

Title: **Quality Control Record Sheet**
GAD Ab ELISA Kit QC Data

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Prepared by: **G Flood**
Approved by: **L Carr**

Kit lot number: KGE424A Kit expiry date: 27 June 2022

Kit manufacture date: 28 June 2021

GAD ₆₅ Coated Wells:	Lot No. <u>GE459</u>	Expiry Date <u>19 October 2022</u>
GAD ₆₅ -Biotin :	Lot No. <u>GEB394</u>	Expiry Date <u>18 October 2022</u>
Recon. Buffer for GAD ₆₅ -Biotin:	Lot No. <u>GBB161</u>	Expiry Date <u>08 October 2022</u>
Streptavidin Peroxidase:	Lot No. <u>GEP420</u>	Expiry Date <u>13 October 2022</u>
Diluent for SA-POD:	Lot No. <u>PB164</u>	Expiry Date <u>01 March 2023</u>
Peroxidase Substrate:	Lot No. <u>PTS175E</u>	Expiry Date <u>13 April 2023</u>
Stop Solution:	Lot No. <u>HESP110</u>	Expiry Date <u>01 March 2023</u>
Concentrated Wash Solution:	Lot No. <u>CW277</u>	Expiry Date <u>08 October 2023</u>
Calibrators:	Lot No. <u>GEC425a</u>	Expiry Date <u>27 June 2022</u>
Controls:	Lot No. <u>GENC425a/GEPC425a</u>	Expiry Date <u>27 June 2022</u>

Calibrator Curve and Controls:

Incubation temp: +22 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.012	0.003
5	0.196	0.058
18	0.602	0.180
35	1.003	0.301
120	2.558	0.771
250	3.665	1.169
2000	>4	2.060

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	1.396	0.423	51.6	53.2	49 ± 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:

11 May 2021

Authorised by:

DR G Flood

Signature:

G Flood

Position:

HEAD OF QC

Date:

14TH JUN 2021