

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

Document: **wi/qcrs/0.30a**

Revision: **0**

Prepared by: **G FLOOD**

Issue date: **20.10.2021**

Approved by: **J BRADBURY**

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**Kit Lot Number:** KMK253

**Kit Expiry Date:** 29 JULY 2024

<sup>125</sup>I-labelled MuSK: MK253

Expiry Date: 29 JULY 2024

Reconstitution Buffer: 172B

Expiry Date: 17 OCTOBER 2024

Anti Human IgG: 181Gr

Expiry Date: 02 MARCH 2025

Precipitation Enhancer: PE195

Expiry Date: 18 MARCH 2025

Wash Solution: 444W

Expiry Date: 21 NOVEMBER 2024

Negative Control: MKN42c

Expiry Date: 02 DECEMBER 2024

Positive Control: MKP42m

Expiry Date: 02 DECEMBER 2024

Specific activity of <sup>125</sup>I-labelled MuSK: 1443 Ci/mmol ( 26.2  $\mu$ Ci/ $\mu$ g)

Total cpm in 50  $\mu$ L of labelled MuSK: 46700

MuSK labelling date: 03 JUNE 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	334	-	-
Positive Control	11538	0.9527	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: 07 JUNE 2024

Authorised by: DR G Flood

Performed by: Jonathon Davies

Signature: [Signature]

Signature: [Signature]

Position: Head of Quality Control

Position: Senior Scientist

Date: 10<sup>TH</sup> JUN 2024