

Title: **Quality Control Record Sheet
VGCC Ab QC Data**

Document: **wi/qcrs/0.15**

Prepared by: **G Flood**

Revision: **8**

Approved by: **J Davies**

Date: **15/08/18**

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Kit Lot Number: LK261 Kit Expiry Date: 01 May 2026

Kit Manufacture Date: 13 February 2026

¹²⁵I-VGCC for total binding lot number: LT261 Expiry Date: 01 May 2026

¹²⁵I-VGCC for non-specific binding lot number: NS261 Expiry Date: 01 May 2026

Dilution buffer lot number: 255LB Expiry Date: 01 May 2026

Anti-human IgG lot number: 29LGe Expiry Date: 01 May 2026

Wash solution lot number: 194LW Expiry Date: 01 May 2026

Negative control lot number: 22LNg Expiry Date: 01 May 2026

Positive control lot number: 27LPe Expiry Date: 01 May 2026

At Manufacture Date: 6168 dpm = 1 fmole

At QC Assay Date¹: 5958 dpm = 1 fmole (conversion factor A)

Counter Efficiency: 76.7 % (B) ²Positive control range: 174 ± 78 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	16903	3.699	17710	3.875		
Negative control	361	0.079	354	0.078	-0.6 (G)	-
Positive control	314	0.069	2399	0.525	182.5 (F)	183.1 (H)
Test sample 1a	374	0.082	3370	0.738	262.3 (F)	262.9 (H)
Test sample 2b	273	0.060	1319	0.289	91.5 (F)	92.1 (H)
Test sample 3c	300	0.066	1467	0.321	102.1 (F)	102.7 (H)
Test sample 4b	317	0.069	1682	0.368	119.5 (F)	120.1 (H)
Test sample 5d	350	0.077	1899	0.416	135.6 (F)	136.2 (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: 16 February 2026

Authorised by: DR G FLOOD

Performed by: Dr. Dale Jones

Signature: *[Signature]*

Signature: *[Signature]*

Position: Head of Quality Control

Position: Scientist

Date: 18TH FEB 2026