

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: VGK94 Kit Expiry Date: 08 Jan 2024
¹²⁵I-Labelled VGKC lot number: VKT94 Expiry Date: 08 Jan 2024
Anti-Human IgG lot number: VKG21 Expiry Date: 01 Dec 2024
Assay Buffer lot number: VKB65 Expiry Date: 19 Mar 2024
Negative Control: VKNC91 Expiry Date: 05 Feb 2024
Positive Controls I and II: VKPCa/b91 Expiry Date: 05 Feb 2024

Tracer manufacture date: 30th October 2023
Total cpm in 50 µL of ¹²⁵I – VGKC: 55315
Specific activity of toxin (K): 3351 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	1372	-	-
Positive Control I	12583	436.5	430 ± 190
Positive Control II	6423	196.7	200 ± 90

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: 03rd November 2023

Authorised by: DR G Flood
Signature: G Flood
Position: HEAD OF QC
Date: 3RD NOV 2023