

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: KGE512B Kit expiry date: 23 June 2025

Kit manufacture date: 24 June 2024

GAD <sub>65</sub> Coated Wells:	Lot No. <u>GE545</u>	Expiry Date <u>24 September 2025</u>
GAD <sub>65</sub> –Biotin :	Lot No. <u>GEB479</u>	Expiry Date <u>24 September 2025</u>
Recon. Buffer for GAD <sub>65</sub> -Biotin:	Lot No. <u>GBB188</u>	Expiry Date <u>06 September 2025</u>
Streptavidin Peroxidase:	Lot No. <u>GEP628</u>	Expiry Date <u>03 October 2025</u>
Diluent for SA-POD:	Lot No. <u>PB180</u>	Expiry Date <u>18 January 2026</u>
Peroxidase Substrate:	Lot No. <u>PTS187G</u>	Expiry Date <u>30 November 2027</u>
Stop Solution:	Lot No. <u>HESP131</u>	Expiry Date <u>11 March 2026</u>
Concentrated Wash Solution:	Lot No. <u>CW389</u>	Expiry Date <u>13 August 2026</u>
Calibrators:	Lot No. <u>GEC509b</u>	Expiry Date <u>23 June 2025</u>
Controls:	Lot No. <u>GENC509b/GEPC509b</u>	Expiry Date <u>23 June 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	0.029	0.009
5	0.186	0.055
18	0.573	0.170
35	0.969	0.288
120	2.728	0.799
250	3.909	1.236
2000	>4	2.005

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	0.380	47.3	47.9	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 Ling Feng

Position:

Laboratory Technician

Date:

19 April 2024

Authorised by:

DR G Flood

Signature:

[Signature]

Position:

HEAD OF QC

Date:

6<sup>TH</sup> JUN 2024