

Title:

Quality Control Record Sheet VGCC Ab QC Data

Document: **wi/qcrs/0.15**Revision: **8**Prepared by: **G Flood**Date: **15/08/18**Approved by: **J Davies**Page **1 of 1**Kit Lot Number: LK237 Kit Expiry Date: 16 DECEMBER 2022Kit Manufacture Date: 30 SEPTEMBER 2022¹²⁵I-VGCC for total binding lot number: LT237 Expiry Date: 16 DECEMBER 2022¹²⁵I-VGCC for non-specific binding lot number: NS237 Expiry Date: 16 DECEMBER 2022Dilution buffer lot number: 231LB Expiry Date: 16 DECEMBER 2022Anti-human IgG lot number: 27LGb Expiry Date: 16 DECEMBER 2022Wash solution lot number: 156LW Expiry Date: 16 DECEMBER 2022Negative control lot number: 20LNh Expiry Date: 16 DECEMBER 2022Positive control lot number: 25LPg Expiry Date: 16 DECEMBER 2022At Manufacture Date: 6112 dpm = 1 fmoleAt QC Assay Date¹: 5904 dpm = 1 fmole (conversion factor A)Counter Efficiency: 74.9 % (B) ²Positive control range: 200 ± 90 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	17995	4.069	17419	3.939		
Negative control	359	0.081	336	0.076	-2.1 (G)	-
Positive control	344	0.078	2759	0.624	218.5(F)	220.6 (H)
Test sample 1	367	0.083	2639	0.597	205.5 (F)	207.6 (H)
Test sample 2b	247	0.056	1178	0.266	84.2 (F)	86.3 (H)
Test sample 3b	345	0.078	2283	0.516	175.3 (F)	177.4 (H)
Test sample 4a	224	0.051	2247	0.508	183.0 (F)	185.1 (H)
Test sample 5d	321	0.073	1887	0.427	141.7 (F)	143.8 (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: 03 OCTOBER 2022Performed by: I. MatthewsSignature: *I. Matthews*Position: Principal ScientistAuthorised by: *DR G Flood*Signature: *G Flood*Position: Head of Quality ControlDate: 5TH OCT 2022