

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

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Approved by: J Davies

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Kit Lot Number: LK244A Kit Expiry Date: 12 January 2024  
Kit Manufacture Date: 27 October 2023  
<sup>125</sup>I-VGCC for total binding lot number: LT244 Expiry Date: 12 January 2024  
<sup>125</sup>I-VGCC for non-specific binding lot number: NS244 Expiry Date: 12 January 2024  
Dilution buffer lot number: 238LB Expiry Date: 12 January 2024  
Anti-human IgG lot number: 27LGk Expiry Date: 12 January 2024  
Wash solution lot number: 167LW Expiry Date: 12 January 2024  
Negative control lot number: 21LNc Expiry Date: 12 January 2024  
Positive control lot number: 26LPb Expiry Date: 12 January 2024

At Manufacture Date: 5516 dpm = 1 fmole  
At QC Assay Date<sup>1</sup>: 5328 dpm = 1 fmole (conversion factor A)  
Counter Efficiency: 73.4 % (B) <sup>2</sup> Positive control range: 195 ± 85 pmol/L

	NSB		T			
Sample	Mean cpm - background	fmol/ Pellet (E)	Mean cpm - background	fmol/ pellet (D)	<sup>125</sup> I-conotoxin labelled VGCC bound (pmol/L serum)	pmol/L serum VGCC Ab (after subtraction of negative control)
Total counts	17563	4.491	16264	4.159		
Negative control	527	0.135	368	0.094	-16.3 (G)	-
Positive control	492	0.126	2077	0.531	162.1 (F)	178.4 (H)
Test sample 1	480	0.123	1474	0.377	101.7 (F)	117.9 (H)
Test sample 2b	397	0.102	906	0.232	52.1 (F)	68.3 (H)
Test sample 3c	522	0.133	1503	0.384	100.3 (F)	116.6 (H)
Test sample 4a	312	0.080	1881	0.481	160.5 (F)	176.7 (H)
Test sample 5d	507	0.130	1844	0.472	136.8 (F)	153.0 (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 Date<sup>1</sup>: 30 October 2023  
Performed by: A. Huckle  
Signature: pp JBradbury  
Position: Senior Technician

Authorised by: DR G Flood  
Signature: [Signature]  
Position: Head of Quality Control  
Date: 2<sup>ND</sup> NOV 2023