

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: KGE478A Kit expiry date: 02 April 2024

Kit manufacture date: 03 April 2023

GAD ₆₅ Coated Wells:	Lot No. <u> GE510 </u>	Expiry Date <u> 12 June 2024 </u>
GAD ₆₅ -Biotin :	Lot No. <u> GEB446 </u>	Expiry Date <u> 11 June 2024 </u>
Recon. Buffer for GAD ₆₅ -Biotin:	Lot No. <u> GBB177 </u>	Expiry Date <u> 15 May 2024 </u>
Streptavidin Peroxidase:	Lot No. <u> GEP530 </u>	Expiry Date <u> 04 June 2024 </u>
Diluent for SA-POD:	Lot No. <u> PB173 </u>	Expiry Date <u> 09 November 2024 </u>
Peroxidase Substrate:	Lot No. <u> PTS181L </u>	Expiry Date <u> 21 April 2026 </u>
Stop Solution:	Lot No. <u> HESP122 </u>	Expiry Date <u> 14 December 2024 </u>
Concentrated Wash Solution:	Lot No. <u> CW341 </u>	Expiry Date <u> 12 June 2025 </u>
Calibrators:	Lot No. <u> GEC475a </u>	Expiry Date <u> 02 April 2024 </u>
Controls:	Lot No. <u> GENC475a/GEPC475a </u>	Expiry Date <u> 02 April 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	0.011	0.003
5	0.167	0.049
18	0.540	0.159
35	0.987	0.291
120	2.712	0.793
250	3.951	1.258
2000	>4	2.245

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	1.373	0.403	50.0	50.9	51 ± 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:

Signature:

Position:

Date:

 Xing
 Zhang Ding Feng
 Laboratory Technician
 18 January 2023

Authorised by:

Signature:

Position:

Date:

 DR G Flood
 G Flood
 HEAD OF QC
 14TH MAR 2023