KITAZATO®

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

PRODUCT: Vitrification Media

REF: 91101
CODE: VT601

(01) 1 4582231 46207 7 (17) 240724 (10) M0727

LOT#: M0727
EXPIRY DATE: 2024-07-24
Year / Month / Date

APPROVED BY: Kazumi Shibata
Quality Control
2023-10-11

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.

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			
		BS	ES	VS1	VS2
Color	Clear, Particle Free/ Rose Pink	Pass	Pass	Pass	Pass
pH	7.20-7.60	7.44	7.46	7.50	7.50
Osmolality[1]	BS:240-300 ES:2300-2800 VS:4900-6000	288	2521	5331	5349
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%		93.33%		
-This Lot	≥ 80%		85.71%		
Gentamicin[5]	< 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.

[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.