

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

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Revision: **11**  
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Page **1 of 1**

Prepared by: **G Flood**  
Approved by: **L Carr**

Kit lot number:                   KGE497                        Kit expiry date:           12 November 2024          

Kit manufacture date:           13 November 2023          

GAD <sub>65</sub> Coated Wells:	Lot No. <u>  GE530                  </u>	Expiry Date <u>  18 March 2025          </u>
GAD <sub>65</sub> -Biotin :	Lot No. <u>  GEB465                  </u>	Expiry Date <u>  01 April 2025          </u>
Recon. Buffer for GAD <sub>65</sub> -Biotin:	Lot No. <u>  GBB183                  </u>	Expiry Date <u>  24 February 2025          </u>
Streptavidin Peroxidase:	Lot No. <u>  GEP588                  </u>	Expiry Date <u>  24 March 2025          </u>
Diluent for SA-POD:	Lot No. <u>  PB177                  </u>	Expiry Date <u>  10 August 2025          </u>
Peroxidase Substrate:	Lot No. <u>  PTS185D                  </u>	Expiry Date <u>  27 April 2027          </u>
Stop Solution:	Lot No. <u>  HESP127                  </u>	Expiry Date <u>  20 September 2025          </u>
Concentrated Wash Solution:	Lot No. <u>  CW367                  </u>	Expiry Date <u>  28 February 2026          </u>
Calibrators:	Lot No. <u>  GEC494                  </u>	Expiry Date <u>  12 November 2024          </u>
Controls:	Lot No. <u>  GENC494/GEPC494          </u>	Expiry Date <u>  12 November 2024          </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	0.004
5	0.185	0.054
18	0.604	0.179
35	1.048	0.311
120	2.935	0.862
250	>4	1.455
2000	>4	2.320

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	1.431	0.421	48.4	50.9	47 ± 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:

                  31 October 2023                  

Authorised by:

                  DR G Flood                  

Signature:

                  G Flood                  

Position:

                  HEAD OF QC                  

Date:

                  2<sup>ND</sup> NOV 2023