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

PRODUCT: Cryotop®

REF: 81111, 81112, 81113, 81114, 81115
CODE: Cryotop (G), (R), (W), (B), (Y)

LOT#: 10204
EXPIRY DATE: 2024-02-04
Year / Month / Date

APPROVED BY: Kazumi Shibata
Quality Assurance
2021-03-11

CERTIFICATE OF ANALYSIS

Indication for Use: Cryotop® is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain human oocytes and/or embryos.

Storage: Store between 15-30 °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
Appearance[1]	Particle Free, No Cracks	Pass
Durability[2]	No Breakage	Pass
Tensile Strength[3]	≥ 5N	Pass
Endotoxin[4]	≤ 0.50 EU/device	0.011
Sterility[5]	No Microbial Growth	Pass
MEA(One Cell)[6]		
-Control	≥ 80%	97%
-This Lot	≥ 80%	100%

[1] No scratches, burrs and foreign objects
[2] Soak Cryotop in liquid nitrogen for 30 seconds.
[3] Pull a film part of Cryotop with digital force gauge.
[4] Bacteria Endotoxins Test, Photometric Techniques in accordance with the USP, EP, JP and AAMI ST72
[5] Sterility Tests, Direct Inoculation in accordance with the USP, EP and JP
[6] 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.