KITAZATO®

Kitazato Corporation
http://www.kitazato.co.jp/

PRODUCT: Vitrification Media

LOT#: G0209
EXPIRY DATE: 2017-05-23
Year / Month / Date

REF: 91171
CODE: VT801

(01) 1 4582231 46076 9 (17) 170523 (10) G0209

APPROVED BY: Kazumi Shibata
Quality Assurance
2017-02-23

## CERTIFICATE OF ANALYSIS

**Indication for Use:** Vitrification Media is used for vitrification and storage of oocytes and/or embryos.

**Storage:** Store between 2-8 ºC.

**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 BioPharma Co., Ltd. have been appro5763ved in accordance with current Good Manufacturing Practice (cGMP). The quality of products was tested and evaluated by quality control procedures.

| ASSAY | SPECIFICATION | RESULT | | | |
|---|---|---|---|---|---|
| | | BS | ES | VS1 | VS2 |
| Color | Clear, Particle Free/ Rose Pink | Pass | Pass | Pass | Pass |
| pH | 7.20-7.60 | 7.46 | 7.49 | 7.51 | 7.51 |
| Osmolarity | BS:240-300<br>ES:2300-2800<br>VS:4900-6000 | 272 | 2452 | 5655 | 5571 |
| Endotoxin[1] | < 0.25 EU/mL | <0.006 | <0.006 | <0.006 | <0.006 |
| Sterility[2] | No Microbial Growth | Pass | Pass | Pass | Pass |
| MEA(One Cell)[3] | | | | | |
| -Control | ≥ 80% | | 100% | | |
| -This Lot | ≥ 80% | | 100% | | |

[1] Bacteria Endotoxins Test, Photometric Techniques in accordance with the USP, EP and JP

[2] Sterility Tests, Direct Inoculation in accordance with the USP, EP and JP

[3] 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.