

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

Document: **wi/qcrs/0.27**

Revision: **11**

Date: **10/10/14**

Page **1 of 1**

Prepared by: **G Flood**

Approved by: **L Carr**

Kit lot number: KGE435A Kit expiry date: 17 October 2022

Kit manufacture date: 18 October 2021

GAD <sub>65</sub> Coated Wells:	Lot No. <u>GE471</u>	Expiry Date <u>01 February 2023</u>
GAD <sub>65</sub> -Biotin :	Lot No. <u>GEB405</u>	Expiry Date <u>08 February 2023</u>
Recon. Buffer for GAD <sub>65</sub> -Biotin:	Lot No. <u>GBB164</u>	Expiry Date <u>14 January 2023</u>
Streptavidin Peroxidase:	Lot No. <u>GEP438</u>	Expiry Date <u>28 January 2023</u>
Diluent for SA-POD:	Lot No. <u>PB167</u>	Expiry Date <u>28 June 2023</u>
Peroxidase Substrate:	Lot No. <u>PTS177A</u>	Expiry Date <u>03 May 2024</u>
Stop Solution:	Lot No. <u>HESP113</u>	Expiry Date <u>14 July 2023</u>
Concentrated Wash Solution:	Lot No. <u>CW292</u>	Expiry Date <u>05 January 2024</u>
Calibrators:	Lot No. <u>GEC436a</u>	Expiry Date <u>17 October 2022</u>
Controls:	Lot No. <u>GENC436a/GEPC436a</u>	Expiry Date <u>17 October 2022</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	0.010
5	0.232	0.079
18	0.644	0.202
35	1.158	0.359
120	2.935	0.887
250	3.961	1.291
2000	>4	2.334

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	1.544	0.462	48.0	47.4	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:

Xing

Signature:

Zhang Qing Feng

Position:

Laboratory Technician

Date:

25 August 2021

Authorised by:

DR G FLOOD

Signature:

G Flood

Position:

HEAD OF QC

Date:

11<sup>TH</sup> OCT 2021