

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

Document: **wi/qcrs/0.37**

Revision: **3**

Prepared by: G Flood

Date:

15.08.18

Approved by: S Stephenson

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Kit lot number: VGK97 Kit Expiry Date: 21 Jun 2024

¹²⁵I-Labelled VGKC lot number: VKT97 Expiry Date: 21 Jun 2024

Anti-Human IgG lot number: VKG23 Expiry Date: 28 Aug 2025

Assay Buffer lot number: VKB66 Expiry Date: 04 Jul 2024

Negative Control: VKNC94 Expiry Date: 21 Jul 2024

Positive Controls I and II: VKPCa/b94 Expiry Date: 21 Jul 2024

Tracer manufacture date: 12th April 2024

Total cpm in 50 µL of ¹²⁵I – VGKC: 57853

Specific activity of toxin (K): 3823 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	1480	-	-
Positive Control I	13628	419.3	415 ± 185
Positive Control II	6950	188.8	185 ± 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

Authorised by: DR G FLOOD

Signature: Fiona Ryrie

Signature: [Signature]

Position: Scientist

Position: HEAD OF QC

Date of assay: 17th April 2024

Date: 18th APR 2024