

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: VGK79 Kit Expiry Date: 17 Sep 2021

<sup>125</sup>I-Labelled VGKC lot number: VKT79 Expiry Date: 17 Sep 2021

Anti-Human IgG lot number: VKG14 Expiry Date: 12 Nov 2022

Assay Buffer lot number: VKB54 Expiry Date: 19 Oct 2021

Negative Control: VKNC76 Expiry Date: 18 Oct 2021

Positive Controls I and II: VKPCa/b76 Expiry Date: 18 Oct 2021

Tracer manufacture date: 9<sup>th</sup> July 2021

Total cpm in 50  $\mu$ L of <sup>125</sup>I – VGKC: 54213

Specific activity of toxin (K): 2906 Ci/mmol

Counter efficiency: 72.3 %

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)
Negative Control	1011	-	-
Positive Control I	10196	417.1	420 $\pm$ 170
Positive Control II	4952	179.0	185 $\pm$ 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 Rylie

Authorised by: DR G Flood

Signature: S Stephenson

Signature: G Flood

Position: Scientist

Position: HEAD OF QC

Date of assay: 14<sup>th</sup> July 2021

Date: 16<sup>th</sup> Jul 2021