KITAZATO®

Kitazato Corporation

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

PRODUCT: Vitrification Media

LOT#: I1205

EXPIRY DATE: 2020-03-19

Year / Month / Date

REF: 91171

CODE: VT801

(01) 1 4582231 46076 9 (17) 200319 (10) I1205

APPROVED BY: Kazumi Shibata
Quality Assurance
2019-12-19

CERTIFICATE OF ANALYSIS

Indication for Use: Vitrification Media is used for vitrification and storage of 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.

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			
		BS	ES	VS1	VS2
Color	Clear, Particle Free/ Rose Pink	Pass	Pass	Pass	Pass
pH	7.20-7.60	7.38	7.44	7.50	7.49
Osmolality[1]	BS:240-300 ES:2300-2800 VS:4900-6000	276	2438	5544	5526
Endotoxin[2]	< 0.25 EU/mL	<0.005	<0.005	<0.005	<0.005
Sterility[3]	No Microbial Growth	Pass	Pass	Pass	Pass
MEA(One Cell)[4]					
-Control	≥ 80%	100%			
-This Lot	≥ 80%	90.48%			

[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.