

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**

Page **1 of 1**

Kit Lot Number: LK252A

Kit Expiry Date: 07 February 2025

Kit Manufacture Date: 22 November 2024

<sup>125</sup>I-VGCC for total binding lot number: LT252

Expiry Date: 07 February 2025

<sup>125</sup>I-VGCC for non-specific binding lot number: NS252

Expiry Date: 07 February 2025

Dilution buffer lot number: 246LB

Expiry Date: 07 February 2025

Anti-human IgG lot number: 27LGw

Expiry Date: 07 February 2025

Wash solution lot number: 179LW

Expiry Date: 07 February 2025

Negative control lot number: 21LNn

Expiry Date: 07 February 2025

Positive control lot number: 26LPm

Expiry Date: 07 February 2025

At Manufacture Date: 6233 dpm = 1 fmole

At QC Assay Date<sup>1</sup>: 6021 dpm = 1 fmole (conversion factor A)

Counter Efficiency: 75.4 % (B)

<sup>2</sup>Positive control range: 190 ± 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>	17156	3.779	17191	3.787		
<b>Negative control</b>	387	0.085	356	0.078	-2.7 (G)	-
<b>Positive control</b>	455	0.100	2540	0.560	183.7 (F)	186.4 (H)
<b>Test sample 1</b>	410	0.090	2354	0.519	171.3 (F)	174.0 (H)
<b>Test sample 2b</b>	377	0.083	1321	0.291	83.2 (F)	85.9 (H)
<b>Test sample 3c</b>	449	0.099	1820	0.401	120.9 (F)	123.6 (H)
<b>Test sample 4b</b>	473	0.104	2108	0.464	144.0(F)	146.8 (H)
<b>Test sample 5d</b>	453	0.100	2228	0.491	156.4(F)	159.1 (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 Date<sup>1</sup>: 25 November 2024

Authorised by: DR G Flood

Performed by: Dr. Dale Jones

Signature: [Signature]

Signature: [Signature]

Position: Head of Quality Control

Position: Scientist

Date: 27<sup>th</sup> Nov 2024