

Title:

# Quality Control Record Sheet

## VGKC Ab Kit QC Data

Prepared by: G Flood

Approved by: S Stephenson

Document:

wi/qcrs/0.37

Revision:

3

Date:

15.08.18

Page

1 of 1

Kit lot number: VGK82 Kit Expiry Date: 18 Mar 2022

<sup>125</sup>I-Labelled VGKC lot number: VKT82 Expiry Date: 18 Mar 2022

Anti-Human IgG lot number: VKG15 Expiry Date: 11 Apr 2023

Assay Buffer lot number: VKB57 Expiry Date: 23 May 2022

Negative Control: VKNC79 Expiry Date: 16 Apr 2022

Positive Controls I and II: VKPCa/b79 Expiry Date: 16 Apr 2022

Tracer manufacture date: 07<sup>th</sup> January 2022Total cpm in 50  $\mu$ L of <sup>125</sup>I - VGKC: 54261Specific activity of toxin (K): 2785 Ci/mmolCounter 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	1229	-	-
Positive Control I	11670	487.3	465 $\pm$ 185
Positive Control II	5962	220.9	215 $\pm$ 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 RyrieSignature: Fiona RyriePosition: ScientistDate of assay: 12<sup>th</sup> January 2022Authorised by: DR G FloodSignature: G FloodPosition: HEAD OF QCDate: 12<sup>th</sup> JAN 2022