

Title:

Quality Control Record Sheet VGCC Ab QC Data

Prepared by: G Flood
Approved by: J Davies

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Kit Lot Number: LK232AKit Expiry Date: 25 MARCH 2022Kit Manufacture Date: 07 JANUARY 2022¹²⁵I-VGCC for total binding lot number: LT232Expiry Date: 25 MARCH 2022¹²⁵I-VGCC for non-specific binding lot number: NS232Expiry Date: 25 MARCH 2022Dilution buffer lot number: 226LBExpiry Date: 25 MARCH 2022Anti-human IgG lot number: 26LGgExpiry Date: 25 MARCH 2022Wash solution lot number: 149LWAExpiry Date: 25 MARCH 2022Negative control lot number: 20LNcExpiry Date: 25 MARCH 2022Positive control lot number: 25LPbExpiry Date: 25 MARCH 2022At Manufacture Date: 6250 dpm = 1 fmoleAt QC Assay Date¹: 6037 dpm = 1 fmole (conversion factor A)Counter Efficiency: 73.4 % (B)² Positive control range: 215 ± 95 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	18108	4.087	17414	3.930		
Negative control	470	0.106	457	0.103	-1.2 (G)	-
Positive control	451	0.102	2622	0.592	196.0 (F)	197.1 (H)
Test sample 1	471	0.106	2112	0.477	148.1 (F)	149.3 (H)
Test sample 2b	367	0.083	1118	0.252	67.8 (F)	69.0 (H)
Test sample 3b	434	0.098	2333	0.526	171.4 (F)	172.6 (H)
Test sample 4a	327	0.074	2328	0.525	180.6 (F)	181.8 (H)
Test sample 5d	486	0.110	1954	0.441	132.5 (F)	133.7 (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: 10 JANUARY 2022Performed by: A. HuckleSignature: pp BradburyPosition: Senior TechnicianAuthorised by: DR G FloodSignature: [Signature]Position: Head of Quality ControlDate: 12th JAN 2022