

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

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Prepared by: G FLOOD
Approved by: J BRADBURY

Kit Lot Number: _____	KMK256A	Kit Expiry Date: <u>14 OCTOBER 2024</u>
¹²⁵ I-labelled MuSK: _____	MK256	Expiry Date: <u>14 OCTOBER 2024</u>
Reconstitution Buffer: _____	173B	Expiry Date: <u>28 FEBRUARY 2025</u>
Anti Human IgG: _____	181Gv	Expiry Date: <u>25 MAY 2025</u>
Precipitation Enhancer: _____	PE196	Expiry Date: <u>04 JUNE 2025</u>
Wash Solution: _____	450W	Expiry Date: <u>04 APRIL 2025</u>
Negative Control: _____	MKN42f	Expiry Date: <u>25 FEBRUARY 2025</u>
Positive Control: _____	MKP43a	Expiry Date: <u>25 FEBRUARY 2025</u>

Specific activity of ¹²⁵I-labelled MuSK: _____ 1879 _____ Ci/mmol (34.2 μCi/μg)

Total cpm in 50 μL of labelled MuSK: _____ 46525 _____

MuSK labelling date: 19 AUGUST 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	394	-	-
Positive Control	10398	0.6633	0.77 ± 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: 22 AUGUST 2024
Performed by: Jonathon Davies
Signature: _____
Position: Senior Scientist

Authorised by: DR G FLOOD
Signature: _____
Position: Head of Quality Control
Date: 23RD AUG 2024