



## 精子冷冻液

型号规格：  
C014-1 2ml×5

### 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清白蛋白。该产品中的人血清白蛋白经检测其 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。应当采取适当预防措施，确保患者对该人血清白蛋白无过敏反应。
7. 为避免污染，使用时请注意采用无菌技术。
8. 取出后产品不能再倒回瓶中继续保存使用。
9. 该产品在规定的储存条件及产品有效期内保持稳定有效。

### 适用范围

该产品适用于人精子的低温冷冻保存。

### 组成成分

|                   |           |       |
|-------------------|-----------|-------|
| L-精氨酸             | L-苏氨酸     | 硫酸镁   |
| L-胱氨酸             | L-色氨酸     | 碳酸氢钠  |
| L-苯基丙氨酸           | L-酪氨酸     | 甘氨酸   |
| L-天门冬酰胺           | L-缬氨酸     | 葡萄糖   |
| L-组氨酸             | L-赖氨酸单盐酸盐 | 乳酸钠   |
| L-天门冬氨酸           | L-丝氨酸     | 牛磺酸   |
| L-异亮氨酸            | 氯化钠       | HEPES |
| L-谷氨酸             | 丙酮酸钠      | MOPS  |
| L-亮氨酸             | 氯化钾       | 氢氧化钠  |
| L-甲硫氨酸            | 氯化钙       | 甘油    |
| L-脯氨酸             | 磷酸二氢钾     |       |
| N(2)-L-丙氨酸-L-谷氨酰胺 |           |       |
| 人血清白蛋白 (5mg/mL)   |           |       |

硫酸庆大霉素 (10 µg/mL)

### 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。
3. 开瓶后产品可在2°C~8°C避光条件下保存7天。
4. 开瓶7天后剩余培养液应丢弃。

### 产品性能指标

1. pH值：pH值 (37°C) 范围在7.2~7.6内。
2. 渗透压：渗透压在200mOsm/kg~280mOsm/kg内 (稀释10倍)。
3. 产品无菌性：产品无菌检验符合无菌规定。

### 禁忌症

对人血清白蛋白、硫酸庆大霉素过敏者禁用。

### 使用方法

1. 产品准备  
先将精子冷冻液提前放置至室温 (20-25°C) 平衡至少30分钟。
  2. 精液处理  
将采集的精液于37°C中静置液化30分钟或以上。
  3. 精液冷冻：
    - 3.1 将液化后的精液转移到15mL无菌离心管中，然后在30-40秒内向上处理完成后精液按 (2:1) 比例逐滴缓慢加入精子冷冻液，如：优化处理后精液体积总量为1.0mL，需加入精子冷冻液的体积约为0.5mL，边加边轻微摇晃，使精液与精子冷冻液充分混合均匀而不分层，制成精液混合物。将混合后的精液混合物按需分装至无菌无酶细胞冻存管中。
    - 3.2 将含精液混合物的冻存管于室温静置10分钟左右。
    - 3.3 将精液冻存管转移至并浸入液氮中长期保存。
- \*少、弱精的样本建议室温放置后将冻存管转移至液氮表面5厘米处的液氮蒸汽中静置10分钟，再将冻存管浸没在液氮中储存。
4. 解冻复苏  
将精液冻存管从液氮中快速取出，立即于37°C水浴中轻轻摇晃至完全解冻并继续孵育5-10分钟。

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医疗器械注册证编号/产品技术要求编号  
Medical device registration number /  
Product technical requirement number



## 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

1. Before using this product, users should read and understand the Operation and precautions.
2. This product cannot be used for injection.
3. This product is sterilized by filtration and is not suitable for re-sterilization.
4. Do not use this product if:
  - The product package is damaged or the seal has been destroyed.
  - The product exceeds the shelf life
  - The product has become turbid or granular.
5. This product contains gentamicin sulfate. Appropriate preventive measures should be taken to ensure that the patients are not allergic to the antibiotic.
6. This product contains human serum albumin derived from human blood. The human serum albumin in this product has been tested to be negative for HIV-Ab, TP, and Anti-HCV, and HBsAg, HBsAb, HBeAg, HBeAb, HBCAb all meet the requirements. All blood products should be considered

potentially infectious. Appropriate precautions should be taken to ensure that the patients do not have an allergic reaction to the human serum albumin.

7. In order to avoid contamination, the media should be used only with aseptic technique.
8. After taken out, the product cannot be poured back to the vial for further storage and use.
9. The product remains stable and effective within the specified storage conditions and the shelf life.
10. Caution: Federal law restricts this device to sale by or on the order of a physician.

## Intended use

This product is intended for cryopreservation of human semen.

## Composition

|                                |                    |
|--------------------------------|--------------------|
| L-arginine                     | L-Serine           |
| L-cystine                      | Sodium chloride    |
| L-phenylalanine                | Sodium pyruvate    |
| L-asparagine                   | Potassium chloride |
| L-histidine                    | Calcium chloride   |
| L-aspartic acid                | HEPES              |
| L-isoleucine                   | MOPS               |
| L-glutamic acid                | Sodium hydroxide   |
| L-leucine                      | Glycerol           |
| L-methionine                   | Taurine            |
| L-proline                      | Magnesium sulfate  |
| L-threonine                    | Sodium bicarbonate |
| L-tryptophan                   | Glycine            |
| L-tyrosine                     | Glucose            |
| L-valine                       | Sodium lactate     |
| L-lysine monohydrochloride     |                    |
| N (2) -L-alanyl-L-glutamine    |                    |
| Human Serum Albumin (5mg / mL) |                    |
| Potassium dihydrogen phosphate |                    |
| Gentamycin sulfate (10 µg/mL)  |                    |

## Storage and Transportation

1. Store dark at 2°C ~ 8°C for 6 months.
2. Store dark at 2°C ~ 8°C during transportation.
3. Product can be used within 7 days from first opening when store dark at 2°C ~ 8°C.
4. The remaining media should be discarded 7 days after opening the bottle.

## Product performance index

1. pH(37°C): 7.2 ~ 7.6.
2. Osmolality:  
200 mOsmol / kg ~ 280 mOsmol / kg (diluted 10 times)
3. Product sterility: Pass.

## Contraindications

Those who are allergic to human serum albumin and gentamicin sulfate are prohibited.

## Operation

1. Product preparation  
Pre-warm the corresponding volume of Sperm Freezing Medium at room temperature (20-25°C) to ensure that the media reaches temperature equilibrium (at least 30 minutes).
2. Semen preparation  
The semen is allowed to liquefy for 37°C at least 30 minutes.
3. Freeze semen  
Transfer the liquefied semen to a sterile 15 mL conical centrifuge tube. Dilute the liquefied semen with equal volume of Sperm Freezing Medium in 30-40s. Add the medium drop by drop onto the semen and mixed carefully after each addition. Aliquot the semen mixture into sterile and non-enzymatic cryotubes.
- 3.2 Keep cryotubes at room temperature for about 10 minutes before freezing.
- 3.3 Transfer the cryotubes quickly into the liquid nitrogen and store at -196 °C.  
\* Suspend cryotubes about 5 cm above the surface of the liquid nitrogen for 10 minutes. Transfer the cryotubes into the liquid nitrogen

and store.  
2. Thaw semen  
Remove cryotubes from -196 °C and place them in a water bath at 37 °C for 5-10 minutes.

## Sperm Freezing Medium