Title:

Quality Control Record Sheet GAD Ab ELISA Kit QC Data

Document:

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Revision: Date:

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Prepared by: G Flood Approved by: L Carr

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KGE411 Kit lot number: __ Kit expiry date: _ 10 January 2022

Kit manufacture date: 11 January 2021 Expiry Date 09 May 2022 GAD₆₅ Coated Wells: Lot No. GE446 GAD₆₅ -Biotin: Lot No. GEB378 Expiry Date 08 May 2022 Recon. Buffer for GAD₆₅-Biotin: Lot No. GBB157 Expiry Date 10 May 2022 Streptavidin Peroxidase: Lot No. GEP395 Expiry Date 03 May 2022 Diluent for SA-POD: Lot No. PB161 Expiry Date 18 October 2022 Peroxidase Substrate: Lot No. PTS173H Expiry Date 19 November 2022 Stop Solution: Lot No. HESP107 Expiry Date 15 September 2022 Concentrated Wash Solution: Lot No. CW262 Expiry Date 19 April 2023 Calibrators: Lot No. GEC413 Expiry Date 10 January 2022 Controls: Lot No. GENC413/GEPC413 Expiry Date 10 January 2022

Calibrator Curve and Controls: Incubation toma:

inbrator curve and controls.		incubation temp	
Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm	
Negative control	0.016	0.016 0.004	
5	0.206	0.061	
18	0.603	0.177	
35	1.155	0.342	
120	2.724	0.805	
250	3.752	1.139	
2000	>4	1.850	

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	1.461	0.432	46.2	46.5	51 ± 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:	Thang Ding feng
Position:	Laboratory Technician
Date:	10 December 2020
Authorised by:	DR G FLOOD
Signature:	5 Muy
Position:	MEAD OF QC
Date:	6TH JAN 2021