

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

Document: **wi/qcrs/0.37**  
 Revision: **3**  
 Date: **15.08.18**  
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Prepared by: G Flood  
 Approved by: S Stephenson

**Kit lot number:** VGK102 **Kit Expiry Date:** 28 Mar 2025  
<sup>125</sup>I-Labelled VGKC lot number: VKT102 Expiry Date: 28 Mar 2025  
 Anti-Human IgG lot number: VKG25 Expiry Date: 27 Feb 2026  
 Assay Buffer lot number: VKB70 Expiry Date: 16 Jun 2025  
 Negative Control: VKNC99 Expiry Date: 26 Apr 2025  
 Positive Controls I and II: VKPCa/b99 Expiry Date: 26 Apr 2025

**Tracer manufacture date:** 17<sup>th</sup> January 2025  
**Total cpm in 50 µL of <sup>125</sup>I – VGKC:** 55260  
**Specific activity of toxin (K):** 3639 **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)
<b>Negative Control</b>	1380	-	-
<b>Positive Control I</b>	12545	404.9	400 ± 180
<b>Positive Control II</b>	6358	180.5	185 ± 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: 22<sup>nd</sup> January 2025

Authorised by: DR G FLOOD  
 Signature: *G Flood*  
 Position: HEAD OF QC  
 Date: 24<sup>th</sup> JAN 2025