

Title:

Quality Control Record Sheet VGCC Ab QC Data

Document:

wi/qcrs/0.15

Revision:

8

Date:

15/08/18

Page

1 of 1

Kit Lot Number: LK241Kit Expiry Date: 28 July 2023Kit Manufacture Date: 12 May 2023¹²⁵I-VGCC for total binding lot number: LT241Expiry Date: 28 July 2023¹²⁵I-VGCC for non-specific binding lot number: NS241Expiry Date: 28 July 2023Dilution buffer lot number: 235LBExpiry Date: 28 July 2023Anti-human IgG lot number: 27LGfExpiry Date: 28 July 2023Wash solution lot number: 161LWExpiry Date: 28 July 2023Negative control lot number: 20LNpExpiry Date: 28 July 2023Positive control lot number: 25LPnExpiry Date: 28 July 2023At Manufacture Date: 5421 dpm = 1 fmoleAt QC Assay Date¹: 5236 dpm = 1 fmole (conversion factor A)Counter Efficiency: 71.2 % (B)² Positive control range: 200 ± 90 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	17075	4.580	17158	4.602		
Negative control	603	0.162	402	0.108	-21.5 (G)	-
Positive control	603	0.162	2235	0.599	175.1 (F)	196.6 (H)
Test sample 1	623	0.167	1931	0.518	140.3 (F)	161.8 (H)
Test sample 2b	612	0.164	1089	0.292	51.2 (F)	72.7 (H)
Test sample 3c	575	0.154	1758	0.472	127.0 (F)	148.5 (H)
Test sample 4a	465	0.125	1980	0.531	162.5 (F)	184.0 (H)
Test sample 5d	654	0.175	1787	0.479	121.6 (F)	143.1 (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: 15 May 2023Performed by: Dr. Ian MatthewsSignature: I. MatthewsPosition: Senior Principal ScientistAuthorised by: DR G FloodSignature: G FloodPosition: Head of Quality ControlDate: 18th MAY 2023