

Title:

Quality Control Record Sheet VGCC Ab QC Data

Document:

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8

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Kit Lot Number: LK260Kit Expiry Date: 06 March 2026Kit Manufacture Date: 19 December 2025¹²⁵I-VGCC for total binding lot number: LT260Expiry Date: 06 March 2026¹²⁵I-VGCC for non-specific binding lot number: NS260Expiry Date: 06 March 2026Dilution buffer lot number: 254LBExpiry Date: 06 March 2026Anti-human IgG lot number: 29LGdExpiry Date: 06 March 2026Wash solution lot number: 192LWExpiry Date: 06 March 2026Negative control lot number: 22LNfExpiry Date: 06 March 2026Positive control lot number: 27LPdExpiry Date: 06 March 2026At Manufacture Date: 6901 dpm = 1 fmoleAt QC Assay Date¹: 6666 dpm = 1 fmole (conversion factor A)Counter Efficiency: 75.8 % (B)² Positive control range: 171 ± 77 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	16526	3.271	17534	3.470		
Negative control	310	0.061	358	0.071	3.8 (G)	-
Positive control	293	0.058	2082	0.412	141.6 (F)	137.8 (H)
Test sample 1a	317	0.063	3222	0.638	230.0 (F)	226.2 (H)
Test sample 2b	228	0.045	1113	0.220	70.1 (F)	66.3 (H)
Test sample 3c	257	0.051	1593	0.315	105.8 (F)	102.0 (H)
Test sample 4b	271	0.054	1608	0.318	105.8 (F)	102.0 (H)
Test sample 5d	294	0.058	1806	0.357	119.7 (F)	115.9 (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: 22 December 2025Authorised by: DR G FloodPerformed by: A. HuckleSignature: [Signature]Signature: A. ifrancePosition: Head of Quality ControlPosition: SNR TECHNICIANDate: 2ND JAN 2026