

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

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Approved by: J Davies

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Kit Lot Number: LK228 Kit Expiry Date: 24 SEPT 2021

Kit Manufacture Date: 09 JULY 2021

¹²⁵I-VGCC for total binding lot number: LT228 Expiry Date: 24 SEPT 2021

¹²⁵I-VGCC for non-specific binding lot number: NS228 Expiry Date: 24 SEPT 2021

Dilution buffer lot number: 222LB Expiry Date: 24 SEPT 2021

Anti-human IgG lot number: 26LGc Expiry Date: 24 SEPT 2021

Wash solution lot number: 145LW Expiry Date: 24 SEPT 2021

Negative control lot number: 19LNn Expiry Date: 24 SEPT 2021

Positive control lot number: 24LPu Expiry Date: 24 SEPT 2021

At Manufacture Date: 5926 dpm = 1 fmole

At QC Assay Date¹: 5658 dpm = 1 fmole (conversion factor A)

Counter Efficiency: 76.3 % (B) ² Positive control range: 195 ± 85 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	18214	4.219	18643	4.319		
Negative control	436	0.101	399	0.092	-3.5 (G)	-
Positive control	443	0.103	2543	0.589	194.6 (F)	198.1 (H)
Test sample 1	558	0.129	2578	0.597	187.1 (F)	190.6 (H)
Test sample 2b	410	0.095	1223	0.283	75.3 (F)	78.8 (H)
Test sample 3b	468	0.108	2202	0.510	160.7 (F)	164.1 (H)
Test sample 4a	333	0.077	1973	0.457	151.9 (F)	155.4 (H)
Test sample 5d	499	0.116	1950	0.452	134.4 (F)	137.9 (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: 13 JULY 2021
Performed by: Dr. Liang Guo
Signature: [Signature]
Position: Senior Scientist

Authorised by: DR G FLOOD
Signature: [Signature]
Position: Head of Quality Control
Date: 16th JUL 2021