

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

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 Revision: 3
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Prepared by: G Flood
 Approved by: S Stephenson

Kit lot number: VGK82 Kit Expiry Date: 18 Mar 2022
¹²⁵I-Labelled VGKC lot number: VKT82 Expiry Date: 18 Mar 2022
 Anti-Human IgG lot number: VKG15 Expiry Date: 11 Apr 2023
 Assay Buffer lot number: VKB57 Expiry Date: 23 May 2022
 Negative Control: VKNC79 Expiry Date: 16 Apr 2022
 Positive Controls I and II: VKPCa/b79 Expiry Date: 16 Apr 2022

Tracer manufacture date: 07th January 2022
 Total cpm in 50 µL of ¹²⁵I – VGKC: 54261
 Specific activity of toxin (K): 2785 Ci/mmol
 Counter efficiency: 73.4 %

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	1229	-	-
Positive Control I	11670	487.3	465 ± 185
Positive Control II	5962	220.9	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 Rylie
 Signature: Fiona Rylie
 Position: Scientist
 Date of assay: 12th January 2022

Authorised by: DR G Flood
 Signature: G Flood
 Position: HEAD OF QC
 Date: 12th JAN 2022