

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: VGK92A Kit Expiry Date: 15 Sep 2023

¹²⁵I-Labelled VGKC lot number: VKT92 Expiry Date: 15 Sep 2023

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

Assay Buffer lot number: VKB63 Expiry Date: 11 Oct 2023

Negative Control: VKNC89 Expiry Date: 16 Oct 2023

Positive Controls I and II: VKPCa/b89 Expiry Date: 16 Oct 2023

Tracer manufacture date: 07th July 2023

Total cpm in 50 μ L of ¹²⁵I – VGKC: 54534

Specific activity of toxin (K): 2903 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	1506	-	-
Positive Control I	10516	409.6	415 \pm 185
Positive Control II	5706	190.9	185 \pm 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 Rylie

Authorised by: DR G FLOOD

Signature: Fiona Rylie

Signature: G Flood

Position: Scientist

Position: HEAD OF QC

Date of assay: 12th July 2023

Date: 12th JULY 2023