

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

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Approved by: J Davies

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Page **1 of 1**

Kit Lot Number: LK240 Kit Expiry Date: 02 June 2023

Kit Manufacture Date: 17 March 2023

¹²⁵I-VGCC for total binding lot number: LT240 Expiry Date: 02 June 2023

¹²⁵I-VGCC for non-specific binding lot number: NS240 Expiry Date: 02 June 2023

Dilution buffer lot number: 234LB Expiry Date: 02 June 2023

Anti-human IgG lot number: 27LGe Expiry Date: 02 June 2023

Wash solution lot number: 160LW Expiry Date: 02 June 2023

Negative control lot number: 20LNn Expiry Date: 02 June 2023

Positive control lot number: 25LPm Expiry Date: 02 June 2023

At Manufacture Date: 5999 dpm = 1 fmole

At QC Assay Date¹: 5795 dpm = 1 fmole (conversion factor A)

Counter Efficiency: 76.3 % (B) ² Positive control range: 215 ± 95 pmol/L

	NSB		T			
Sample	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	16443	3.719	17592	3.979		
Negative control	476	0.108	355	0.080	-10.9 (G)	-
Positive control	493	0.111	2843	0.643	212.6 (F)	223.5 (H)
Test sample 1	511	0.116	2661	0.602	194.5 (F)	205.4 (H)
Test sample 2b	451	0.102	1165	0.263	64.5 (F)	75.4 (H)
Test sample 3c	475	0.107	1867	0.422	125.9 (F)	136.8 (H)
Test sample 4a	378	0.085	2438	0.551	186.3 (F)	197.2 (H)
Test sample 5d	508	0.115	1943	0.439	129.8 (F)	140.7 (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 March 2023

Performed by: Dr. Ian Matthews

Signature: *I Matthews*

Position: Senior Principal Scientist

Authorised by: *DR G Flood*

Signature: *G Flood*

Position: Head of Quality Control

Date: 23RD MAR 2023