

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: KGE491B Kit expiry date: 15 October 2024

Kit manufacture date: 16 October 2023

GAD <sub>65</sub> Coated Wells:	Lot No. <u>GE525</u>	Expiry Date <u>10 January 2025</u>
GAD <sub>65</sub> -Biotin :	Lot No. <u>GEB459</u>	Expiry Date <u>16 January 2025</u>
Recon. Buffer for GAD <sub>65</sub> -Biotin:	Lot No. <u>GBB182</u>	Expiry Date <u>17 January 2025</u>
Streptavidin Peroxidase:	Lot No. <u>GEP572</u>	Expiry Date <u>17 January 2025</u>
Diluent for SA-POD:	Lot No. <u>PB175</u>	Expiry Date <u>30 May 2025</u>
Peroxidase Substrate:	Lot No. <u>PTS183N</u>	Expiry Date <u>24 October 2026</u>
Stop Solution:	Lot No. <u>HESP125</u>	Expiry Date <u>31 May 2025</u>
Concentrated Wash Solution:	Lot No. <u>CW361</u>	Expiry Date <u>16 January 2026</u>
Calibrators:	Lot No. <u>GEC488b</u>	Expiry Date <u>15 October 2024</u>
Controls:	Lot No. <u>GENC488b/GEPC488b</u>	Expiry Date <u>15 October 2024</u>

**Calibrator Curve and Controls:**

Incubation temp: +22 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.020	0.006
5	0.178	0.051
18	0.562	0.165
35	0.998	0.293
120	3.007	0.880
250	>4	1.436
2000	>4	2.396

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	1.443	0.422	49.6	51.6	53 ± 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:

Xing

Signature:

Zhang Xing Feng

Position:

Laboratory Technician

Date:

04 August 2023

Authorised by:

DR JILL CLARK

Signature:

Jill Clark

Position:

pp HEAD OF QC

Date:

16 OCTOBER 2023