

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

Document: **wi/qcrs/0.27**

Revision: **11**

Date: **10/10/14**

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Prepared by: **G Flood**

Approved by: **L Carr**

Kit lot number: KGE540B Kit expiry date: 17 August 2026

Kit manufacture date: 18 August 2025

GAD ₆₅ Coated Wells:	Lot No. <u>GE573</u>	Expiry Date <u>10 September 2026</u>
GAD ₆₅ –Biotin :	Lot No. <u>GEB508</u>	Expiry Date <u>06 September 2026</u>
Recon. Buffer for GAD ₆₅ -Biotin:	Lot No. <u>GBB198</u>	Expiry Date <u>10 September 2026</u>
Streptavidin Peroxidase:	Lot No. <u>GEP698</u>	Expiry Date <u>12 September 2026</u>
Diluent for SA-POD:	Lot No. <u>PB185</u>	Expiry Date <u>17 February 2027</u>
Peroxidase Substrate:	Lot No. <u>PTS191E</u>	Expiry Date <u>11 November 2028</u>
Stop Solution:	Lot No. <u>HESP138</u>	Expiry Date <u>02 February 2027</u>
Concentrated Wash Solution:	Lot No. <u>CW431</u>	Expiry Date <u>09 September 2027</u>
Calibrators:	Lot No. <u>GEC537b</u>	Expiry Date <u>17 August 2026</u>
Controls:	Lot No. <u>GENC537b/GEPC537b</u>	Expiry Date <u>17 August 2026</u>

Calibrator Curve and Controls:

Incubation temp: +22 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.040	0.019
5	0.194	0.057
18	0.549	0.162
35	1.050	0.310
120	2.818	0.823
250	>4	1.381
2000	>4	2.038

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	1.364	0.399	46.5	48.1	51 ± 15

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.

Assay performed by: Lorraine Carr

Signature: L Carr

Position: Deputy Head of Operations

Date: 31 March 2025

Authorised by: DR G Flood

Signature: G Flood

Position: HEAD OF QC

Date: 1ST AUG 2025