

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

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

Kit Lot Number: LK247 Kit Expiry Date: 03 May 2024
Kit Manufacture Date: 16 February 2024
¹²⁵I-VGCC for total binding lot number: LT247 Expiry Date: 03 May 2024
¹²⁵I-VGCC for non-specific binding lot number: NS247 Expiry Date: 03 May 2024
Dilution buffer lot number: 241LB Expiry Date: 03 May 2024
Anti-human IgG lot number: 27LGp Expiry Date: 03 May 2024
Wash solution lot number: 170LW Expiry Date: 03 May 2024
Negative control lot number: 21LNf Expiry Date: 03 May 2024
Positive control lot number: 26LPe Expiry Date: 03 May 2024

At Manufacture Date: 6365 dpm = 1 fmole
At QC Assay Date¹: 6148 dpm = 1 fmole (conversion factor A)
Counter Efficiency: 76.3 % (B) ²Positive control range: 190 ± 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	17147	3.655	17299	3.688		
Negative control	298	0.064	295	0.063	-0.3 (G)	-
Positive control	275	0.059	2473	0.527	187.4 (F)	187.7 (H)
Test sample 1	270	0.058	2350	0.501	177.4 (F)	177.6 (H)
Test sample 2b	260	0.055	1204	0.257	80.5 (F)	80.7 (H)
Test sample 3c	302	0.064	1598	0.341	110.5 (F)	110.8 (H)
Test sample 4a	226	0.048	2318	0.494	178.4 (F)	178.6 (H)
Test sample 5d	296	0.063	1959	0.418	141.8 (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: 19 February 2024
Performed by: Dr. Dale Jones
Signature: *Dale Jones*
Position: Scientist

Authorised by: *DR G FLOOD*
Signature: *G Flood*
Position: Head of Quality Control
Date: 21ST FEB 2024