

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

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Approved by: **L Carr**

Kit lot number: KGE531 Kit expiry date: 02 February 2026

Kit manufacture date: 03 February 2025

GAD <sub>65</sub> Coated Wells:	Lot No. <u>GE564</u>	Expiry Date <u>18 May 2026</u>
GAD <sub>65</sub> –Biotin :	Lot No. <u>GEB499</u>	Expiry Date <u>12 May 2026</u>
Recon. Buffer for GAD <sub>65</sub> -Biotin:	Lot No. <u>GBB195</u>	Expiry Date <u>21 May 2026</u>
Streptavidin Peroxidase:	Lot No. <u>GEP677</u>	Expiry Date <u>20 May 2026</u>
Diluent for SA-POD:	Lot No. <u>PB183</u>	Expiry Date <u>16 September 2026</u>
Peroxidase Substrate:	Lot No. <u>PTS189H</u>	Expiry Date <u>09 May 2028</u>
Stop Solution:	Lot No. <u>HESP136</u>	Expiry Date <u>28 October 2026</u>
Concentrated Wash Solution:	Lot No. <u>CW416</u>	Expiry Date <u>20 April 2027</u>
Calibrators:	Lot No. <u>GEC528</u>	Expiry Date <u>02 February 2026</u>
Controls:	Lot No. <u>GENC528/GEPC528</u>	Expiry Date <u>02 February 2026</u>

**Calibrator Curve and Controls:**

Incubation temp: +21 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.013	0.005
5	0.160	0.048
18	0.470	0.140
35	0.897	0.266
120	2.627	0.766
250	3.972	1.221
2000	>4	1.933

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	1.271	0.373	50.0	50.4	50 ± 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:

Xing

Signature:

Zhang Xingfeng

Position:

Laboratory Technician

Date:

10 December 2024

Authorised by:

DR G Flood

Signature:

G Flood

Position:

HEAD OF QC

Date:

27<sup>TH</sup> JAN 2025