



玻璃化冷冻液

型号规格：
C006-3 F1:5ml×2
F2:5ml×2

标识解释

	过滤灭菌
	生产批号
	生产日期
	有效期
	储存温度
	避光

注意事项和警告

1. 在使用该产品前,使用者应阅读和理解使用方法、注意事项,并掌握正确的使用程序。
2. 本产品不能用于注射。
3. 本产品为无菌产品,不适于再次灭菌。
4. 如果出现下列情况,请勿使用本产品:
 - 产品包装出现损坏,或封印已经损毁。
 - 产品已经超过保质期。
 - 产品已经变色、浑浊,或出现颗粒状物质。
5. 本产品含硫酸庆大霉素。应当采取适当预防措施,确保患者对该抗生素无过敏反应。
6. 本产品含有源自人类血液的人血白蛋白。该产品中的人血白蛋白经检测其HIV-Ab、TP、Anti-HCV 均呈阴性,HBsAg、HBsAb、HBeAg、HBeAb、HBcAb均符合规定。所有的血液制品均应视为具有潜在传染性。
7. 本产品适用于一次性使用。开瓶后,将剩余未用的产品丢弃。
8. 为避免污染,使用时请注意采用无菌技术。
9. 本产品可与日本Kitazato产品进行配合使用,体外鼠胚试验:囊胚形成率≥80%,检测结果如下:

品牌	玻璃化冷冻液批号	复苏率	囊胚形成率
Kitazato	Y20060201	100%	94.4%

其他厂家产品未进行试验。

- 10 该产品在规定的储存条件及产品有效期内保持稳定有效。
11. 本产品中含有二甲基亚砜,根据国家标准 GB/T 16886.5-2017《医疗器械生物学评价 第5部分:体外细胞毒性试验》进行检测。

适用范围

该产品适用于胚胎期胚胎的玻璃化冷冻。

组成成分

L-苏氨酸	L-苯基丙氨酸	牛磺酸
L-缬氨酸	L-精氨酸单盐酸盐	氯化钾
L-亮氨酸	L-赖氨酸单盐酸盐	氯化钙
L-谷氨酸	L-胱氨酸二盐酸盐	氯化钠
L-脯氨酸	L-天门冬氨酸	葡萄糖
L-色氨酸	丙酮酸钠	乳酸钠
L-丝氨酸	碳酸氢钠	甘氨酸
L-异亮氨酸	磷酸二氢钾	乙二醇
L-甲硫氨酸	L-天门冬酰胺	硫酸镁
L-组氨酸盐酸盐水合物	4-羟乙基哌嗪乙磺酸	
L-酪氨酸二钠盐二水合物	3-(N-吗啉基)丙磺酸	
N(2)-L-丙氨酸-L-谷氨酰胺	氢氧化钠	
人血白蛋白(10mg/mL)	二甲基亚砜	

冷冻液1:F1
基础成分 硫酸庆大霉素(7.5μg/mL)
冷冻液2:F2
基础成分 硫酸庆大霉素(5.4μg/mL),海藻糖

储存运输条件及有效期

1. 2°C~8°C密闭避光可保存6个月。
2. 运输应在2°C~8°C密闭避光条件下进行。

产品性能指标

- 1.pH值:F1~F2各组分pH值范围(37°C)均在7.2~7.6内。
- 2.渗透压:
F1渗透压在222 mOsmol/kg~422 mOsmol/kg内(稀释10倍);
F2渗透压在494 mOsmol/kg~694 mOsmol/kg内(稀释10倍)。
- 3.细菌内毒素检测:F1~F2各组分内细菌内毒素含量均<0.2 EU/mL。
- 4.产品无菌性:F1~F2各组分无菌检验均符合无菌规定。
- 5.体外鼠胚试验:囊胚形成率≥80%。

禁忌症

对人血白蛋白过敏者禁用。

使用方法

1. 该玻璃化冷冻操作应该在室温(22-28°C)下进行,使用前把冷冻液1(F1)和冷冻液2(F2)放置在室温下平衡,至少30分钟。
2. 用移液管注入1.0mL冷冻液1(F1)到培养皿中。
3. 小心地转移胚胎(每次不得超过三个)到冷冻液1(F1)中平衡6分钟,最多不超过15分钟,尽量减少带出培养液。
4. 当胚胎在冷冻液1(F1)中平衡时,取1.0mL冷冻液2(F2),加到培养皿中。
5. 小心地转移冷冻液1(F1)中平衡好的胚胎(每次不得超过三个)到冷冻液2(F2)中,并轻轻吹打胚胎,使胚胎沉入底部,携带液体量在1μL

左右,迅速浸入到液氮里面,(胚胎接触到冷冻液2(F2)起,至胚胎转到冷冻载体并浸入到液氮中止,整个过程时间维持在50-70秒内完成)。

注:

- ① 如果需要玻璃化冷冻更多的胚胎,重复上述2-5步骤,需要使用新的器皿以及新鲜的冷冻液1(F1)和冷冻液2(F2)。
- ② 冷冻囊胚时应先进行人工皱缩操作,然后再按照1-5步骤操作。尽量冷冻4级或以上即膨大阶段的囊胚。
- ③ 操作所有液体时尽量避免气泡产生。
- ④ 每次转移胚胎的时候应尽量减少携带上种培养液。
- ⑤ 冷冻液1(F1)和冷冻液2(F2)在室温下操作。

