Title:

## Quality Control Record Sheet VGKC Ab Kit QC Data

Prepared by: G Flood Approved by: S Stephenson

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Kit lot number: VGK9	8	Kit Expiry Date:	16 Aug 2024
<sup>125</sup> I-Labelled VGKC lot number: _	VKT98	Expiry Date:	16 Aug 2024
Anti-Human IgG lot number:	VKG23	Expiry Date:	28 Aug 2025
Assay Buffer lot number:	VKB68	Expiry Date:	07 Nov 2024
Negative Control:	VKNC95	Expiry Date:	16 Sep 2024
Positive Controls I and II:	VKPCa/b95	Expiry Date:	16 Sep 2024

Tracer manufacture date: 07th June 2024 Total cpm in 50 µL of 125I - VGKC: 58536 Specific activity of toxin (K): 3813 Ci/mmol 72.3 % Counter efficiency:

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	1407	-	-
Positive Control I	12993	401.0	390 ± 170
Positive Control II	6374	171.9	170 ± 70

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: NR & FLOOD
Signature: Fora Nyiu	Signature: 5
Position: Scientist	Position: NEAD OF QC
Date of assay: 12 <sup>th</sup> June 2024	Date: 13 T JUN 2024