

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

Document: **wi/qcrs/0.15**
Revision: **8**
Date: **15/08/18**
Page **1** of **1**

Prepared by: **G Flood**
Approved by: **J Davies**

Kit Lot Number: LK251A Kit Expiry Date: 13 December 2024
Kit Manufacture Date: 27 September 2024
¹²⁵I-VGCC for total binding lot number: LT251 Expiry Date: 13 December 2024
¹²⁵I-VGCC for non-specific binding lot number: NS251 Expiry Date: 13 December 2024
Dilution buffer lot number: 245LB Expiry Date: 13 December 2024
Anti-human IgG lot number: 27LGv Expiry Date: 13 December 2024
Wash solution lot number: 177LW Expiry Date: 13 December 2024
Negative control lot number: 21LNM Expiry Date: 13 December 2024
Positive control lot number: 26LPk Expiry Date: 13 December 2024

At Manufacture Date: 6541 dpm = 1 fmole
At QC Assay Date¹: 6318 dpm = 1 fmole (conversion factor A)
Counter Efficiency: 75.1 % (B) ² Positive control range: 195 ± 85 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	17074	3.598	17497	3.688		
Negative control	406	0.086	398	0.084	-0.7 (G)	-
Positive control	476	0.100	2746	0.579	191.4 (F)	192.1 (H)
Test sample 1	429	0.090	2435	0.513	169.1 (F)	169.8 (H)
Test sample 2b	344	0.072	1229	0.259	74.6 (F)	75.3 (H)
Test sample 3c	412	0.087	1670	0.352	106.1 (F)	106.8 (H)
Test sample 4b	374	0.079	2073	0.437	143.2 (F)	143.8 (H)
Test sample 5d	388	0.082	2189	0.461	151.8 (F)	152.5 (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: 30 September 2024
Performed by: Dr. Ian Matthews
Signature: I.Matth's
Position: Senior Principal Scientist

Authorised by: DR G Flood
Signature: [Signature]
Position: Head of Quality Control
Date: 3RD OCT 2024