

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

Document: **wi/qcrs/0.27**

Revision: **11**

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Prepared by: **G Flood**

Approved by: **L Carr**

Kit lot number: KGE472C Kit expiry date: 05 February 2024

Kit manufacture date: 06 February 2023

GAD ₆₅ Coated Wells:	Lot No. <u>GE504</u>	Expiry Date <u>26 March 2024</u>
GAD ₆₅ -Biotin :	Lot No. <u>GEB440</u>	Expiry Date <u>20 March 2024</u>
Recon. Buffer for GAD ₆₅ -Biotin:	Lot No. <u>GBB175</u>	Expiry Date <u>21 March 2024</u>
Streptavidin Peroxidase:	Lot No. <u>GEP520</u>	Expiry Date <u>19 April 2024</u>
Diluent for SA-POD:	Lot No. <u>PB172</u>	Expiry Date <u>23 August 2024</u>
Peroxidase Substrate:	Lot No. <u>PTS181E</u>	Expiry Date <u>21 April 2026</u>
Stop Solution:	Lot No. <u>HESP120</u>	Expiry Date <u>23 August 2024</u>
Concentrated Wash Solution:	Lot No. <u>CW333</u>	Expiry Date <u>22 February 2025</u>
Calibrators:	Lot No. <u>GEC469c</u>	Expiry Date <u>05 February 2024</u>
Controls:	Lot No. <u>GENC469c/GEPC469c</u>	Expiry Date <u>15 February 2024</u>

Calibrator Curve and Controls:

Incubation temp: +21 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.015	0.004
5	0.202	0.062
18	0.569	0.172
35	0.947	0.288
120	2.728	0.815
250	3.794	1.264
2000	>4	2.480

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	1.290	0.383	47.5	47.8	53 ± 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:

04 November 2022

Authorised by:

DR G Flood

Signature:

G Flood

Position:

HEAD OF QC

Date:

24th JAN 2023