

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: **KGE486B** Kit expiry date: **20 August 2024**

Kit manufacture date: **21 August 2023**

GAD ₆₅ Coated Wells:	Lot No. <u> GE520 </u>	Expiry Date <u> 22 November 2024 </u>
GAD ₆₅ -Biotin :	Lot No. <u> GEB454 </u>	Expiry Date <u> 21 November 2024 </u>
Recon. Buffer for GAD ₆₅ -Biotin:	Lot No. <u> GBB180 </u>	Expiry Date <u> 18 October 2024 </u>
Streptavidin Peroxidase:	Lot No. <u> GEP562 </u>	Expiry Date <u> 24 November 2024 </u>
Diluent for SA-POD:	Lot No. <u> PB174 </u>	Expiry Date <u> 12 February 2025 </u>
Peroxidase Substrate:	Lot No. <u> PTS183F </u>	Expiry Date <u> 24 October 2026 </u>
Stop Solution:	Lot No. <u> HESP124 </u>	Expiry Date <u> 02 April 2025 </u>
Concentrated Wash Solution:	Lot No. <u> CW352 </u>	Expiry Date <u> 05 October 2025 </u>
Calibrators:	Lot No. <u> GEC483b </u>	Expiry Date <u> 20 August 2024 </u>
Controls:	Lot No. <u> GENC483b/GEPC483b </u>	Expiry Date <u> 20 August 2024 </u>

Calibrator Curve and Controls:

Incubation temp: **+22** °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.012	0.003
5	0.178	0.051
18	0.596	0.173
35	1.044	0.306
120	2.856	0.832
250	>4	1.430
2000	>4	2.317

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	1.420	0.416	49.2	51.9	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 Lingfeng

Position:

 Laboratory Technician

Date:

 09 June 2023

Authorised by:

 DR G Flood

Signature:

 [Signature]

Position:

 HEAD OF QC

Date:

 8TH AUG 2023