Title:

## Quality Control Record Sheet VGKC Ab Kit QC Data

Prepared by: G Flood Approved by: S Stephenson Document: Revision:

wi/qcrs/0.37

Date: Page

15.08.18 1 of 1

 Kit lot number:
 VGK93
 Kit Expiry Date:
 10 Nov 2023

 125 I-Labelled VGKC lot number:
 VKT93
 Expiry Date:
 10 Nov 2023

 Anti-Human IgG lot number:
 VKG21
 Expiry Date:
 01 Dec 2024

 Assay Buffer lot number:
 VKB64
 Expiry Date:
 27 Dec 2023

 Negative Control:
 VKNC90
 Expiry Date:
 10 Dec 2023

 Positive Controls I and II:
 VKPCa/b90
 Expiry Date:
 10 Dec 2023

Tracer manufacture date: 01st September 2023

Total cpm in 50 μL of <sup>125</sup>I – VGKC: \_\_\_\_\_\_

Specific activity of toxin (K): \_\_\_\_\_\_ 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	рМ	Range (pM)
Negative Control	1326	-	-
Positive Control I	9673	418.3	435 ± 195
Positive Control II	5017	185.0	190 ± 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: RONG Ngru	Signature: 5
Position: Scientist	Position: LEAD OF QC
Date of assay: 06 <sup>th</sup> September 2023	Date: 7 TM SEP 2023