

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

Document: **wi/qcrs/0.27**

Revision: **11**

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Prepared by: **G Flood**

Approved by: **L Carr**

Kit lot number: KGE583A Kit expiry date: 13 September 2027

Kit manufacture date: 14 September 2026

GAD ₆₅ Coated Wells:	Lot No. <u>GE616</u>	Expiry Date <u>30 November 2027</u>
GAD ₆₅ -Biotin :	Lot No. <u>GEB553</u>	Expiry Date <u>28 November 2027</u>
Recon. Buffer for GAD ₆₅ -Biotin:	Lot No. <u>GBB212</u>	Expiry Date <u>30 November 2027</u>
Streptavidin Peroxidase:	Lot No. <u>GEP804</u>	Expiry Date <u>03 December 2027</u>
Diluent for SA-POD:	Lot No. <u>PB192</u>	Expiry Date <u>30 April 2028</u>
Peroxidase Substrate:	Lot No. <u>PTS197Q</u>	Expiry Date <u>13 October 2029</u>
Stop Solution:	Lot No. <u>HESP150</u>	Expiry Date <u>30 April 2028</u>
Concentrated Wash Solution:	Lot No. <u>CW515</u>	Expiry Date <u>09 December 2028</u>
Calibrators:	Lot No. <u>GEC580a</u>	Expiry Date <u>13 September 2027</u>
Controls:	Lot No. <u>GENC580a/GEPC580a</u>	Expiry Date <u>13 September 2027</u>

Calibrator Curve and Controls:

Incubation temp: +23 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.019	0.007
5	0.197	0.058
18	0.556	0.163
35	1.077	0.319
120	2.889	0.844
250	>4	1.411
2000	>4	2.088

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	1.478	0.434	50.8	51.6	50 ± 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:

20 July 2026

Authorised by:

DR G Flood

Signature:

G Flood

Position:

HEAD OF QC

Date:

2nd SEP 2026