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

Prepared by: G Flood
Approved by: J Davies

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Kit Lot Number: LK226 Kit Expiry Date: 04 JUNE 2021

Kit Manufacture Date: 19 MARCH 2021

^{125}I-VGCC for total binding lot number: LT226 Expiry Date: 04 JUNE 2021

^{125}I-VGCC for non-specific binding lot number: NS226 Expiry Date: 04 JUNE 2021

Dilution buffer lot number: 220LB Expiry Date: 04 JUNE 2021

Anti-human IgG lot number: 26LGa Expiry Date: 04 JUNE 2021

Wash solution lot number: 143LW Expiry Date: 04 JUNE 2021

Negative control lot number: 19LNk Expiry Date: 04 JUNE 2021

Positive control lot number: 24LPp Expiry Date: 04 JUNE 2021

At Manufacture Date: 5169 dpm = 1 *f*mole

At QC Assay Date[1]: 4993 dpm = 1 *f*mole (conversion factor A)

Counter Efficiency: 76.25 % (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	17631	4.631	18139	4.764		
Negative control	330	0.087	380	0.100	5.2 (G)	-
Positive control	378	0.099	1837	0.483	153.3 (F)	148.1 (H)
Test sample 1	471	0.124	1866	0.490	146.6 (F)	141.3 (H)
Test sample 2b	398	0.105	1064	0.280	70.0 (F)	64.7 (H)
Test sample 3b	376	0.099	1991	0.523	169.7 (F)	164.5 (H)
Test sample 4a	265	0.069	1710	0.449	151.8 (F)	146.6 (H)
Test sample 5d	411	0.108	1879	0.494	154.2 (F)	149.0 (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[1]: 22 MARCH 2021

Performed by: Dr. Liang Guo

Signature:

Position: Senior Scientist

Authorised by: OR G Flood

Signature:

Position: **Head of Quality Control**

Date: 26TH MAR 2021