

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

Document: **wi/qcrs/0.37**
Revision: **3**
Date: **15.08.18**
Page **1 of 1**

Prepared by: G Flood
Approved by: S Stephenson

Kit lot number: VGK77 Kit Expiry Date: 28 May 2021
¹²⁵I-Labelled VGKC lot number: VKT77 Expiry Date: 28 May 2021
 Anti-Human IgG lot number: VKG13 Expiry Date: 13 Jul 2022
 Assay Buffer lot number: VKB53 Expiry Date: 05 Jul 2021
 Negative Control: VKNC74 Expiry Date: 28 Jun 2021
 Positive Controls I and II: VKPCa/b74 Expiry Date: 28 Jun 2021

Tracer manufacture date: 19th March 2021
 Total cpm in 50 μ L of ¹²⁵I – VGKC: 52793
 Specific activity of toxin (K): 2729 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	1024	-	-
Positive Control I	9996	433.8	420 \pm 120
Positive Control II	4861	185.6	190 \pm 60

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: Scientific Assistant
 Date of assay: 24th March 2021

Authorised by: SARAH NUTE
 Signature: *SRNUTE*
 Position: pp HEAD OF QC
 Date: 25 MAR 2021