

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

Document: **wi/qcrs/0.15**
Revision: **8**
Date: **15/08/18**
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Approved by: **J Davies**

Kit Lot Number: LK248A Kit Expiry Date: 28 June 2024
Kit Manufacture Date: 12 April 2024
¹²⁵I-VGCC for total binding lot number: LT248 Expiry Date: 28 June 2024
¹²⁵I-VGCC for non-specific binding lot number: NS248 Expiry Date: 28 June 2024
Dilution buffer lot number: 242LB Expiry Date: 28 June 2024
Anti-human IgG lot number: 27LGr Expiry Date: 28 June 2024
Wash solution lot number: 172LW Expiry Date: 28 June 2024
Negative control lot number: 21LNg Expiry Date: 28 June 2024
Positive control lot number: 26LPf Expiry Date: 28 June 2024

At Manufacture Date: 6339 dpm = 1 fmole
At QC Assay Date¹: 6123 dpm = 1 fmole (conversion factor A)
Counter Efficiency: 76.3 % (B) ²Positive control range: 195 ± 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	19313	4.134	18398	3.938		
Negative control	509	0.109	411	0.088	-8.4 (G)	-
Positive control	448	0.096	2898	0.620	209.8 (F)	218.2 (H)
Test sample 1	444	0.095	2702	0.578	193.3(F)	201.7 (H)
Test sample 2b	382	0.082	1297	0.278	78.3 (F)	86.7 (H)
Test sample 3c	437	0.093	1900	0.407	125.3 (F)	133.7 (H)
Test sample 4a	365	0.078	2684	0.574	198.5 (F)	206.9 (H)
Test sample 5d	468	0.100	2278	0.488	155.0 (F)	163.4 (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: 15 April 2024
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: 19TH APR 2024