

Title: **Quality Control Record Sheet
MuSK Ab Assay QC Data**

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Approved by: J BRADBURY

Kit Lot Number: <u>KMK255A</u>	Kit Expiry Date: <u>16 SEPTEMBER 2024</u>
¹²⁵ I-labelled MuSK: <u>MK255</u>	Expiry Date: <u>16 SEPTEMBER 2024</u>
Reconstitution Buffer: <u>173B</u>	Expiry Date: <u>28 FEBRUARY 2025</u>
Anti Human IgG: <u>181Gu</u>	Expiry Date: <u>28 APRIL 2025</u>
Precipitation Enhancer: <u>PE195</u>	Expiry Date: <u>18 MARCH 2025</u>
Wash Solution: <u>450W</u>	Expiry Date: <u>04 APRIL 2025</u>
Negative Control: <u>MKN42e</u>	Expiry Date: <u>28 JANUARY 2025</u>
Positive Control: <u>MKP42p</u>	Expiry Date: <u>28 JANUARY 2025</u>

Specific activity of ¹²⁵I-labelled MuSK: 1814 Ci/mmol (33.0 μ Ci/ μ g)

Total cpm in 50 μ L of labelled MuSK: 45822

MuSK labelling date: 22 JULY 2024

% Counter Efficiency: 72.3

¹²⁵I Decay Table:

QC date (weeks after labelling date)	Decay factor
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

Positive Control	Mean cpm	Nmol/L	Range (nmol/L)
Negative Control	413	-	-
Positive Control	11653	0.7719	0.77 \pm 0.38

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 Date: 25 JULY 2024
Performed by: Jonathon Davies
Signature: [Signature]
Position: Senior Scientist

Authorised by: DR G FLOOD
Signature: [Signature]
Position: Head of Quality Control
Date: 25th JULY 2024