

Title: **Quality Control Record Sheet**  
**VGCC Ab QC Data**

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Revision: **8**  
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Approved by: **J Davies**

Kit Lot Number:           LK226           Kit Expiry Date: 04 JUNE 2021  
Kit Manufacture Date:           19 MARCH 2021            
<sup>125</sup>I-VGCC for total binding lot number:           LT226           Expiry Date: 04 JUNE 2021  
<sup>125</sup>I-VGCC for non-specific binding lot number:           NS226           Expiry Date: 04 JUNE 2021  
Dilution buffer lot number:           220LB           Expiry Date: 04 JUNE 2021  
Anti-human IgG lot number:           26LGa           Expiry Date: 04 JUNE 2021  
Wash solution lot number:           143LW           Expiry Date: 04 JUNE 2021  
Negative control lot number:           19LNk           Expiry Date: 04 JUNE 2021  
Positive control lot number:           24LPp           Expiry Date: 04 JUNE 2021

At Manufacture Date:           5169           dpm = 1 fmole  
At QC Assay Date<sup>1</sup>:           4993           dpm = 1 fmole (conversion factor A)  
Counter Efficiency: 76.25 % (B) <sup>2</sup>Positive control range: 180 ± 80 pmol/L

Sample	NSB		T			
	Mean cpm - background	fmol/ Pellet (E)	Mean cpm - background	fmol/ pellet (D)	<sup>125</sup> I-conotoxin labelled VGCC bound (pmol/L serum)	pmol/L serum VGCC Ab (after subtraction of negative control)
<b>Total counts</b>	17631	4.631	18139	4.764		
<b>Negative control</b>	330	0.087	380	0.100	5.2 (G)	-
<b>Positive control</b>	378	0.099	1837	0.483	153.3 (F)	148.1 (H)
<b>Test sample 1</b>	471	0.124	1866	0.490	146.6 (F)	141.3 (H)
<b>Test sample 2b</b>	398	0.105	1064	0.280	70.0 (F)	64.7 (H)
<b>Test sample 3b</b>	376	0.099	1991	0.523	169.7 (F)	164.5 (H)
<b>Test sample 4a</b>	265	0.069	1710	0.449	151.8 (F)	146.6 (H)
<b>Test sample 5d</b>	411	0.108	1879	0.494	154.2 (F)	149.0 (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 Date<sup>1</sup>:           22 MARCH 2021            
Performed by:           Dr. Liang Guo            
Signature:           *[Signature]*            
Position:           Senior Scientist          

Authorised by:           *OR G FLOOD*            
Signature:           *[Signature]*            
Position:           Head of Quality Control            
Date:           26<sup>TH</sup> MAR 2021