

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

Document: **wi/qcrs/0.15**

Revision: **8**

Prepared by: **G Flood**

Date: **15/08/18**

Approved by: **J Davies**

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Kit Lot Number: LK265

Kit Expiry Date: 11 December 2026

Kit Manufacture Date: 25 September 2026

¹²⁵I-VGCC for total binding lot number: LT265

Expiry Date: 11 December 2026

¹²⁵I-VGCC for non-specific binding lot number: NS265

Expiry Date: 11 December 2026

Dilution buffer lot number: 259LB

Expiry Date: 11 December 2026

Anti-human IgG lot number: 29LGk

Expiry Date: 11 December 2026

Wash solution lot number: 202LW

Expiry Date: 11 December 2026

Negative control lot number: 22LNn

Expiry Date: 11 December 2026

Positive control lot number: 27LPk

Expiry Date: 11 December 2026

At Manufacture Date: 6011 dpm = 1 fmole

At QC Assay Date¹: 5806 dpm = 1 fmole (conversion factor A)

Counter Efficiency: 75.8 % (B)

² Positive control range: 165 ± 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	16745	3.805	17448	3.965		
Negative control	456	0.104	398	0.091	-5.2 (G)	-
Positive control	503	0.114	2288	0.520	162.2 (F)	167.4 (H)
Test sample 1b	441	0.100	3161	0.718	247.2(F)	252.4 (H)
Test sample 2b	365	0.083	1325	0.301	87.2 (F)	92.4 (H)
Test sample 3c	377	0.086	1737	0.395	123.7 (F)	128.9 (H)
Test sample 4b	398	0.090	1899	0.432	136.5 (F)	141.7 (H)
Test sample 5d	419	0.095	1997	0.454	143.4 (F)	148.6 (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: 28 September 2026

Authorised by: DR G Flood

Performed by: Dr. Ian Matthews

Signature: [Signature]

Signature: [Signature]

Position: Head of Quality Control

Position: Senior Principal Scientist

Date: 30TH SEP 2026