

PRODUCT: Thawing Media

LOT#: M0604

EXPIRY DATE: 2024-06-12

Year / Month / Date

REF: 91121

CODE: VT602



(01) 1 4582231 46069 1 (17) 240612 (10) M0604

APPROVED BY:

Kazumi Shibata
Quality Control
2023-07-24**CERTIFICATE OF ANALYSIS****Indication for Use:** Thawing Media is used for thawing vitrified oocytes and/or embryos.**Storage:** Store between 2-8 °C.**Caution:** Federal law restricts this device to sale by or on the order of a physician or practitioner trained in its use.

The product has been manufactured by Kitazato Corporation in conformity with requirements of ISO13485 Quality management system. The quality of products was tested and evaluated by quality control procedures.

| ASSAY | SPECIFICATION | RESULT | | | |
|----------------------------|---------------------------------|--------|--------|--------|--------|
| | | TS1 | TS2 | DS | WS |
| Color | Clear, Particle Free/ Rose Pink | Pass | Pass | Pass | Pass |
| pH | 7.20-7.60 | 7.29 | 7.29 | 7.31 | 7.30 |
| Osmolality ¹ | TS:1600-2000 | | | | |
| | DS:830-1020 | 1894 | 1886 | 928 | 265 |
| | WS:240-300 | | | | |
| Endotoxin ² | < 0.25 EU/mL | <0.006 | <0.006 | <0.006 | <0.006 |
| Sterility ³ | No Microbial Growth | Pass | Pass | Pass | Pass |
| MEA(One Cell) ⁴ | | | | | |
| | -Control | ≥ 80% | 93.33% | | |
| | -This Lot | ≥ 80% | 90.48% | | |
| Gentamicin ⁵ | < 50µg/mL | Pass | Pass | Pass | Pass |

¹ Osmotic pressure is measured either by osmolality; with freezing point in mOsm/L or by osmolality; with vapor pressure osmometry in mmol/kg.p

² Bacteria Endotoxins Test, Photometric Techniques in accordance with the USP, EP and JP

³ Sterility Tests, Direct Inoculation in accordance with the USP, EP and JP

⁴ One cell mouse embryo testing is performed using fresh mouse embryos. Test results indicate the percentage of mouse embryos developing to fully expanded blastocysts after 96 hours in culture medium.

⁵ Gentamicin quantitative assay is conducted. The acceptance criteria required is less than 50ug/mL.