

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:                     KGE428                          Kit expiry date:                     25 July 2022                    

Kit manufacture date:                     26 July 2021                    

GAD <sub>65</sub> Coated Wells:	Lot No. <u>                    GE464                    </u>	Expiry Date <u>                    24 November 2022                    </u>
GAD <sub>65</sub> -Biotin :	Lot No. <u>                    GEB398                    </u>	Expiry Date <u>                    30 November 2022                    </u>
Recon. Buffer for GAD <sub>65</sub> -Biotin:	Lot No. <u>                    GBB162                    </u>	Expiry Date <u>                    05 November 2022                    </u>
Streptavidin Peroxidase:	Lot No. <u>                    GEP429                    </u>	Expiry Date <u>                    24 November 2022                    </u>
Diluent for SA-POD:	Lot No. <u>                    PB165                    </u>	Expiry Date <u>                    03 May 2023                    </u>
Peroxidase Substrate:	Lot No. <u>                    PTS175H                    </u>	Expiry Date <u>                    13 April 2023                    </u>
Stop Solution:	Lot No. <u>                    HESP111                    </u>	Expiry Date <u>                    04 May 2023                    </u>
Concentrated Wash Solution:	Lot No. <u>                    CW283                    </u>	Expiry Date <u>                    01 December 2023                    </u>
Calibrators:	Lot No. <u>                    GEC429                    </u>	Expiry Date <u>                    25 July 2022                    </u>
Controls:	Lot No. <u>                    GENC429/GEPC429                    </u>	Expiry Date <u>                    25 July 2022                    </u>

**Calibrator Curve and Controls:**

Incubation temp:                     +23                     °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.017	0.005
5	0.209	0.062
18	0.567	0.169
35	1.109	0.332
120	2.680	0.798
250	3.767	1.197
2000	>4	1.993

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	1.489	0.442	49.3	50.0	52 ± 10

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:

                    16 June 2021                    

Authorised by:

                    DR G Flood                    

Signature:

                    G Flood                    

Position:

                    HEAD OF QC                    

Date:

                    7<sup>th</sup> JUL 2021