

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

Document: **wi/qcrs/0.37**

Prepared by: G Flood

Date:

Revision: **15.08.18**

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Approved by: S Stephenson

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Kit lot number: V GK88 **Kit Expiry Date:** 03 Feb 2023
¹²⁵I-Labelled VGKC lot number: VKT88 Expiry Date: 03 Feb 2023
Anti-Human IgG lot number: VKG19 Expiry Date: 23 May 2024
Assay Buffer lot number: VKB61 Expiry Date: 26 Mar 2023
Negative Control: VKNC85 Expiry Date: 04 Mar 2023
Positive Controls I and II: VKPCa/b85 Expiry Date: 04 Mar 2023

Tracer manufacture date: 25th November 2022

Total cpm in 50 µL of ¹²⁵I – VGKC: 55343

Specific activity of toxin (K): 2963 **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	1255	-	-
Positive Control I	10705	414.6	440 ± 200
Positive Control II	5607	190.9	195 ± 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

Authorised by: DR G FLOOD

Signature: Fiona Rylie

Signature: G Flood

Position: Scientist

Position: HEAD OF QC

Date of assay: 30th November 2022

Date: 1ST DEC 2022