

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: LK236 Kit Expiry Date: 21 OCTOBER 2022
Kit Manufacture Date: 05 AUGUST 2022
¹²⁵I-VGCC for total binding lot number: LT236 Expiry Date: 21 OCTOBER 2022
¹²⁵I-VGCC for non-specific binding lot number: NS236 Expiry Date: 21 OCTOBER 2022
Dilution buffer lot number: 230LB Expiry Date: 21 OCTOBER 2022
Anti-human IgG lot number: 27LGa Expiry Date: 21 OCTOBER 2022
Wash solution lot number: 154LW Expiry Date: 21 OCTOBER 2022
Negative control lot number: 20LNq Expiry Date: 21 OCTOBER 2022
Positive control lot number: 25LPf Expiry Date: 21 OCTOBER 2022

At Manufacture Date: 5885 dpm = 1 fmole

At QC Assay Date¹: 5685 dpm = 1 fmole (conversion factor A)

Counter Efficiency: 74.9 % (B) ² Positive control range: 210 ± 95 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	17302	4.063	17330	4.070		
Negative control	422	0.099	379	0.089	-4.1 (G)	-
Positive control	452	0.106	2869	0.674	227.0 (F)	231.1 (H)
Test sample 1	483	0.113	2753	0.647	213.3 (F)	217.3 (H)
Test sample 2b	344	0.081	1215	0.285	81.8 (F)	85.9 (H)
Test sample 3c	432	0.102	1783	0.419	126.8 (F)	130.9 (H)
Test sample 4a	316	0.074	2509	0.589	206.0 (F)	210.1 (H)
Test sample 5d	439	0.103	1954	0.459	142.3 (F)	146.3 (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: 08 AUGUST 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: 11th AUG 2022