| | | | |
|---|---|---|---|
| Title: | **Quality Control Record Sheet** $^{125}$**I-labelled MuSK QC Data** | Document: | wi/qcrs/0.30a |
| | | Revision: | 0 |
| Prepared by: | G FLOOD | Issue date: | 20.10.2021 |
| Approved by: | J BRADBURY | Page | 1 of 1 |

**Kit Lot Number:** KMK239 **Kit Expiry Date:** 21 AUGUST 2023

$^{125}$I-labelled MuSK: MK239 Expiry Date: 21 AUGUST 2023

Reconstitution Buffer: 169B Expiry Date: 19 DECEMBER 2023

Anti Human IgG: 180Gad Expiry Date: 02 APRIL 2024

Precipitation Enhancer: PE189 Expiry Date: 19 FEBRUARY 2024

Wash Solution: 431W Expiry Date: 02 JANUARY 2024

Negative Control: MKN41c Expiry Date: 02 JANUARY 2024

Positive Control: MKP41h Expiry Date: 02 JANUARY 2024

Specific activity of $^{125}$I-labelled MuSK: 1770 Ci/mmol ( 32.2 μCi/μg)

Total cpm in 50 μL of labelled MuSK: 45121

MuSK labelling date: 26 JUNE 2023

% Counter Efficiency: 72.3

$^{125}$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 | 342 | - | - |
| Positive Control | 10396 | 0.6972 | 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: 29 JUNE 2023

Performed by: Jonathon Davies

Signature:

Position: Senior Scientist

Authorised by: DR G FLOOD

Signature:

Position: **Head of Quality Control**

Date: 29TH JUN 2023