

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

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Kit Lot Number: LK243Kit Expiry Date: 17 November 2023Kit Manufacture Date: 01 September 2023¹²⁵I-VGCC for total binding lot number: LT243Expiry Date: 17 November 2023¹²⁵I-VGCC for non-specific binding lot number: NS243Expiry Date: 17 November 2023Dilution buffer lot number: 237LBExpiry Date: 17 November 2023Anti-human IgG lot number: 27LGhExpiry Date: 17 November 2023Wash solution lot number: 165LWExpiry Date: 17 November 2023Negative control lot number: 21LNbExpiry Date: 17 November 2023Positive control lot number: 26LPaExpiry Date: 17 November 2023At Manufacture Date: 5879 dpm = 1 fmoleAt QC Assay Date¹: 5679 dpm = 1 fmole (conversion factor A)Counter Efficiency: 76.2 % (B)² Positive control range: 190 ± 80 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	17503	4.045	16243	3.754		
Negative control	618	0.143	480	0.111	-12.8 (G)	-
Positive control	609	0.141	2557	0.591	180.0 (F)	192.8 (H)
Test sample 1	584	0.135	2067	0.478	137.0 (F)	149.8 (H)
Test sample 2b	689	0.159	1368	0.316	62.8 (F)	75.5 (H)
Test sample 3c	596	0.138	1699	0.393	102.0 (F)	114.7 (H)
Test sample 4a	470	0.109	2461	0.569	184.0 (F)	196.8 (H)
Test sample 5d	587	0.136	2025	0.468	132.9 (F)	145.7 (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 Date¹: 04 September 2023Authorised by: DR G FloodPerformed by: Dr. Dale JonesSignature: [Signature]Signature: [Signature]Position: Head of Quality ControlPosition: ScientistDate: 8th SEP 2023