KITAZATO®

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

PRODUCT: Thawing Media

REF: 91121
CODE: VT602

(01) 1 4582231 46069 1 (17) 210708 (10) J0716

LOT#: J0716
EXPIRY DATE: 2021-07-08
Year / Month / Date

APPROVED BY: Kazumi Shibata
Quality Assurance
2020-08-21

CERTIFICATE OF ANALYSIS

Indication for Use: Thawing Media is used for thawing vitrified 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 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	7.36	7.36	7.35	7.36
Osmolality[1]	TS:1600-2000 DS:830-1020 WS:240-300	1810	1813	920	280
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.