

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: KGE521B Kit expiry date: 13 October 2025

Kit manufacture date: 14 October 2024

GAD ₆₅ Coated Wells:	Lot No. <u>GE554</u>	Expiry Date <u>08 January 2026</u>
GAD ₆₅ -Biotin :	Lot No. <u>GEB489</u>	Expiry Date <u>07 January 2026</u>
Recon. Buffer for GAD ₆₅ -Biotin:	Lot No. <u>GBB191</u>	Expiry Date <u>13 December 2025</u>
Streptavidin Peroxidase:	Lot No. <u>GEP646</u>	Expiry Date <u>02 January 2026</u>
Diluent for SA-POD:	Lot No. <u>PB182</u>	Expiry Date <u>27 June 2026</u>
Peroxidase Substrate:	Lot No. <u>PTS187R</u>	Expiry Date <u>30 November 2027</u>
Stop Solution:	Lot No. <u>HESP133</u>	Expiry Date <u>19 June 2026</u>
Concentrated Wash Solution:	Lot No. <u>CW402</u>	Expiry Date <u>02 January 2027</u>
Calibrators:	Lot No. <u>GEC518a</u>	Expiry Date <u>13 October 2025</u>
Controls:	Lot No. <u>GENC518a/GEPC518a</u>	Expiry Date <u>13 October 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	0.017	0.003
5	0.175	0.048
18	0.549	0.159
35	0.948	0.277
120	2.799	0.816
250	3.890	1.193
2000	>4	2.056

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	1.324	0.386	48.4	48.7	49 ± 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 Xing Feng

Position:

Laboratory Technician

Date:

05 August 2024

Authorised by:

DR G Flood

Signature:

G Flood

Position:

HEAD OF QC

Date:

30th SEP 2024