Title:

Quality Control Record Sheet GAD Ab ELISA Kit QC Data

Document: Revision:

wi/qcrs/0.27

Date:

11 10/10/14

Prepared by: G Flood

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Approved by: L Carr

Kit lot number: KGE501C

Kit expiry date: 03 March 2025

Kit manufacture date: 04 March 2024

GAD₆₅ Coated Wells:

Lot No. GE534

Expiry Date 06 May 2025

GAD₆₅ -Biotin:

Lot No. GEB468

Expiry Date 05 May 2025

Recon. Buffer for GAD₆₅-Biotin:

Concentrated Wash Solution:

Lot No. GBB185 Lot No. GEP598

Expiry Date 21 May 2025

Streptavidin Peroxidase: Diluent for SA-POD:

Lot No. PB179

Expiry Date 12 May 2025 Expiry Date 13 November 2025

Peroxidase Substrate:

Lot No. PTS185L Lot No. HESP128 Expiry Date 27 April 2027

Expiry Date 02 November 2025

Stop Solution:

Lot No. CW374

Expiry Date 29 April 2026

Calibrators:

Lot No. GEC498c

Expiry Date 03 March 2025

Controls:

Lot No. GENC498c/GEPC498c Expiry Date 03 March 2025

Calibrator Curve and Controls:

Incubation temp:

+22

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Cambrator Curve and Controls.	Subation tempC		
Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm	
Negative control	0.026	0.008	
5	0.161	0.047	
18	0.499	0.148	
35	0.890	0.263	
120	2.690	0.787	
250	3.844	1.187	
2000	>4	2.030	

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	1.236	0.363	47.9	48.3	51 ± 15

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: Signature: Position:

Thang Ring

Laboratory Technician

Date:

14 December 2023

Authorised by:

Signature:

Position:

Date:

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FEB