

PRODUCT: Ultra-Fast Warm

LOT#: N1222

EXPIRY DATE: 2025-12-16

Year / Month / Date

REF: 91255

CODE: VT602UF-TSx4



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APPROVED BY:

Kazumi Shibata
Quality Control

2025-02-12

CERTIFICATE OF ANALYSIS

Indication for Use: Ultra-Fast Warm is used for warming of oocytes (MII) and 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 |
|----------------------------|---------------------------------|--------|
| Color | Clear, Particle Free/ Rose Pink | Pass |
| pH | 7.20-7.60 | 7.27 |
| Osmolality ¹ | TS:1600-2000 | 1896 |
| Endotoxin ² | < 0.25 EU/mL | <0.007 |
| Sterility ³ | No Microbial Growth | Pass |
| MEA(One Cell) ⁴ | | |
| -Control | ≥ 80% | 100% |
| -This Lot | ≥ 80% | 90.48% |
| Gentamicin ⁵ | 20-50µg/mL | Pass |

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. This is the result of Ultra-Fast Warm using VT602UF

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