

Title:

Quality Control Record Sheet VGCC Ab QC Data

Document: **wi/qcrs/0.15**Revision: **8**Date: **15/08/18**Page **1 of 1**Kit Lot Number: LK233 Kit Expiry Date: 06 MAY 2022Kit Manufacture Date: 18 FEBRUARY 2022¹²⁵I-VGCC for total binding lot number: LT233 Expiry Date: 06 MAY 2022¹²⁵I-VGCC for non-specific binding lot number: NS233 Expiry Date: 06 MAY 2022Dilution buffer lot number: 227LB Expiry Date: 06 MAY 2022Anti-human IgG lot number: 26LGh Expiry Date: 06 MAY 2022Wash solution lot number: 150LW Expiry Date: 06 MAY 2022Negative control lot number: 20LNd Expiry Date: 06 MAY 2022Positive control lot number: 25LPc Expiry Date: 06 MAY 2022At Manufacture Date: 5843 dpm = 1 fmoleAt QC Assay Date¹: 5644 dpm = 1 fmole (conversion factor A)Counter Efficiency: 75.9 % (B) ² Positive control range: 225 ± 100 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	17917	4.183	18194	4.247		
Negative control	458	0.107	360	0.084	-9.2 (G)	-
Positive control	452	0.106	2570	0.600	197.7 (F)	206.9 (H)
Test sample 1	463	0.108	2377	0.555	178.7 (F)	187.9 (H)
Test sample 2b	379	0.088	1135	0.265	70.6 (F)	79.8 (H)
Test sample 3c	428	0.100	1689	0.394	117.7 (F)	127.0 (H)
Test sample 4a	344	0.080	2206	0.515	173.9 (F)	183.1 (H)
Test sample 5d	455	0.106	1753	0.409	121.2 (F)	130.4 (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: 21 FEBRUARY 2022Performed by: Dr. Liang GuoSignature: [Signature]Position: Senior ScientistAuthorised by: DR G FloodSignature: [Signature]Position: Head of Quality ControlDate: 23RD FEB 2022