

CERTIFICATE OF ANALYSIS

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Product Description: Muscle Injury Panel 3 (mouse) Kit
Kit Catalog Numbers: K15186C-Series
Kit Lot Number: K0040462
Expiration Date: 31 May 2021

Acceptance Data/ Percent Recovery Specifications:

| Spot | Name | Calibrator | | Muscle Injury Panel 3 (mouse) Control 1 | | Muscle Injury Panel 3 (mouse) Control 2 | | Muscle Injury Panel 3 (mouse) Control 3 | |
|------|-------|------------|-------|---|-------|---|-------|---|-------|
| | | Recovery | CV | Recovery | CV | Recovery | CV | Recovery | CV |
| 1 | cTnI | 80% - 120% | < 20% | 75% - 125% | < 20% | 75% - 125% | < 20% | 75% - 125% | < 20% |
| 3 | FABP3 | 80% - 120% | < 20% | 75% - 125% | < 20% | 75% - 125% | < 20% | 75% - 125% | < 20% |
| 5 | MyI3 | 80% - 120% | < 20% | 75% - 125% | < 20% | 75% - 125% | < 20% | 75% - 125% | < 20% |
| 6 | sTnI | 80% - 120% | < 20% | 75% - 125% | < 20% | 75% - 125% | < 20% | 75% - 125% | < 20% |

| Spot | Name | LLOQ | | | ULOQ | | |
|------|-------|--------|------------|-------|-------|------------|-------|
| | | Value | Recovery | CV | Value | Recovery | CV |
| 1 | cTnI | 0.0700 | 75% - 125% | < 25% | 20.0 | 80% - 120% | < 20% |
| 3 | FABP3 | 1.00 | 75% - 125% | < 25% | 26.8 | 80% - 120% | < 20% |
| 5 | MyI3 | 0.300 | 75% - 125% | < 25% | 41.4 | 80% - 120% | < 20% |
| 6 | sTnI | 0.505 | 75% - 125% | < 25% | 155 | 80% - 120% | < 20% |

Acceptance Data/ Non Specific Binding Specifications:

| Spot | Name | NSB Spec |
|------|-------|----------|
| 1 | cTnI | < 1.0% |
| 3 | FABP3 | < 1.0% |
| 5 | MyI3 | < 1.0% |
| 6 | sTnI | < 1.0% |

Stock Concentration of Material Tested :

| Spot | Name | Item | Conc | Units |
|------|-------|---|------|-------|
| 1 | cTnI | 20X Calibrator | 618 | ng/mL |
| | | Muscle Injury Panel 3 (mouse) Control 1 | 43.2 | ng/mL |
| | | Muscle Injury Panel 3 (mouse) Control 2 | 5.88 | ng/mL |
| | | Muscle Injury Panel 3 (mouse) Control 3 | 1.6 | ng/mL |
| 3 | FABP3 | 20X Calibrator | 1550 | ng/mL |
| | | Muscle Injury Panel 3 (mouse) Control 1 | 48.6 | ng/mL |
| | | Muscle Injury Panel 3 (mouse) Control 2 | 12.2 | ng/mL |
| | | Muscle Injury Panel 3 (mouse) Control 3 | 4.64 | ng/mL |
| 5 | MyI3 | 20X Calibrator | 866 | ng/mL |
| | | Muscle Injury Panel 3 (mouse) Control 1 | 105 | ng/mL |
| | | Muscle Injury Panel 3 (mouse) Control 2 | 26.6 | ng/mL |
| | | Muscle Injury Panel 3 (mouse) Control 3 | 1.8 | ng/mL |

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| | | | | |
|---|------|---|------|-------|
| 6 | sTnI | 20X Calibrator | 4680 | ng/mL |
| | | Muscle Injury Panel 3 (mouse) Control 1 | 195 | ng/mL |
| | | Muscle Injury Panel 3 (mouse) Control 2 | 31.6 | ng/mL |
| | | Muscle Injury Panel 3 (mouse) Control 3 | 5.04 | ng/mL |

Control data was generated utilizing internal reference controls.

