

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

Page

1 of 1

Kit lot number: VGK90 **Kit Expiry Date:** 26 May 2023

¹²⁵I-Labelled VGKC lot number: VKT90 Expiry Date: 26 May 2023

Anti-Human IgG lot number: VKG20 Expiry Date: 13 Aug 2024

Assay Buffer lot number: VKB62 Expiry Date: 13 Jun 2023

Negative Control: VKNC87A Expiry Date: 26 Jun 2023

Positive Controls I and II: VKPCa/b87 Expiry Date: 26 Jun 2023

Tracer manufacture date: 17th March 2023

Total cpm in 50 µL of ¹²⁵I – VGKC: 55839

Specific activity of toxin (K): 3336 **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	1068	-	-
Positive Control I	10648	382.1	390 ± 190
Positive Control II	5490	176.4	170 ± 80

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: 24th March 2023

Date: 24TH MAR 2023