

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

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Revision: **11**  
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Prepared by: **G Flood**  
Approved by: **L Carr**

Kit lot number:                     KGE528B                          Kit expiry date:           05 January 2026          

Kit manufacture date:           06 January 2025          

GAD <sub>65</sub> Coated Wells:	Lot No. <u>  GE561                    </u>	Expiry Date <u>  13 April 2026          </u>
GAD <sub>65</sub> -Biotin :	Lot No. <u>  GEB496                    </u>	Expiry Date <u>  13 April 2026          </u>
Recon. Buffer for GAD <sub>65</sub> -Biotin:	Lot No. <u>  GBB194                    </u>	Expiry Date <u>  13 April 2026          </u>
Streptavidin Peroxidase:	Lot No. <u>  GEP670                    </u>	Expiry Date <u>  14 April 2026          </u>
Diluent for SA-POD:	Lot No. <u>  PB183                    </u>	Expiry Date <u>  16 September 2026          </u>
Peroxidase Substrate:	Lot No. <u>  PTS189G                    </u>	Expiry Date <u>  09 May 2028                    </u>
Stop Solution:	Lot No. <u>  HESP135                    </u>	Expiry Date <u>  23 September 2026          </u>
Concentrated Wash Solution:	Lot No. <u>  CW412                    </u>	Expiry Date <u>  01 April 2027                    </u>
Calibrators:	Lot No. <u>  GEC525b                    </u>	Expiry Date <u>  05 January 2026          </u>
Controls:	Lot No. <u>  GENC525b/GEPC525b          </u>	Expiry Date <u>  05 January 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	0.022	0.008
5	0.174	0.052
18	0.517	0.153
35	0.908	0.270
120	2.646	0.772
250	3.850	1.180
2000	>4	1.991

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	1.238	0.365	47.6	48.2	48 ± 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 Qingfeng                    

Position:

                    Laboratory Technician                    

Date:

                    31 October 2024                    

Authorised by:

                    DR G FLOOD                    

Signature:

                    G Flood                      
                    HEAD OF QC                    

Position:

Date:

                    17<sup>th</sup> DEC 2024