Concentrations provided in this table refer to the stock concentration of the calibrators. For top of the standard curve concentrations, please refer to the Standard Curve Data

Standard Curve Data:

| cTnI - Spot 1 | | |
|---------------|------------|-----|
| Conc. ng/mL | ECL Signal | %CV |
| 30.9 | 556,000 | 7.7 |
| 7.72 | 144,000 | 8.9 |
| 1.93 | 27,000 | 5.1 |
| 0.483 | 5,520 | 9.2 |
| 0.121 | 1,360 | 6.7 |
| 0.0302 | 394 | 6.4 |
| 0.00754 | 169 | 4.8 |
| 0.00 | 84 | 8.0 |

| FABP3 - Spot 3 | | |
|----------------|------------|-----|
| Conc. ng/mL | ECL Signal | %CV |
| 77.5 | 87,000 | 5.8 |
| 19.4 | 60,800 | 6.0 |
| 4.84 | 22,200 | 4.3 |
| 1.21 | 4,090 | 8.7 |
| 0.303 | 1,050 | 5.1 |
| 0.0757 | 599 | 4.2 |
| 0.0189 | 501 | 4.7 |
| 0.00 | 493 | 6.0 |

| MyI3 - Spot 5 | | |
|---------------|------------|-----|
| Conc. ng/mL | ECL Signal | %CV |
| 43.3 | 95,400 | 5.9 |
| 10.8 | 21,500 | 5.7 |
| 2.71 | 4,930 | 6.0 |
| 0.677 | 1,290 | 5.5 |
| 0.169 | 410 | 8.5 |
| 0.0423 | 205 | 5.9 |
| 0.0106 | 147 | 7.3 |
| 0.00 | 131 | 7.2 |

| sTnI - Spot 6 | | |
|---------------|------------|------|
| Conc. ng/mL | ECL Signal | %CV |
| 234 | 624,000 | 5.8 |
| 58.5 | 162,000 | 2.4 |
| 14.6 | 33,300 | 2.8 |
| 3.66 | 7,380 | 2.6 |
| 0.914 | 2,040 | 3.7 |
| 0.229 | 666 | 5.4 |
| 0.0571 | 337 | 16.0 |
| 0.00 | 210 | 34.0 |

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Components:

| Description | Lot Number | Storage Temperature | Expiration Date |
|--|------------------|---------------------|-----------------|
| Muscle Injury Panel 3 (mouse) Plate | Z0056485 | 2-8°C | 31 Aug 2021 |
| Anti-ms cTnI Antibody | D0040831 | 2-8°C | 30 Nov 2022 |
| Anti-ms FABP3 Antibody | D0040832 | 2-8°C | 31 Dec 2022 |
| Anti-ms MyI3 Antibody | D0040833 | 2-8°C | 31 Aug 2022 |
| Anti-ms sTnI Antibody | D0040834 | 2-8°C | 31 Aug 2022 |
| Muscle Injury Panel 3 (mouse) Calibrator Blend | A0040244 | ≤ -70°C | 30 Jun 2022 |
| Diluent 33 | M0330012 | ≤ -10°C | 31 Oct 2021 |
| Diluent 30 | M0300026 | ≤ -10°C | 31 Oct 2021 |
| DTT | R0010649 | ≤ -10°C | 31 May 2021 |
| EDTA pH 8.0 | R0010660 | Room Temperature | 31 Oct 2021 |
| MSD Read Buffer T | Not Kit Specific | Not Kit Specific | N/A |

Statement:

The above product is intended for Research Use Only. Not for use in Diagnostic Procedures.

| | Name | Function | Signature | Date |
|------------------------|---------------|----------|--|-------------|
| Review/Approval | Karen Hamilla | Quality |  | 14 APR 2020 |