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生产许可证编号:

医疗器械注册证编号/产品技术要求编号:

医疗器械注册证编号:

产品技术要求编号:

说明书核准及修改日期:

核准日期:

版本号:AIVFO-210102-01-01



DMSO Vitrification Kit

C006-3 F1:5ml×2
F2:5ml×2

Explanation of Symbols

	Sterilized using aseptic processing techniques
	Batch code
	Date of manufacture
	Use-by date
	Temperature limitation
	Keep away from sunlight

Precautions and Warnings

- Before using this product, users should read and understand the operation and precautions.
- This product cannot be used for injection.
- This product is sterilized by filtration and is not suitable for re-sterilization.
- Do not use this product if:
 - Product packaging is damaged, or the seal has been destroyed.
 - The product exceeds the shelf life.
 - The product has become discolored, cloudy, or granular.
- This product contains gentamicin sulfate. Appropriate precautions should be taken to ensure that the patients are not allergic to the antibiotic.
- This product contains human serum albumin derived from human blood. The human serum albumin in the product has been tested to be negative for HIV-AB, TP and anti-HCV, and HBsAg, HBsAb, HBeAg, HBeAb and HBcAb all meet the requirements. All blood products should be considered potentially infectious.
- This product is suitable for single use. After opening the bottle, discard the remaining unused product.

8. In order to avoid contamination, please use aseptic technique.

9. This product can be used with Kitazato products of mainstream companies in the market, mouse embryo assay(MEA)-1-Cell MEA≥80%, the test results are as follows:

Brand	Vitrification thawing lot number	Recovery rate	Blastocyst formation rate
Kitazato	Y20060201	100%	94.4%

Other manufacturers' s products have not been tested.

10. The product shall remain stable and effective within the specified storage conditions and the shelf life.

11. This product contains dimethyl sulfoxide, which is detected according to the national standard GB/T 16886.5-2017 biological Evaluation of Medical Devices part 5: In Vitro Cytotoxicity Test.

Intended use

This product is suitable for vitrification and freezing of embryo.

Composition

L - serine	Taurine
L - valine	Glycine
L - leucine	Glucose
L - proline	Sodium lactate
L - threonine	Ethylene glycol
L - isoleucine	Calcium chloride
L - methionine	Sodium chloride
L - tryptophan	Magnesium sulfate
L - glutamic acid	Potassium chloride
Sodium hydroxide	
L - arginine hydrochloride	
L - cystine dihydrochloride	
L - tyrosine disodium salt dihydrate	
4 - hydroxyethyl piperazine ethyl sulfonic acid	

L - asparagine
L - aspartic acid
L - phenylalanine
Dimethyl sulfoxide
Pyruvic acid sodium
Sodium bicarbonate
N(2) - L - alanyl - L - glutamine
L - lysine monohydrochloride
L - histidine hydrochloride hydrate
Potassium dihydrogen phosphate
Human Serum Albumin(10mg/mL)
3 - (N-morpholine) propyl sulfonic acid

F1

Base ingredients: Gentamicin sulfate (7.5µg/mL).

F2

Basic ingredients: Gentamicin sulfate (5.4µg/mL), trehalose.

Storage and Transportation

- Store dark at 2°C~8°C for 6 months.
- Store dark at 2°C~8°C during transportation.

Product performance index

- 1.pH (37°C) : 7.2~7.6 .
2.Osmolality :
F1: 222 mOsmol/kg ~ 422 mOsmol/kg (diluted 10 times);
F2 : 494 mOsmol/kg ~ 694 mOsmol/kg (diluted 10 times).
3. Endotoxin : < 0.2EU /mL.
4. Product sterility : Pass.
5. 1-Cell Mouse embryo assay : ≥80%.

Contraindications

Those who are allergic to human serum albumin are prohibited.

Operation

- Procedures are to be done at room temperature (22-28°C) for at least 30 minutes to use.
 - Prepare a dish with 1.0mL of F1.
 - Carefully transfer the embryos (no more than three at a time) to balance in F1 for 6 minutes to a maximum of 15 minutes, with minimal removal of culture medium.
 - When the embryos were balanced in F1, 1.0mL F2 was taken and added to the dish.
 - Carefully remove the embryos equilibrated in F1 to F2, under microscope observation, gently pipette the embryos, if floating, and place at the bottom. With minimal volume less than 1µL of F2, and immediately plunge it into LN(2). Whole procedure should be completed in 50-70s.
- Note:
- If vitrification is required to freeze more embryos, repeat steps 2-5 above, using new utensils and fresh frozen liquid 1(F1) and frozen liquid 2(F2).
 - When freezing blastocyst, artificial shrinkage should be performed first, and then according to steps 1~5. Try to freeze the blastocyst of grade 4 or above, which is the stage of expansion.
 - Try to avoid bubbles when handling all liquids.
 - Minimize the carry-over of the culture medium each time the embryo is transferred.
 - F1 and F2 should be operated at room temperature.