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

PRODUCT: Thawing Media

LOT#: K0624
EXPIRY DATE: 2022-06-21
Year / Month / Date

REF: 91121
CODE: VT602

(01) 1 4582231 46069 1 (17) 220621 (10) K0624

APPROVED BY: Kazumi Shibata
Quality Control
2021-08-02

CERTIFICATE OF ANALYSIS

Indication for Use: Thawing Media is used for thawing 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.

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			
			TS1	TS2	DS	WS
Color		Clear, Particle Free/ Rose Pink	Pass	Pass	Pass	Pass
pH		7.20-7.60	7.32	7.29	7.40	7.37
Osmolality[1]		TS:1600-2000 DS:830-1020 WS:240-300	1835	1838	911	291
Endotoxin[2]		< 0.25 EU/mL	<0.008	<0.008	<0.008	<0.008
Sterility[3]		No Microbial Growth	Pass	Pass	Pass	Pass
MEA(One Cell)[4]						
	-Control	≥ 80%	100%			
	-This Lot	≥ 80%	95.24%			
Gentamicin[5]		Spots are same	Pass	Pass	Pass	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.p
[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.
[5] Thin layer chromatography is used for Gentamicin assay. The main three spots are commensurate to the position and color of spots obtained from the standard solution.