

CERTIFICATE OF ANALYSIS

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Product Description: Muscle Injury Panel 1 (rat) Kit
Kit Lot Number: K0040511
Expiration Date: 30 Sep 2022
Kit Catalog Numbers: K15181C-Series

Precision and Accuracy Specifications:

| Spot | Name | Calibrator | | Muscle Injury Panel 1 Control 1 | | Muscle Injury Panel 1 Control 2 | | Muscle Injury Panel 1 Control 3 | |
|------|-------|------------|-------|---------------------------------|-------|---------------------------------|-------|---------------------------------|-------|
| | | Recovery | CV | Recovery | CV | Recovery | CV | Recovery | CV |
| 1 | cTnI | 80% - 120% | < 20% | 75% - 125% | < 20% | 75% - 125% | < 20% | 75% - 125% | < 20% |
| 2 | cTnT | 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 | Myl3 | 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 | 0.0977 | 80% - 120% | < 20% | 15.0 | 80% - 120% | < 20% |
| 2 | cTnT | 0.488 | 80% - 120% | < 20% | 35.0 | 80% - 120% | < 20% |
| 3 | FABP3 | 0.391 | 75% - 125% | < 25% | 15.0 | 75% - 125% | < 25% |
| 5 | Myl3 | 0.170 | 75% - 125% | < 25% | 44.0 | 80% - 120% | < 20% |
| 6 | sTnI | 0.781 | 80% - 120% | < 20% | 160 | 80% - 120% | < 20% |

Non-Specific Binding Specifications:

| Spot | Name | cTnI | cTnT | FABP3 | Myl3 | sTnI |
|------|-------|---------|---------|--------|--------|--------|
| 1 | cTnI | NA | < 1.0% | < 1.0% | < 1.0% | < 1.0% |
| 2 | cTnT | < 1.0% | NA | < 1.0% | < 1.0% | < 1.0% |
| 3 | FABP3 | < 1.0% | < 1.0% | NA | < 1.0% | < 1.0% |
| 5 | Myl3 | < 1.0% | < 1.0% | < 1.0% | NA | < 1.0% |
| 6 | sTnI | < 65.0% | < 15.0% | < 1.0% | < 1.0% | NA |

Stock Concentration of Calibrator:

| Spot | Name | Conc. | Units |
|------|-------|-------|-------|
| 1 | cTnI | 354 | ng/mL |
| 2 | cTnT | 1036 | ng/mL |
| 3 | FABP3 | 2060 | ng/mL |
| 5 | Myl3 | 1402 | ng/mL |
| 6 | sTnI | 4300 | ng/mL |


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Lot-Specific Components:

| Description | Lot Number | Storage Temperature | Expiration Date |
|--|------------|---------------------|-----------------|
| Muscle Injury Panel 1 (rat) Plate | Z0056850 | 2-8°C | 30 Jun 2023 |
| Anti-rcTnI Antibody | D0040944 | 2-8°C | 30 Jun 2024 |
| Anti-rat cTnT Antibody | D0040942 | 2-8°C | 31 May 2024 |
| Anti-rat FABP3 Antibody | D0040941 | 2-8°C | 30 Sep 2024 |
| Anti-rat Myl3 Antibody | D0040943 | 2-8°C | 31 May 2024 |
| Anti-rat sTnI Antibody | D0040945 | 2-8°C | 30 Jun 2024 |
| Muscle Injury Panel 1 (rat) Calibrator Blend | A0040258 | ≤ -70°C | 30 Sep 2022 |
| Diluent 7 | M0070066 | ≤ -10°C | 30 Jun 2023 |
| Diluent 30 | M0300031 | ≤ -10°C | 31 Dec 2022 |

Additional components may be provided to execute the assay. Additional components are not lot-specific.

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

| | Name | Function | Signature | Date |
|-----------------|---------------|----------|---|-------------|
| Review/Approval | Karen Hamilla | Quality |  | 11 MAY 2021 |