

For Oocytes and Embryos

Vitrification Solution Set (110) Instructions for Users

Contents:

-2 vials of 1.8 ml Equilibration Solution (ES) -4 vials of 1.8 ml Vitrification Solution (VS)

Composition:

This vitrification solution consists of 2 kinds of solutions. These solutions contain Gentamicin as an antimicrobial agent. Vitri Step1: Equilibrium Solution (ES) contains ethylene glycol and DMSO as a cryoprotectant. Vitri Step2: Vitrification Solution (VS) contains ethylene glycol and DMSO as a cryoprotectant. As a guide, this Set is for up to 10 vitrification processes. However, once the vial is opened, the solution cannot be reused.

Caution: Federal Law Restricts this device to sale by or on the order of a physical or practitioner trained in its use. Indications for use: The solution is used to vitrify the human oocytes and embryos.

Attention during Storage:

Solutions must be kept in the refrigerator at 2-8°C until the expiration date; these products can be used under the room temperature. Use before the expiration date indicated on the each of the labels.

Preparation:

- Leave ES and VS under room temperature for at least 1 hour before vitrification.
- Do not use an electronic oven to warm up to room temperature instead of incubator.
- For reference, read the user manual carefully before use and follow the instructions.
- Fill a container with liquefied nitrogen (LN2).
- Use a Pasteur pipet whose mouth diameter just fits each size of oocyte/embryo (140-150 µm) and blastocyst (160-200 µm).

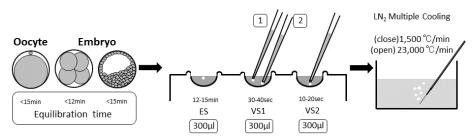
Instructions:

- 1. Fill the 1st well of a Vitri Plate with 300 µl of ES, and both 2nd and 3rd wells with 300 µl of VS.
- 2. Put an oocyte/embryo on the surface of ES in the 1st well.
- The oocyte/embryo will sink and begin to shrink, and then gradually return to the original size (maximum time is 15 min for oocytes and blastocysts, and 12 min for embryos at other stages).
- 4. Transfer the oocyte/embryo from the 1st well to the half depth of the 2nd well. The oocyte/embryo immediately floats to the surface of VS while being washed.
- After washing the inside of the pipette with fresh VS media, aspirate and transfer the oocyte/embryo to the bottom of the well. Wait until the oocyte/embryo stops floating in VS.
- 6. Transfer the oocyte/embryo to the half depth of the 3rd well, and stir the media by pipette about 5 times.

7. Aspirate the oocyte/embryo to the tip of the pipette, and put it on the end of thin film attached to the Cryotec seat with a minimum (0.01 to 0.1µl) volume of VS. For open system, submerge the Cryotec into liquid nitrogen directly and then cover the Cryotec with cap.

For closed system, cover the Cryotec with cap and and heat seal the Cryotec using heated tweezers to achieve the closed system, then immerse the capped Cryotec into liquid nitrogen.

8. Store the Cryotec in a LN2-filled tank.





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Specification:

- Sterility: Filtration (SAL10-3)
- Endotoxin < 0.6EU/ml (LAL)
- 1-Cell MEA ≧80% developed to blastocyst within 96hrs.
- Cooling rate: 1,500°C/min (Closed)
 - 23,000 °C/min (Open)

Caution:

This product is single use only. When this product is reused without discarding, there is a possibility of contamination.

It is prohibited to reuse or re-sterilize.

Discard the residual solution, and do not reuse it.

If the valid date is expired, discard it immediately.

This product must be operated by fully qualified experts. Otherwise, do not use it.

Do not use if the product is exposed to a contaminated material or becomes turbid.

Do not use this product except the intended use.

Do not modify this product in any cases.

Do not use the product if the sterile packaging is damaged or if the product is damaged or defective.

Avoid any damage caused by heavy physical impact or heavyweight objects.

Opening and use of this product with aseptic technique is strongly recommended due to risk of contamination.

Discard this product in an appropriate manner in accordance with the regulations of your local authority.

Combined use with Plate and Cryotec is recommended.

The results of each lot are described in Certificate of Analysis and available upon request.

Product only for in vitro use.

Manufacturer: REPROLIFE Inc.

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Symbols

No	Symbol	Description	No	Symbol	Description	No	Symbol	Description
1	***	'Manufacturer'	6	2°C	'Temperature limitation'	11		'Don't use if unit package is opened or damaged'
2	REF	'Product code'	7	淡	'Keep away from sunlight'	12	STERILE A	'Filtration Sterilization'
3	LOT	'Batch code'	8	بر ا	'Keep dry'	13	i	'Consult instructions for use'
4	\sim	'Manufacturer date'	9	\otimes	'Do not reuse'			
5	Σ	'Use by'	10	STEP	'Do not resterilize'			

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