

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: VGK84 Kit Expiry Date: 23 Jun 2022
¹²⁵I-Labelled VGKC lot number: VKT84 Expiry Date: 23 Jun 2022
 Anti-Human IgG lot number: VKG16 Expiry Date: 01 Aug 2023
 Assay Buffer lot number: VKB58 Expiry Date: 06 Aug 2022
 Negative Control: VKNC81 Expiry Date: 24 Jul 2022
 Positive Controls I and II: VKPCa/b81 Expiry Date: 24 Jul 2022

Tracer manufacture date: 14th April 2022
 Total cpm in 50 µL of ¹²⁵I – VGKC: 54253
 Specific activity of toxin (K): 2889 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	1043	-	-
Positive Control I	10222	429.2	435 ± 195
Positive Control II	5251	196.8	205 ± 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: 21st April 2022

Authorised by: DR G Flood
 Signature: *G Flood*
 Position: HEAD OF QC
 Date: 22nd APR 2022