

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

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Prepared by: G Flood  
Approved by: S Stephenson

Kit lot number: VGK78 Kit Expiry Date: 23 Jul 2021  
<sup>125</sup>I-Labelled VGKC lot number: VKT78 Expiry Date: 23 Jul 2021  
 Anti-Human IgG lot number: VKG13 Expiry Date: 13 Jul 2022  
 Assay Buffer lot number: VKB54 Expiry Date: 19 Oct 2021  
 Negative Control: VKNC75 Expiry Date: 23 Aug 2021  
 Positive Controls I and II: VKPCa/b75 Expiry Date: 23 Aug 2021

Tracer manufacture date: 14<sup>th</sup> May 2021  
 Total cpm in 50  $\mu$ L of <sup>125</sup>I – VGKC: 56449  
 Specific activity of toxin (K): 2957 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	1092	-	-
Positive Control I	10544	421.8	430 $\pm$ 120
Positive Control II	5548	198.8	200 $\pm$ 60

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: 19<sup>th</sup> May 2021

Authorised by: *DR G Flood*  
 Signature: *G Flood*  
 Position: HEAD of QC  
 Date: 21<sup>st</sup> MAY 2021