Title:

Quality Control Record Sheet MuSK Ab Assay QC Data

Prepared by:

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Approved by: J BRADBURY

Document:

wi/qcrs/0.30a

Revision:

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20.10.2021

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| Kit Lot Number: | KMK264 | | Kit Expiry Date: 28 APRIL 2025 |
|--|----------|-------|--------------------------------|
| 125 I-labelled MuSK: | | | Expiry Date: 28 APRIL 2025 |
| Reconstitution Buffer: | | | Expiry Date: 25 SEPTEMBER 2025 |
| Anti Human IgG: | 185Ge | | Expiry Date: 09 DECEMBER 2025 |
| Precipitation Enhancer: | PE198 | | Expiry Date: 31 OCTOBER 2025 |
| Wash Solution: | 457W | | Expiry Date: 07 SEPTEMBER 2025 |
| Negative Control: | MKN42r | | Expiry Date: 09 SEPTEMBER 2025 |
| Positive Control: | MKP44e | | Expiry Date: 09 SEPTEMBER 2025 |
| Specific activity of ¹²⁵ I-labelled MuSK: | | 1857 | Ci/mmol (33.8 μCi/μg) |
| Total cpm in 50 μL of labelled MuSK: | | 46539 | |
| MuSK labelling date: 03 MAR | RCH 2025 | | |
| % Counter Efficiency: | 73.4 | | |

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 | 409 | - | - |
| Positive Control | 15200 | 0.9774 | 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: | 06 MARCH 2025 | |
|---------------|------------------|---|
| Performed by: | Jonathon Davies | _ |
| Signature: | | _ |
| Position: | Senior Scientist | |

| Authorised by: _ | SARAH NUTE | |
|------------------|------------|--|
| Signature: | Senute | |

Position: Position: Head of Quality Control

Date: 06 MAR 2025