

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

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Approved by: J BRADBURY

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| | |
|--|---|
| Kit Lot Number: <u>KMK254</u> | Kit Expiry Date: <u>19 AUGUST 2024</u> |
| ¹²⁵ I-labelled MuSK: <u>MK254</u> | Expiry Date: <u>19 AUGUST 2024</u> |
| Reconstitution Buffer: <u>172B</u> | Expiry Date: <u>17 OCTOBER 2024</u> |
| Anti Human IgG: <u>181Gt</u> | Expiry Date: <u>31 MARCH 2025</u> |
| Precipitation Enhancer: <u>PE195</u> | Expiry Date: <u>18 MARCH 2025</u> |
| Wash Solution: <u>444W</u> | Expiry Date: <u>21 NOVEMBER 2024</u> |
| Negative Control: <u>MKN42d</u> | Expiry Date: <u>31 DECEMBER 2024</u> |
| Positive Control: <u>MKP42n</u> | Expiry Date: <u>31 DECEMBER 2024</u> |

Specific activity of ¹²⁵I-labelled MuSK: 1715 Ci/mmol (31.2 μ Ci/ μ g)

Total cpm in 50 μ L of labelled MuSK: 46430

MuSK labelling date: 24 JUNE 2024

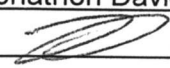
% Counter Efficiency: 72.3

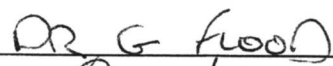
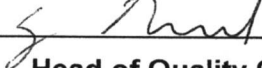
¹²⁵I Decay Table:

| 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 | 377 | - | - |
| Positive Control | 12475 | 0.8659 | 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: 27 JUNE 2024
Performed by: Jonathon Davies
Signature: 
Position: Senior Scientist

Authorised by: 
Signature: 
Position: Head of Quality Control
Date: 27TH JUN 2024