

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

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Approved by: J BRADBURY

<b>Kit Lot Number:</b> <u>KMK251</u>	<b>Kit Expiry Date:</b> <u>28 JUNE 2024</u>
<sup>125</sup> I-labelled MuSK: <u>MK251</u>	Expiry Date: <u>28 JUNE 2024</u>
Reconstitution Buffer: <u>172B</u>	Expiry Date: <u>17 OCTOBER 2024</u>
Anti Human IgG: <u>181Gp</u>	Expiry Date: <u>05 FEBRUARY 2025</u>
Precipitation Enhancer: <u>PE194</u>	Expiry Date: <u>30 JANUARY 2025</u>
Wash Solution: <u>444W</u>	Expiry Date: <u>21 NOVEMBER 2024</u>
Negative Control: <u>MKN42b</u>	Expiry Date: <u>05 NOVEMBER 2024</u>
Positive Control: <u>MKP42k</u>	Expiry Date: <u>05 NOVEMBER 2024</u>

Specific activity of <sup>125</sup>I-labelled MuSK: 1839 Ci/mmol ( 33.4 µCi/µg)

Total cpm in 50 µL of labelled MuSK: 45266

MuSK labelling date: 03 MAY 2024

% Counter Efficiency: 72.3

<sup>125</sup>I 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	271	-	-
Positive Control	12040	0.804	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: 12 MAY 2024  
Performed by: Janet Bradbury  
Signature: J Bradbury  
Position: Head of Operations

Authorised by: DR G Flood  
Signature: G Flood  
Position: Head of Quality Control  
Date: 13<sup>th</sup> MAY 2024