

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

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Approved by: J Davies

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Page 1 of 1

Kit Lot Number: LK227 Kit Expiry Date: 30 JULY 2021
Kit Manufacture Date: 14 MAY 2021
¹²⁵I-VGCC for total binding lot number: LT227 Expiry Date: 30 JULY 2021
¹²⁵I-VGCC for non-specific binding lot number: NS227 Expiry Date: 30 JULY 2021
Dilution buffer lot number: 221LB Expiry Date: 30 JULY 2021
Anti-human IgG lot number: 26LGb Expiry Date: 30 JULY 2021
Wash solution lot number: 144LW Expiry Date: 30 JULY 2021
Negative control lot number: 19LNM Expiry Date: 30 JULY 2021
Positive control lot number: 24LPr Expiry Date: 30 JULY 2021

At Manufacture Date: 5508 dpm = 1 fmole
At QC Assay Date¹: 5260 dpm = 1 fmole (conversion factor A)
Counter Efficiency: 73.4 % (B) ²Positive control range: 160 ± 70 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	17488	4.530	18034	4.671		
Negative control	378	0.098	362	0.094	-1.6 (G)	-
Positive control	449	0.116	1854	0.480	145.6 (F)	147.2 ² (H)
Test sample 1	504	0.130	1604	0.415	114.0 (F)	115.6 (H)
Test sample 2b	448	0.116	1242	0.322	82.3 (F)	83.9 (H)
Test sample 3b	400	0.103	2087	0.541	174.9 (F)	176.5 (H)
Test sample 4a	300	0.078	1768	0.458	152.1 (F)	153.7 (H)
Test sample 5d	425	0.110	1927	0.499	155.7 (F)	157.3 (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: 18 MAY 2021
Performed by: J BRADBURY
Signature: J Bradbury
Position: Head of Operations

Authorised by: DR G Flood
Signature: G Flood
Position: Head of Quality Control
Date: 21st MAY 2021