Title:

Quality Control Record Sheet ¹²⁵I-labelled MuSK QC Data

Prepared by:

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Approved by: J E

J BRADBURY

Document:

wi/qcrs/0.30a

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| Kit Lot Number: | KMK249 | | Kit Expiry Date: 28 MAY 2024 | | |
|--|----------|-------------------------------------|-------------------------------------|--|--|
| ¹²⁵ I-labelled MuSK: | MK249 | | Expiry Date: 28 MAY 2024 | | |
| Reconstitution Buffer: | 172B | | Expiry Date: 17 OCTOBER 2024 | | |
| Anti Human IgG: | 181Gn | | Expiry Date: 07 JANUARY 2025 | | |
| Precipitation Enhancer: | PE194 | 4 Expiry Date: 30 JANUARY 2025 | | | |
| Wash Solution: | 444W | | Expiry Date: 21 NOVEMBER 2024 | | |
| Negative Control: | MKN42a | Expiry Date: <u>07 OCTOBER 2024</u> | | | |
| Positive Control: | MKP42h | | Expiry Date: <u>07 OCTOBER 2024</u> | | |
| Specific activity of ¹²⁵ I-labelled MuSK: | | 2034 | Ci/mmol (37.0 μCi/μg) | | |
| Total cpm in 50 μL of labelled | MuSK: | 49164 | | | |
| MuSK labelling date: 02 APF | RIL 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 | 414 | - | - |
| Positive Control | 13356 | 0.7811 | 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: 05 APRIL 2024

Performed by: ______Jonathon Davies

Signature:

Position: Senior Scientist

Authorised by: DR G FLOOD

Signature: 3 Mun

Position: Head of Quality Control

Date: 5Th APR 2024