

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: VGK113 Kit Expiry Date: 04 December 2026
¹²⁵I-Labelled VGKC lot number: VKT113 Expiry Date: 04 Dec 2026
Anti-Human IgG lot number: VKG35 Expiry Date: 13 Mar 2028
Assay Buffer lot number: VKB75 Expiry Date: 12 Feb 2027
Negative Control: VKNC110 Expiry Date: 04 Jan 2027
Positive Controls I and II: VKPCa/b110 Expiry Date: 04 Jan 2027

Tracer manufacture date: 25th September 2026
Total cpm in 50 µL of ¹²⁵I – VGKC: 55543
Specific activity of toxin (K): 2737 Ci/mmol
Counter efficiency: 75.8 %

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	1564	-	-
Positive Control I	11215	443.9	452 ± 226
Positive Control II	6586	230.9	239 ± 119

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: F Rylie
Position: Scientist
Date of assay: 30th September 2026

Authorised by: DR G FLOOD
Signature: G Flood
Position: HEAD OF QC
Date: 30th SEP 2026