

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

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Approved by: J Davies

Document: **wi/qcrs/0.15**
Revision: **8**
Date: **15/08/18**
Page: **1 of 1**

Kit Lot Number: LK239 Kit Expiry Date: 07 April 2023
Kit Manufacture Date: 20 January 2023
¹²⁵I-VGCC for total binding lot number: LT239 Expiry Date: 07 April 2023
¹²⁵I-VGCC for non-specific binding lot number: NS239 Expiry Date: 07 April 2023
Dilution buffer lot number: 233LB Expiry Date: 07 April 2023
Anti-human IgG lot number: 27LGd Expiry Date: 07 April 2023
Wash solution lot number: 159LW Expiry Date: 07 April 2023
Negative control lot number: 20LNm Expiry Date: 07 April 2023
Positive control lot number: 25LPk Expiry Date: 07 April 2023

At Manufacture Date: 6333 dpm = 1 fmole
At QC Assay Date¹: 6117 dpm = 1 fmole (conversion factor A)
Counter Efficiency: 76.3 % (B) ² Positive control range: 230 ± 100 pmol/L

	NSB		T			
Sample	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	18033	3.864	17932	3.842		
Negative control	438	0.094	341	0.073	-8.3 (G)	-
Positive control	472	0.101	2903	0.622	208.4(F)	216.6 (H)
Test sample 1	520	0.111	2820	0.604	197.1 (F)	205.4 (H)
Test sample 2b	406	0.087	1196	0.256	67.7 (F)	76.0 (H)
Test sample 3c	437	0.094	2064	0.442	139.5 (F)	147.8 (H)
Test sample 4a	368	0.079	2499	0.535	182.6 (F)	190.9 (H)
Test sample 5d	472	0.101	1909	0.409	123.2 (F)	131.5 (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: 23 January 2023
Performed by: Dr. Ian Matthews
Signature: *IMat*
Position: Principal Scientist

Authorised by: *DR G Flood*
Signature: *G Flood*
Position: Head of Quality Control
Date: 26th JAN 2023