab Positive	94.8	95.5	90±35	92.5	92.9	90±35
ZnT8 Ab Positive	55.6	55.3	53±21	54.7	54.5	54±21

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: Fiona Ryrie
 Signature: *Fiona Ryrie*
 Position: Scientist
 Date: 17/18 October 2024

Authorised by: DR G Flood
 Signature: *G Flood*
 Position: HEAD OF QC
 Date: 22nd Nov 2024