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

Prepared by: G Flood
Approved by: J Davies

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

Kit Lot Number: LK238 Kit Expiry Date: 10 FEBRUARY 2023

Kit Manufacture Date: 25 NOVEMBER 2022

^{125}I-VGCC for total binding lot number: LT238 Expiry Date: 10 FEBRUARY 2023

^{125}I-VGCC for non-specific binding lot number: NS238 Expiry Date: 10 FEBRUARY 2023

Dilution buffer lot number: 232LB Expiry Date: 10 FEBRUARY 2023

Anti-human IgG lot number: 27LGc Expiry Date: 10 FEBRUARY 2023

Wash solution lot number: 157LW Expiry Date: 10 FEBRUARY 2023

Negative control lot number: 20LNk Expiry Date: 10 FEBRUARY 2023

Positive control lot number: 25LPh Expiry Date: 10 FEBRUARY 2023

At Manufacture Date: 6507 dpm = 1 *f*mole

At QC Assay Date[1]: 6285 dpm = 1 *f*mole (conversion factor A)

Counter Efficiency: 76.3 % (B)

[2] Positive control range: 195 ± 85 pmol/L

	NSB		T			
Sample	**Mean cpm - background**	***f*mol/ Pellet (E)**	**Mean cpm - background**	***f*mol/ pellet (D)**	**^{125}I-conotoxin labelled VGCC bound (pmol/L serum)**	**pmol/L serum VGCC Ab (after subtraction of negative control)**
Total counts	17108	3.568	17798	3.711		
Negative control	372	0.078	351	0.073	-1.8 (G)	-
Positive control	363	0.076	2978	0.621	218.0 (F)	219.8 (H)
Test sample 1	342	0.071	2878	0.600	211.6 (F)	213.4 (H)
Test sample 2b	307	0.064	1237	0.258	77.6 (F)	79.4 (H)
Test sample 3c	371	0.077	1942	0.405	131.1 (F)	132.9 (H)
Test sample 4a	267	0.056	2406	0.502	178.4 (F)	180.2 (H)
Test sample 5d	422	0.088	1873	0.391	121.0 (F)	122.7 (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 Date[1]: 28 NOVEMBER 2022

Performed by: pp I. Matthews

Signature: JBradbury

Position: Principal Scientist

Authorised by: DR G FLOOD

Signature: G Flood

Position: **Head of Quality Control**

Date: 2ND DEC 2022