

Title:

Quality Control Record Sheet VGCC Ab QC Data

Document: **wi/qcrs/0.15**Revision: **8**Date: **15/08/18**Page **1 of 1**Prepared by: **G Flood**Approved by: **J Davies**Kit Lot Number: **LK235**Kit Expiry Date: **26 AUGUST 2022**Kit Manufacture Date: **10 JUNE 2022**¹²⁵I-VGCC for total binding lot number: **LT235**Expiry Date: **26 AUGUST 2022**¹²⁵I-VGCC for non-specific binding lot number: **NS235**Expiry Date: **26 AUGUST 2022**Dilution buffer lot number: **229LB**Expiry Date: **26 AUGUST 2022**Anti-human IgG lot number: **26LGm**Expiry Date: **26 AUGUST 2022**Wash solution lot number: **153LW**Expiry Date: **26 AUGUST 2022**Negative control lot number: **20LNf**Expiry Date: **26 AUGUST 2022**Positive control lot number: **25LPe**Expiry Date: **26 AUGUST 2022**At Manufacture Date: **5360** dpm = 1 fmoleAt QC Assay Date¹: **5118** dpm = 1 fmole (conversion factor A)Counter Efficiency: **75.1 % (B)**² Positive control range: **190 ± 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	17948	4.670	17731	4.613		
Negative control	488	0.127	385	0.100	-10.7 (G)	-
Positive control	459	0.119	2438	0.634	205.9 (F)	216.7 (H)
Test sample 1	549	0.143	2369	0.616	189.4 (F)	200.2 (H)
Test sample 2b	384	0.100	1128	0.293	77.4 (F)	88.2 (H)
Test sample 3c	431	0.112	1740	0.453	136.2 (F)	146.9 (H)
Test sample 4a	349	0.091	2123	0.552	184.7 (F)	195.4 (H)
Test sample 5d	458	0.119	1853	0.482	145.2 (F)	156.0 (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: **14 JUNE 2022**Performed by: **I. Matthews**Signature: **I. Matthews**Position: **Principal Scientist**Authorised by: **DR G Flood**Signature: **G Flood**Position: **Head of Quality Control**Date: **16th JUN 2022**