

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:                     **KGE459B**                     Kit expiry date:                     **21 August 2023**                    

Kit manufacture date:                     **22 August 2022**                    

GAD <sub>65</sub> Coated Wells:	Lot No. <u>          <b>GE492</b>          </u>	Expiry Date <u>          <b>25 October 2023</b>          </u>
GAD <sub>65</sub> -Biotin :	Lot No. <u>          <b>GEB427</b>          </u>	Expiry Date <u>          <b>24 October 2023</b>          </u>
Recon. Buffer for GAD <sub>65</sub> -Biotin:	Lot No. <u>          <b>GBB171</b>          </u>	Expiry Date <u>          <b>05 October 2023</b>          </u>
Streptavidin Peroxidase:	Lot No. <u>          <b>GEP486</b>          </u>	Expiry Date <u>          <b>27 October 2023</b>          </u>
Diluent for SA-POD:	Lot No. <u>          <b>PB170</b>          </u>	Expiry Date <u>          <b>14 February 2024</b>          </u>
Peroxidase Substrate:	Lot No. <u>          <b>PTS179H</b>          </u>	Expiry Date <u>          <b>30 September 2024</b>          </u>
Stop Solution:	Lot No. <u>          <b>HESP117</b>          </u>	Expiry Date <u>          <b>10 March 2024</b>          </u>
Concentrated Wash Solution:	Lot No. <u>          <b>CW315</b>          </u>	Expiry Date <u>          <b>19 October 2024</b>          </u>
Calibrators:	Lot No. <u>          <b>GEC457b</b>          </u>	Expiry Date <u>          <b>21 August 2023</b>          </u>
Controls:	Lot No. <u>          <b>GENC457b/GEPC457b</b>          </u>	Expiry Date <u>          <b>21 August 2023</b>          </u>

**Calibrator Curve and Controls:** Incubation temp:           **+22**           °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.024	0.006
5	0.202	0.060
18	0.536	0.159
35	0.954	0.284
120	2.727	0.817
250	3.892	1.342
2000	>4	2.285

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	1.361	0.403	49.9	51.9	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.

Assay performed by: \_\_\_\_\_  
 Signature:                     **Xing**                      
                    **Zhang Xing feng**                      
 Position:                     **Laboratory Technician**                      
 Date:                     **25 May 2022**                    

Authorised by: \_\_\_\_\_  
 Signature:                     **DR G Flood**                      
                    **G Flood**                      
 Position:                     **HEAD OF QC**                      
 Date:                     **12<sup>th</sup> AUG 2022**