

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

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 Revision: **8**
 Date: **15/08/18**
 Page: **1 of 1**

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

Kit Lot Number: LK253 Kit Expiry Date: 03 April 2025
 Kit Manufacture Date: 16 January 2025
¹²⁵I-VGCC for total binding lot number: LT253 Expiry Date: 03 April 2025
¹²⁵I-VGCC for non-specific binding lot number: NS253 Expiry Date: 03 April 2025
 Dilution buffer lot number: 247LB Expiry Date: 03 April 2025
 Anti-human IgG lot number: 27LGx Expiry Date: 03 April 2025
 Wash solution lot number: 180LW Expiry Date: 03 April 2025
 Negative control lot number: 21LNp Expiry Date: 03 April 2025
 Positive control lot number: 26LPn Expiry Date: 03 April 2025

At Manufacture Date: 7064 dpm = 1 fmole
 At QC Assay Date¹: 6745 dpm = 1 fmole (conversion factor A)
 Counter Efficiency: 73.4 % (B) ²Positive control range: 180 ± 80 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	17814	3.598	17747	3.585		
Negative control	416	0.084	437	0.088	1.7 (G)	-
Positive control	404	0.082	2608	0.527	178.1 (F)	176.4 (H)
Test sample 1	365	0.074	1953	0.394	128.3 (F)	126.6 (H)
Test sample 2b	244	0.049	1194	0.241	76.8 (F)	75.1 (H)
Test sample 3c	382	0.077	1916	0.387	123.9 (F)	122.2 (H)
Test sample 4b	400	0.081	2191	0.443	144.7(F)	143.0 (H)
Test sample 5d	411	0.083	2191	0.443	143.8(F)	142.1 (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: 20 January 2025
 Performed by: A. Huckle
 Signature: A. Huckle
 Position: Snr TECHNICIAN

Authorised by: DR G Flood
 Signature: G Flood
 Position: Head of Quality Control
 Date: 22ND JAN 2025