

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

Document: **wi/qcrs/0.37**

Prepared by: G Flood

Date:

Revision: **3**

Approved by: S Stephenson

15.08.18

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Kit lot number: V GK85 Kit Expiry Date: 19 Aug 2022
¹²⁵I-Labelled VGKC lot number: VKT85 Expiry Date: 19 Aug 2022
Anti-Human IgG lot number: VKG16 Expiry Date: 01 Aug 2023
Assay Buffer lot number: VKB59 Expiry Date: 04 Oct 2022
Negative Control: VKNC82 Expiry Date: 19 Sep 2022
Positive Controls I and II: VKPCa/b82 Expiry Date: 19 Sep 2022

Tracer manufacture date: 10th June 2022

Total cpm in 50 µL of ¹²⁵I – VGKC: 55204

Specific activity of toxin (K): 2723 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	1201	-	-
Positive Control I	10657	451.3	460 ± 180
Positive Control II	5804	219.7	230 ± 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

Authorised by: DR G FLOOD

Signature: Fiona Ryrie

Signature: G Flood

Position: Scientist

Position: HEAD OF QC

Date of assay: 15th June 2022

Date: 16th JUN 2022