

Prepared by: G Flood
 Approved by: L Carr

Kit lot number: KGE406B Kit expiry date: 13 December 2021

Kit manufacture date: 14 December 2020

GAD ₆₅ Coated Wells:	Lot No. <u>GE440</u>	Expiry Date <u>14 March 2022</u>
GAD ₆₅ -Biotin :	Lot No. <u>GEB372</u>	Expiry Date <u>13 March 2022</u>
Recon. Buffer for GAD ₆₅ -Biotin:	Lot No. <u>GBB155</u>	Expiry Date <u>19 February 2022</u>
Streptavidin Peroxidase:	Lot No. <u>GEP391</u>	Expiry Date <u>28 March 2022</u>
Diluent for SA-POD:	Lot No. <u>PB160</u>	Expiry Date <u>19 August 2022</u>
Peroxidase Substrate:	Lot No. <u>PTS173D</u>	Expiry Date <u>19 November 2022</u>
Stop Solution:	Lot No. <u>HESP107</u>	Expiry Date <u>15 September 2022</u>
Concentrated Wash Solution:	Lot No. <u>CW259</u>	Expiry Date <u>07 March 2023</u>
Calibrators:	Lot No. <u>GEC409b</u>	Expiry Date <u>13 December 2021</u>
Controls:	Lot No. <u>GENC409b/GEPC409b</u>	Expiry Date <u>13 December 2021</u>

Calibrator Curve and Controls:

Incubation temp: +22 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.022	0.007
5	0.223	0.067
18	0.631	0.187
35	1.233	0.368
120	2.897	0.859
250	>4	1.295
2000	>4	1.921

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)
Positive	1.592	0.470	47.2	48.1	51 ± 10

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:

Xing

Signature:

Zhang Xing feng

Position:

Laboratory Technician

Date:

21 October 2020

Authorised by:

DR G FLOOD

Signature:

G Flood

Position:

HEAD OF QC

Date:

15TH DEC 2020