

Title:

Quality Control Record Sheet VGCC Ab QC Data

Document: **wi/qcrs/0.15**Revision: **8**Date: **15/08/18**Page **1 of 1**Kit Lot Number: LK263Kit Expiry Date: 21 August 2026Kit Manufacture Date: 05 June 2026¹²⁵I-VGCC for total binding lot number: LT263Expiry Date: 21 August 2026¹²⁵I-VGCC for non-specific binding lot number: NS263Expiry Date: 21 August 2026Dilution buffer lot number: 257LBExpiry Date: 21 August 2026Anti-human IgG lot number: 29LGgExpiry Date: 21 August 2026Wash solution lot number: 198LWExpiry Date: 21 August 2026Negative control lot number: 22LNkExpiry Date: 21 August 2026Positive control lot number: 27LPgExpiry Date: 21 August 2026At Manufacture Date: 5643 dpm = 1 fmoleAt QC Assay Date¹: 5451 dpm = 1 fmole (conversion factor A)Counter Efficiency: 75.8 % (B)² Positive control range: 166 ± 74 pmol/L

Sample	NSB		T			
	Mean cpm - background	fmol/ Pellet (E)	Mean cpm - background	fmol/ pellet (D)	¹²⁵ I-conotoxin labelled VGCC bound (pmol/L serum)	pmol/L serum VGCC Ab (after subtraction of negative control)
Total counts	16543	4.004	17060	4.129		
Negative control	311	0.075	361	0.087	4.8 (G)	-
Positive control	336	0.081	1878	0.455	149.3 (F)	144.4 (H)
Test sample 1b	340	0.082	2570	0.622	215.9 (F)	211.0 (H)
Test sample 2b	267	0.065	982	0.238	69.2 (F)	64.4 (H)
Test sample 3c	284	0.069	1432	0.347	111.1 (F)	106.3 (H)
Test sample 4b	298	0.072	1544	0.374	120.6 (F)	115.8 (H)
Test sample 5d	333	0.081	1640	0.397	126.5 (F)	121.7 (H)

Assay date (weeks after QC assay)	Decay factor (C)	Assay date (weeks after QC assay)	Decay factor (C)
Up to 1 week	1.00	+ 6 – 7 weeks	0.61
+ 1 – 2 weeks	0.92	+ 7 – 8 weeks	0.56
+ 2 – 3 weeks	0.85	+ 8 – 9 weeks	0.52
+ 3 – 4 weeks	0.78	+ 9 – 10 weeks	0.48
+ 4 – 5 weeks	0.72	+ 10 – 11 weeks	0.44
+ 5 – 6 weeks	0.66		

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.

QC Assay Date¹: 08 June 2026Performed by: A. HuckleSignature: A. HucklePosition: Snr TechnicianAuthorised by: DR G FloodSignature: [Signature]Position: Head of Quality ControlDate: 10th JUN 2026