

Title: **Quality Control Record Sheet  
VGKC Ab Kit QC Data**

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Revision: **3**  
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Prepared by: G Flood  
Approved by: S Stephenson

Kit lot number:           V GK103           Kit Expiry Date:           23 May 2025            
<sup>125</sup>I-Labelled VGKC lot number:           VKT103           Expiry Date:           23 May 2025            
Anti-Human IgG lot number:           VKG27           Expiry Date:           17 Aug 2026            
Assay Buffer lot number:           VKB70           Expiry Date:           16 Jun 2025            
Negative Control:           VKNC100           Expiry Date:           23 Jun 2025            
Positive Controls I and II:           VKPCa/b100           Expiry Date:           23 Jun 2025          

Tracer manufacture date:           14<sup>th</sup> March 2025            
Total cpm in 50 µL of <sup>125</sup>I – VGKC:           53432            
Specific activity of toxin (K):           4133           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	1786	-	-
Positive Control I	14718	412.9	430 ± 190
Positive Control II	8129	202.5	220 ± 100

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            
Signature:           Fiona Ryrie            
Position:           Scientist            
Date of assay:           19<sup>th</sup> March 2025          

Authorised by:           DR G FLOOD            
Signature:           G Flood            
Position:           HEAD OF QC            
Date:           19<sup>th</sup> MAR 2025