Title:

Quality Control Record Sheet GAD Ab ELISA Kit QC Data

Document: Revision:

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Date:

10/10/14

Page

1 of 1

Prepared by: G Flood Approved by: L Carr

Kit expiry date: _____13 November 2023

Kit manufacture date: <u>14 November 2022</u>

GAD₆₅ Coated Wells: Lot No. GE503 GAD₆₅-Biotin:

Kit lot number: KGE471

Lot No. GEB439

Expiry Date 11 March 2024 Expiry Date 13 March 2024

Recon. Buffer for GAD₆₅-Biotin: Streptavidin Peroxidase:

Lot No. GBB175 Expiry Date 21 March 2024

Diluent for SA-POD:

Lot No. GEP516 Expiry Date 29 March 2024 Lot No. PB172 Expiry Date 23 August 2024

Peroxidase Substrate:

Lot No. PTS181D Expiry Date 21 April 2026

Stop Solution: Concentrated Wash Solution:

Lot No. HESP120 Lot No. CW331

Expiry Date 23 August 2024 Expiry Date 22 March 2025

Calibrators:

Lot No. GEC468

Expiry Date 13 November 2023

Controls:

Date:

Lot No. GENC468/GEPC468

Expiry Date 13 November 2023

Calibrator Curve and Controls:

Incubation temp

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Odibiator Odive and Controls.		incubation temp*C		
Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm		
Negative control	0.010	0.002		
5	0.183	0.052		
18	0.544	0.159		
35	1.007	0.297		
120	2.588	0.770		
250	3.670	1.262		
2000	>4	2.159		

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	1.280	0.378	45.9	47 4	46 ± 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.

NOV 2022

Assay performed by:	Xing
Signature:	Thang Ling feng
Position:	Laboratory Technician
Date:	14 October 2022
Authorised by:	DR G FLOOD
Signature:	5 Rund
Position:	MEAD OF QC