

PRODUCT: Vitrification Media

LOT#: G0119

EXPIRY DATE: 2017.05.09

Year / Month / Date

REF: 91171

CODE: VT801



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Quality Assurance
2017.02.09

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 BioPharma Co., Ltd. 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	7.35	7.40	7.50	7.49
Osmolarity	BS:240-300	288	2554	5400	5544
	ES:2300-2800 VS:4900-6000				
Endotoxin ¹	< 0.25 EU/mL	<0.006	<0.006	<0.006	<0.006
Sterility ²	No Microbial Growth	Pass	Pass	Pass	Pass
MEA(One Cell) ³					
-Control	≥ 80%		100%		
-This Lot	≥ 80%		95.2%		

¹ Bacteria Endotoxins Test, Photometric Techniques in accordance with the USP, EP and JP

² Sterility Tests, Direct Inoculation in accordance with the USP, EP and JP

³ 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.