

PRODUCT: Thawing Media

LOT#: M1218
EXPIRY DATE: 2024-12-08
Year / Month / DateREF: 91121
CODE: VT602

(01) 1 4582231 46069 1 (17) 241208 (10) M1218


APPROVED BY: Kazumi Shibata
Quality Control
2024-02-28

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	7.37	7.38	7.39	7.39
Osmolality ¹	TS:1600-2000				
	DS:830-1020	1886	1911	926	266
	WS:240-300				
Endotoxin ²	< 0.25 EU/mL	<0.007	<0.007	<0.007	0.007
Sterility ³	No Microbial Growth	Pass	Pass	Pass	Pass
MEA(One Cell) ⁴	-Control		100%		
	-This Lot	≥ 80%	85.71%		
Gentamicin ⁵	20-50µg/mL	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 Gentamicin quantitative assay is conducted. The acceptance criteria required is less than 50ug/mL.