

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: KGE423 Kit expiry date: 30 May 2022

Kit manufacture date: ^{31 May}~~07 June~~ 2021

GAD₆₅ Coated Wells: Lot No. GE458 Expiry Date 12 October 2022
GAD₆₅-Biotin : Lot No. GEB393 Expiry Date 05 October 2022
Recon. Buffer for GAD₆₅-Biotin: Lot No. GBB160 Expiry Date 03 September 2022
Streptavidin Peroxidase: Lot No. GEP420 Expiry Date 13 October 2022
Diluent for SA-POD: Lot No. PB164 Expiry Date 01 March 2023
Peroxidase Substrate: Lot No. PTS175D Expiry Date 13 April 2023
Stop Solution: Lot No. HESP110 Expiry Date 01 March 2023
Concentrated Wash Solution: Lot No. CW276 Expiry Date 22 September 2023
Calibrators: Lot No. GEC424 Expiry Date 30 May 2022
Controls: Lot No. GENC424/GEPC424 Expiry Date 30 May 2022

Calibrator Curve and Controls:

Incubation temp: +21 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.017	0.005
5	0.212	0.064
18	0.555	0.165
35	1.016	0.306
120	2.628	0.780
250	3.668	1.125
2000	>4	2.079

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	1.472	0.438	52.7	52.8	52 ± 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 Dingfeng
 Laboratory Technician

Position:

Date:

 28 April 2021

Authorised by:

 DR G FLOOD

Signature:

 G Flood
 HEAD OF QC

Position:

Date:

 17th MAY 2021