Title:

**Quality Control Record Sheet** GAD Ab ELISA Kit QC Data

Document: Revision:

wi/gcrs/0.27

Date:

10/10/14

Prepared by: Approved by: G Flood L Carr

Page

1 of 1

Kit expiry date: 15 September 2025 Kit lot number: KGE520A

Kit manufacture date: 16 September 2024

GAD<sub>65</sub> Coated Wells:

Lot No. GE553

Expiry Date 24 December 2025

GAD<sub>65</sub> -Biotin:

Lot No. GEB488

Expiry Date 23 December 2025 Expiry Date 13 December 2025

Streptavidin Peroxidase:

Recon. Buffer for GAD<sub>65</sub>-Biotin:

Lot No. GBB191 Lot No. GEP645

Expiry Date 27 December 2025

Diluent for SA-POD:

Lot No. PB182 Lot No. PTS187R

Expiry Date 30 November 2027

Peroxidase Substrate: Stop Solution:

Lot No. HESP133

Expiry Date 19 June 2026

Expiry Date 27 June 2026

Concentrated Wash Solution:

Lot No. CW401

Expiry Date 25 December 2026 Expiry Date 15 September 2025

Calibrators:

Controls:

Lot No. GEC517a

Lot No. GENC517a/GEPC517a Expiry Date 15 September 2025

Calibrator Curve and Controls:

Incubation temp:

+22

°C **Calibrator Concentration** Absorbance at Absorbance at 405 nm (units per mL) 450 nm 0.005 0.014 Negative control 0.055 5 0.188 18 0.574 0.171 35 0.301 1.018 120 2.779 0.814 >4 1.317 250 2.090 >4 2000

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	1.362	0.401	48.1	49.5	50 ± 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:

Xing

Signature:

Position:

Laboratory Technician

Date:

19 July 2024

Authorised by:

Signature:

Position:

Date:

AJG