

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

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Approved by: **L Carr**

Kit lot number: KGE501B Kit expiry date: 04 February 2025

Kit manufacture date: 05 February 2024

GAD ₆₅ Coated Wells:	Lot No. <u>GE534</u>	Expiry Date <u>06 May 2025</u>
GAD ₆₅ -Biotin :	Lot No. <u>GEB468</u>	Expiry Date <u>05 May 2025</u>
Recon. Buffer for GAD ₆₅ -Biotin:	Lot No. <u>GBB185</u>	Expiry Date <u>21 May 2025</u>
Streptavidin Peroxidase:	Lot No. <u>GEP598</u>	Expiry Date <u>12 May 2025</u>
Diluent for SA-POD:	Lot No. <u>PB179</u>	Expiry Date <u>13 November 2025</u>
Peroxidase Substrate:	Lot No. <u>PTS185L</u>	Expiry Date <u>27 April 2027</u>
Stop Solution:	Lot No. <u>HESP128</u>	Expiry Date <u>02 November 2025</u>
Concentrated Wash Solution:	Lot No. <u>CW374</u>	Expiry Date <u>29 April 2026</u>
Calibrators:	Lot No. <u>GEC498b</u>	Expiry Date <u>04 February 2025</u>
Controls:	Lot No. <u>GENC498b/GEPC498b</u>	Expiry Date <u>04 February 2025</u>

Calibrator Curve and Controls:

Incubation temp: +22 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.026	0.008
5	0.161	0.047
18	0.499	0.148
35	0.890	0.263
120	2.690	0.787
250	3.844	1.187
2000	>4	2.030

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	1.236	0.363	47.9	48.3	51 ± 15

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:

Signature:

Position:

Date:

Xing

Zhang Xing feng

Laboratory Technician

14 December 2023

Authorised by:

Signature:

Position:

Date:

SARAH NUTE

SRNUTE

AP HEAD OF QC

23 JAN 2024