

PRODUCT: Thawing Media

LOT#: H0802

EXPIRY DATE: 2018-11-16

Year / Month / Date

REF: 91182

CODE: VT802



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Quality Assurance
2018-08-17

CERTIFICATE OF ANALYSIS

Indication for Use: Thawing Media is used for thawing and recovery of 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.

We certify that products manufactured by Kitazato Corporation have been approved in accordance with current Good Manufacturing Practice (cGMP). 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 | 7.35 | 7.37 | 7.38 | 7.39 |
| Osmolarity ¹ | TS:1600-2000 | | | | |
| | DS:830-1020 | 1929 | 1918 | 935 | 273 |
| | 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% | | 100% | | |
| -This Lot | ≥ 80% | | 100% | | |

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

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.