

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

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 Revision: **3**
 Date: **15.08.18**
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Prepared by: G Flood
 Approved by: S Stephenson

Kit lot number: VGK100 Kit Expiry Date: 06 Dec 2024
¹²⁵I-Labelled VGKC lot number: VKT100 Expiry Date: 06 Dec 2024
 Anti-Human IgG lot number: VKG24 Expiry Date: 19 Dec 2025
 Assay Buffer lot number: VKB69 Expiry Date: 14 Feb 2025
 Negative Control: VKNC97 Expiry Date: 06 Jan 2025
 Positive Controls I and II: VKPCa/b97 Expiry Date: 06 Jan 2025

Tracer manufacture date: 27th September 2024
 Total cpm in 50 µL of ¹²⁵I – VGKC: 51120
 Specific activity of toxin (K): 3563 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	1295	-	-
Positive Control I	11603	381.7	385 ± 175
Positive Control II	5794	166.6	175 ± 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: 02nd October 2024

Authorised by: *DR G Flood*
 Signature: *G Flood*
 Position: HEAD OF QC
 Date: 2nd OCT 2024