

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

Prepared by: G Flood  
Approved by: S Stephenson

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Kit lot number: VGK83 Kit Expiry Date: 02 May 2022  
<sup>125</sup>I-Labelled VGKC lot number: VKT83 Expiry Date: 02 May 2022  
 Anti-Human IgG lot number: VKG16 Expiry Date: 01 Aug 2023  
 Assay Buffer lot number: VKB58 Expiry Date: 06 Aug 2022  
 Negative Control: VKNC80 Expiry Date: 27 May 2022  
 Positive Controls I and II: VKPCa/b80 Expiry Date: 27 May 2022

Tracer manufacture date: 21<sup>st</sup> February 2022  
 Total cpm in 50 µL of <sup>125</sup>I – VGKC: 54145  
 Specific activity of toxin (K): 2650 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	1100	-	-
Positive Control I	11302	502.3	480 ± 190
Positive Control II	5516	217.4	215 ± 85

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: 25<sup>th</sup> February 2022

Authorised by: SARAH NUTE  
 Signature: *SRNute*  
 Position: pp HEAD OF QC  
 Date: 25 FEB 2022