

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

Document: **wi/qcrs/0.27**  
 Revision: **11**  
 Date: **10/10/14**  
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Prepared by: **G Flood**  
 Approved by: **L Carr**

Kit lot number: KGE400/A Kit expiry date: 20 September 2021  
 Kit manufacture date: 21 September 2020

GAD<sub>65</sub> Coated Wells: Lot No. GE431 Expiry Date 01 December 2021  
 GAD<sub>65</sub>-Biotin : Lot No. GEB366 Expiry Date 30 November 2021  
 Recon. Buffer for GAD<sub>65</sub>-Biotin: Lot No. GBB153 Expiry Date 05 November 2021  
 Streptavidin Peroxidase: Lot No. GEP376 Expiry Date 22 December 2021  
 Diluent for SA-POD: Lot No. PB158 Expiry Date 05 May 2022  
 Peroxidase Substrate: Lot No. PTS171B Expiry Date 27 February 2022  
 Stop Solution: Lot No. HESP105 Expiry Date 13 May 2022  
 Concentrated Wash Solution: Lot No. CW253 Expiry Date 10 December 2022  
 Calibrators: Lot No. GEC403 Expiry Date 20 September 2021  
 Controls: Lot No. GENC403/GEPC403 Expiry Date 20 September 2021

**Calibrator Curve and Controls:**

Incubation temp: +22 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.008	0.001
5	0.202	0.060
18	0.608	0.181
35	1.076	0.322
120	2.807	0.839
250	3.784	1.236
2000	>4	2.154

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	1.381	0.407	45.6	45.7	46 ± 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 Xingfeng  
Laboratory Technician  
28 July 2020

Authorised by:

Signature:

Position:

Date:

DR G FLOOD  
G Flood  
HEAD OF QC  
10<sup>TH</sup> SEP 2020