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

Prepared by: G Flood
Approved by: J Davies

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Date: **15/08/18**
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Kit Lot Number: LK242 Kit Expiry Date: 22 September 2023

Kit Manufacture Date: 07 July 2023

^{125}I-VGCC for total binding lot number:	LT242	Expiry Date: 22 September 2023
^{125}I-VGCC for non-specific binding lot number:	NS242	Expiry Date: 22 September 2023
Dilution buffer lot number:	236LB	Expiry Date: 22 September 2023
Anti-human IgG lot number:	27LGg	Expiry Date: 22 September 2023
Wash solution lot number:	163LW	Expiry Date: 22 September 2023
Negative control lot number:	21LNa	Expiry Date: 22 September 2023
Positive control lot number:	25LPp	Expiry Date: 22 September 2023

At Manufacture Date: 6162 dpm = 1 *f*mole

At QC Assay Date[1]: 5952 dpm = 1 *f*mole (conversion factor A)

Counter Efficiency: 73.4 % (B)

[2] Positive control range: 180 ± 80 pmol/L

	NSB		T			
Sample	**Mean cpm - background**	***f*mol/ Pellet (E)**	**Mean cpm - background**	***f*mol/ pellet (D)**	**^{125}I-conotoxin labelled VGCC bound (pmol/L serum)**	**pmol/L serum VGCC Ab (after subtraction of negative control)**
Total counts	17836	4.083	17412	3.986		
Negative control	512	0.117	353	0.081	-14.6 (G)	-
Positive control	451	0.103	2196	0.503	159.8 (F)	174.3 (H)
Test sample 1	452	0.103	1529	0.350	98.6 (F)	113.2 (H)
Test sample 2b	463	0.106	1100	0.252	58.3 (F)	72.9 (H)
Test sample 3c	454	0.104	1650	0.378	109.5 (F)	124.1 (H)
Test sample 4a	325	0.074	2193	0.502	171.0 (F)	185.6 (H)
Test sample 5d	472	0.108	2005	0.459	140.4 (F)	154.9 (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 Date[1]: 10 July 2023
Performed by: A. Huckle
Signature: A. Huckle
Position: Senior Technician

Authorised by: DR G FLOOD
Signature: G Flood
Position: **Head of Quality Control**
Date: 13TH JULY 2023