

Title:

Quality Control Record Sheet

VGKC Ab Kit QC Data

Prepared by: G Flood

Approved by: S Stephenson

Document:

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3

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Kit lot number: VGK108Kit Expiry Date: 27 February 2026¹²⁵I-Labelled VGKC lot number: VKT108Expiry Date: 27 Feb 2026Anti-Human IgG lot number: VKG31Expiry Date: 19 Apr 2027Assay Buffer lot number: VKB73Expiry Date: 04 May 2026Negative Control: VKNC105Expiry Date: 04 Apr 2026Positive Controls I and II: VKPCa/b105Expiry Date: 04 Apr 2026Tracer manufacture date: 19th December 2025Total cpm in 50 μ L of ¹²⁵I – VGKC: 54967Specific activity of toxin (K): 3545 Ci/mmolCounter efficiency: 75.8 %

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	1803	-	-
Positive Control I	14099	436.6	425 \pm 212
Positive Control II	8529	238.8	226 \pm 113

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: F RyriePosition: ScientistDate of assay: 24th December 2025Authorised by: DR G FloodSignature: G FloodPosition: HEAD OF QCDate: 2nd JAN 2026