

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

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Page **1 of 1**

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

Kit lot number: KGE401B Kit expiry date: 18 October 2021

Kit manufacture date: 19 October 2020

GAD ₆₅ Coated Wells:	Lot No. <u>GE432 </u>	Expiry Date <u>15 December 2021 </u>
GAD ₆₅ -Biotin :	Lot No. <u>GEB367 </u>	Expiry Date <u>14 December 2021 </u>
Recon. Buffer for GAD ₆₅ -Biotin:	Lot No. <u>GBB154 </u>	Expiry Date <u>25 December 2021 </u>
Streptavidin Peroxidase:	Lot No. <u>GEP376 </u>	Expiry Date <u>22 December 2021 </u>
Diluent for SA-POD:	Lot No. <u>PB159 </u>	Expiry Date <u>30 June 2022 </u>
Peroxidase Substrate:	Lot No. <u>PTS171B </u>	Expiry Date <u>27 February 2022 </u>
Stop Solution:	Lot No. <u>HESP106 </u>	Expiry Date <u>02 June 2022 </u>
Concentrated Wash Solution:	Lot No. <u>CW254 </u>	Expiry Date <u>25 December 2022 </u>
Calibrators:	Lot No. <u>GEC404b </u>	Expiry Date <u>18 October 2021 </u>
Controls:	Lot No. <u>GENC404b/GEPC404b </u>	Expiry Date <u>18 October 2021 </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	0.200	0.059
18	0.581	0.172
35	1.152	0.341
120	2.840	0.841
250	>4	1.223
2000	>4	2.057

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	1.571	0.464	49.5	50.3	49 ± 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 Qingfeng

Position:

 Laboratory Technician

Date:

 05 August 2020

Authorised by:

 DR G Flood

Signature:

 G Flood

Position:

 HEAD OF QC

Date:

 1st OCT 2020