Title: Quality Control I GAD Ab ELISA I	Document: wi/qcrs/0.27 Revision: 11 Date: 10/10/14					
Prepared by: G Flood Page Approved by: L Carr Date:						
Kit lot number: KGE4	02 April 2024					
Kit manufacture date: <u>03 April</u>	2023					
GAD ₆₅ Coated Wells:	Lot No. <u>GE510</u>	Expiry Date <u>12 June 2024</u>				
GAD ₆₅ -Biotin :	Lot No. <u>GEB446</u>	Expiry Date <u>11 June 2024</u>				
Recon. Buffer for GAD ₆₅ -Biotin:	Lot No. <u>GBB177</u>	Expiry Date <u>15 May 2024</u>				
Streptavidin Peroxidase:	Lot No. <u>GEP530</u>	Expiry Date <u>04 June 2024</u>				
Diluent for SA-POD:	Lot No. <u>PB173</u>	Expiry Date <u>09 November 2024</u>				
Peroxidase Substrate:	Lot No. <u>PTS181L</u>	Expiry Date 21 April 2026				
Stop Solution:	Lot No. HESP122	Expiry Date <u>14 December 2024</u>				
Concentrated Wash Solution:	Lot No. <u>CW341</u>	Expiry Date <u>12 June 2025</u>				
Calibrators:	Lot No. <u>GEC475a</u>	Expiry Date <u>02 April 2024</u>				
Controls:	Lot No. GENC475a/GEPC475a	Expiry Date 02 April 2024				

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Calibrator Curve and Controls:	Incubation temp:	+21	_°C		
Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorba 405			
Negative control	0.011	0.00	0.003		
5	0.167	0.04	0.049		
18	0.540	0.15	0.159		
35	0.987	0.29	0.291		
120	2.712	0.79	0.793		
250	3.951	1.2	1.258		
2000	>4	2.24	45		

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	1.373	0.403	50.0	50.9	51 ± 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.

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Assay performed by:	Xing
Signature:	Thang Ring feng
Position:	Laboratory Technician
Date:	18 January 2023
Authorised by:	DR G FLOOD
Signature:	5 Kunt
Position:	MEAD OF QC
Date:	14 TA MAR 2023