Title:

Quality Control Record Sheet GAD Ab ELISA Kit QC Data

Document: Revision:

wi/gcrs/0.27

Date:

10/10/14

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Prepared by: G Flood Approved by: L Carr

Kit lot number: _____ KGE403A Kit expiry date: 15 November 2021

Kit manufacture date: 16 November 2020

GAD₆₅ Coated Wells: Lot No. GE436 Expiry Date 02 February 2022

GAD₆₅-Biotin: Lot No. GEB369 Expiry Date 12 January 2022

Recon. Buffer for GAD₆₅-Biotin: Lot No. GBB154 Expiry Date 25 December 2021

Streptavidin Peroxidase: Lot No. GEP383 Expiry Date 10 February 2022

Diluent for SA-POD: Lot No. PB159 Expiry Date 30 June 2022 Peroxidase Substrate:

Lot No. PTS173B Expiry Date 19 November 2022 Stop Solution: Lot No. HESP106 Expiry Date 02 June 2022

Concentrated Wash Solution: Lot No. CW256 Expiry Date 13 January 2023

Calibrators: Lot No. GEC406a Expiry Date 15 November 2021

Controls: Lot No. GENC406a/GEPC406a Expiry Date 15 November 2021

Calibrator Curve and Controls:	Incubation temp: +22 °C		
Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm	
Negative control	0.018 0.005		
5	0.210	0.061	
18	0.630	0.187	
35	1.079	0.322	
120	2.719	0.812	
250	3.685	1.171	
2000	>4	1.895	

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	1.487	0.442	50.3	51.0	50 ± 10

Materials of human origin used in the manufacture of this product have been tested and found nonreactive for HIV1 and 2 and HCV antibodies and HBsAg at the time of testing.

Assay performed by:	Xing		
Signature:	2hang Ling Leng		
Position:	Laboratory Technician		
Data	44.0 4 4 0000		

Date: 14 September 2020

Authorised by: Signature: Position:

Date: