

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

Document: **wi/qcrs/0.15**

Revision: **8**

Date: **15/08/18**

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Prepared by: **G Flood**

Approved by: **J Davies**

Kit Lot Number: LK249

Kit Expiry Date: 23 August 2024

Kit Manufacture Date: 07 June 2024

¹²⁵I-VGCC for total binding lot number: LT249

Expiry Date: 23 August 2024

¹²⁵I-VGCC for non-specific binding lot number: NS249

Expiry Date: 23 August 2024

Dilution buffer lot number: 243LB

Expiry Date: 23 August 2024

Anti-human IgG lot number: 27LGt

Expiry Date: 23 August 2024

Wash solution lot number: 173LW

Expiry Date: 23 August 2024

Negative control lot number: 21LNh

Expiry Date: 23 August 2024

Positive control lot number: 26LPg

Expiry Date: 23 August 2024

At Manufacture Date: 5758 dpm = 1 fmole

At QC Assay Date¹: 5562 dpm = 1 fmole (conversion factor A)

Counter Efficiency: 76.2 % (B)

²Positive control range: 205 ± 85 pmol/L

Sample	NSB		T			
	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	17569	4.145	18729	4.419		
Negative control	360	0.085	446	0.105	8.1 (G)	-
Positive control	381	0.090	2579	0.609	207.4 (F)	199.3 (H)
Test sample 1	328	0.077	2441	0.576	199.5 (F)	191.3 (H)
Test sample 2b	320	0.076	1384	0.327	100.4 (F)	92.3 (H)
Test sample 3c	335	0.079	1915	0.452	149.1 (F)	141.0 (H)
Test sample 4a	284	0.067	1606	0.379	124.7 (F)	116.6 (H)
Test sample 5d	383	0.090	2091	0.493	161.2 (F)	153.1 (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: 10 June 2024

Authorised by: DR G FLOOD

Performed by: Dr. Dale Jones

Signature: [Signature]

Signature: [Signature]

Position: Head of Quality Control

Position: Scientist

Date: 12th JUN 2024