

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: KGE535A Kit expiry date: 30 March 2026

Kit manufacture date: 31 March 2025

GAD <sub>65</sub> Coated Wells:	Lot No. <u>GE568</u>	Expiry Date <u>20 July 2026</u>
GAD <sub>65</sub> -Biotin :	Lot No. <u>GEB503</u>	Expiry Date <u>19 July 2026</u>
Recon. Buffer for GAD <sub>65</sub> -Biotin:	Lot No. <u>GBB196</u>	Expiry Date <u>02 July 2026</u>
Streptavidin Peroxidase:	Lot No. <u>GEP688</u>	Expiry Date <u>23 July 2026</u>
Diluent for SA-POD:	Lot No. <u>PB184</u>	Expiry Date <u>26 November 2026</u>
Peroxidase Substrate:	Lot No. <u>PTS191A</u>	Expiry Date <u>11 November 2028</u>
Stop Solution:	Lot No. <u>HESP137</u>	Expiry Date <u>27 November 2026</u>
Concentrated Wash Solution:	Lot No. <u>CW422</u>	Expiry Date <u>08 June 2027</u>
Calibrators:	Lot No. <u>GEC532a</u>	Expiry Date <u>30 March 2026</u>
Controls:	Lot No. <u>GENC532a/GEPC532a</u>	Expiry Date <u>30 March 2026</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	0.007
5	0.166	0.049
18	0.552	0.163
35	0.952	0.282
120	2.607	0.760
250	>4	1.270
2000	>4	1.972

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	1.335	0.391	52.0	53.0	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:

p.p Xing

Signature:

L Carr

Position:

Laboratory Technician

Date:

06 February 2025

Authorised by:

DR G Flood

Signature:

G Flood

Position:

HEAD OF QC

Date:

11<sup>TH</sup> MAR 2025