

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: LK234

Kit Expiry Date: 30 JUNE 2022

Kit Manufacture Date: 14 APRIL 2022

¹²⁵I-VGCC for total binding lot number: LT234

Expiry Date: 30 JUNE 2022

¹²⁵I-VGCC for non-specific binding lot number: NS234

Expiry Date: 30 JUNE 2022

Dilution buffer lot number: 228LB

Expiry Date: 30 JUNE 2022

Anti-human IgG lot number: 26LGk

Expiry Date: 30 JUNE 2022

Wash solution lot number: 151LW

Expiry Date: 30 JUNE 2022

Negative control lot number: 20LNe

Expiry Date: 30 JUNE 2022

Positive control lot number: 25LPd

Expiry Date: 30 JUNE 2022

At Manufacture Date: 5916 dpm = 1 fmole

At QC Assay Date¹: 5584 dpm = 1 fmole (conversion factor A)

Counter Efficiency: 73.4 % (B)

² Positive control range: 205 ± 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	17165	4.188	16870	4.116		
Negative control	500	0.122	414	0.101	-8.5 (G)	-
Positive control	493	0.120	2226	0.543	169.1 (F)	177.5 (H)
Test sample 1	516	0.126	1736	0.424	119.1 (F)	127.5 (H)
Test sample 2b	445	0.109	1026	0.250	56.7 (F)	65.1 (H)
Test sample 3c	482	0.117	1596	0.389	108.8 (F)	117.2 (H)
Test sample 4a	365	0.089	1949	0.475	154.6 (F)	163.0 (H)
Test sample 5d	505	0.123	1803	0.440	126.7 (F)	135.1 (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: 19 APRIL 2022

Performed by: A. HUCKLE

Signature: A. ifrane

Position: SNR LABORATORY TECHNICIAN

Authorised by: DR G FLOOD

Signature: 

Position: Head of Quality Control

Date: 21ST APR 2022