

Title: **Quality Control Record Sheet  
VGKC Ab Kit QC Data**

Document: **wi/qcrs/0.37**

Revision: **3**

Prepared by: G Flood

Date:

**15.08.18**

Approved by: S Stephenson

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Kit lot number: VGK87 Kit Expiry Date: 09 Dec 2022

<sup>125</sup>I-Labelled VGKC lot number: VKT87 Expiry Date: 09 Dec 2022

Anti-Human IgG lot number: VKG17 Expiry Date: 24 Oct 2023

Assay Buffer lot number: VKB60 Expiry Date: 20 Jan 2023

Negative Control: VKNC84 Expiry Date: 09 Jan 2023

Positive Controls I and II: VKPCa/b84 Expiry Date: 09 Jan 2023

Tracer manufacture date: 30<sup>th</sup> September 2022

Total cpm in 50 µL of <sup>125</sup>I – VGKC: 56666

Specific activity of toxin (K): 3049 Ci/mmol

Counter efficiency: 73.4 %

Assay date (weeks after manufacture)	Decay factor (A)
Up to 1 week	1.0
+1 – 2 weeks	1.1
+2 – 3 weeks	1.2
+3 - 4 weeks	1.3
+4 – 5 weeks	1.4
+5 – 6 weeks	1.5
+6 – 7 weeks	1.6
+7 – 8 weeks	1.75
+8 – 9 weeks	1.9
+9 – 10 weeks	2.1

	Mean cpm	pM	Range (pM)
<b>Negative Control</b>	1128	-	-
<b>Positive Control I</b>	11649	448.5	435 ± 175
<b>Positive Control II</b>	5481	185.6	185 ± 75

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.

Assay performed by: Fiona Ryrie

Signature: Fiona Ryrie

Position: Scientist

Date of assay: 05<sup>th</sup> October 2022

Authorised by: DR G FLOOD

Signature: [Signature]

Position: HEAD OF QC

Date: 5<sup>th</sup> OCT 2022