

Embryo Frozen & Thawing plate



For laboratory procedures only; other uses must be qualified by the end user.

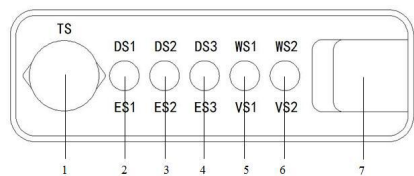
| Product Name | Model | Size |
|-------------------------------|----------|------|
| Embryo Frozen & Thawing plate | RBC-2014 | / |

Intended Use

The product is intended for vitrification freezing or thawing with Vitrification Kit or Vitrification Thawing Kit, specifically designed for high quality sperm, oocytes or different stage of embryos.

Product Description

The product is a rectangular plate, and there are six wells distributed on the surface in order, which is designed to place medium in Vitrification Kit or Vitrification thawing Kit. The leftmost well is called TS well which is larger than the other wells, it is used to place TS medium. Other wells are used to place drops of ES, VS or DS, WS.. Putting oocytes or embryos into wells with the drops of medium in accordance with the instructions of the Vitrification Kit or Vitrification Thawing Kit.



1- TS well 2- DS1/ES1 well 3-DS2/ES2 well 4- DS3/ES3 well 5-WS1/VS1 well 6-WS2/VS2 well
Fig. 1

Schematic diagram of Embryo Frozen & Thawing plate

Quality Assurance

Sterilized by Gamma ray.
ChP sterility test passed.
One-cell MEA tested and passed with 80% or greater blastocyst at 96 hours.
ChP Endotoxin test passed with <0.5 EU/set.
A Certificate of Analysis is available for this product.

Direction for Use

- The procedure of vitrification freezing (reference Vtrification Kit instruction)
 - 1.1. Warm equilibration solution (ES) and vitrification solution to room temperature (23-27°C) from 2-4°C refrigerator.

2. Prepare liquid nitrogen container with liquid nitrogen and ensure a sufficient depth to submerge a cryo-holder or goblet on a cryocane and place near to microscope.
3. Label the NO.7 well with necessary patient's information. (Fig.1)
4. Aseptically dispense two ES drops(50-100 μL) into the NO.2 and NO.3 well of Embryo Frozen & Thawing plate(hereafter referred to as "the plate"), marked ES1 and ES2 drop.(Fig.1)
5. Transfer oocyte(s) or embryo(s) to ES1 drop for 6 minutes, then move oocyte(s) or embryo(s) around once, and then expose them in ES2 undisturbed for another 6 minutes. (NOTE: Oocyte (s) or embryo(s) will shrink and then gradually return to original size, indicating that equilibration is complete. For oocytes , may use different diluted concentration accordingly).
6. During above equilibration in ES, aseptically dispense two (2) 50-100 μL drops of VS (VS1, VS2) in the NO.5 and NO.6 well of the plate, marked VS1 and VS2 drop(Fig.1).
7. Transfer oocyte(s) or embryo(s) with minimal volume of medium from ES2 to VS1 for 30 seconds, then another 30 Seconds in VS2.
8. Place the iVitri®-straw or-EZ under a microscope (iVitri® Logo should be up) and adjust the focus on the black mark on the top tip and put the oocytes or embryos (1~3) near to the black mark and remove any excess of vitrification solution to keep as minimal volume of vitrification solution (0.5-1.0 μl). The black mark makes easier the cover up.

NOTE:For oocyte freezing, may add one more step of HEPES (12mg/ml rHSA):ES1 (1:1) for 4 minutes. (The mixed droplet can be placed in the NO.1 well of the plate.)

1. The procedure of vitrification thawing (reference Vtrification thawing Kit instruction)

- 1.1. Warm thawing solution (TS) and dilution solution (DS)and washing solution (WS) to room temperature (23-27°C) from 2-4°C refrigerator. Pre-warm aliquot of TS about 200-300 μl in the NO.1 well of labeled plate to 37 °C before use.
- 1.2. Aseptically dispense two (2) 50-100 μL drops for each of DS and WS respectively in NO.2,3 well and NO.4,5 well of the plate in room temperature. (Fig.1)
- 1.3. Take out the patient's canister from the Dewar and place it into a Styrofoam box or container with LN₂ covering completely the iVitri®-straw or -EZ and check patient's information on the label.

- 1.4. With long tweezers grasps the iVitri®-straw or -EZ body and take it out from the cane (goblet).
 - 1.5. With long tweezers grabs the cover, and pull cover out without taking the iVitri®-straw or -EZ body out the LN₂, leave it always inside LN₂.
 - 1.6. Quickly take off the iVitri®-straw or-EZ body (Logo face down) from LN₂ and face down into pre-warmed TS drop at 37°C for one minute on the microscope stage or laminar hold surface (Fig. 1), and then transfer the oocyte(s) or the embryo(s) from TS to DS1 and DS2 for 2 minute, respectively.
 - 1.7. Transfer the oocyte(s) or embryos from DS to WS for 2×2 minutes (Fig. 2), and then washed with culture medium once to put into incubator for culture.
- 2. NOTE: It's necessary to change operation steps when thawing oocytes as follows**
- 2.1. the oocytes is placed in TS: DS(1:1) mixed droplets (The droplet can be placed in the DS1 well) ,and equilibrate medium for six minutes after thawing.
 - 2.2. Then transferred the oocytes to DS2 well and DS3 well (each of wells placed a drop DS medium) ,and equilibrae medium for two minutes.
 - 2.3. Transfer the oocyte(s) from DS3 well to WS1 well (The well can be placed with the TS: DS(1:1) mixture volume of about 100 μL), and equilibrate medium for two minutes.
 - 2.4. Transfer the oocyte(s) from WS1 well to WS2 well (dispensing the WS medium volume of about 100 μL), and equilibrate medium for two minutes., Then wash the oocyte(s) in the medium and culture in the incubator.

Precautions

Do not re-use the product, please destroy it after use.
The product has been sterilized by gamma ray and the period of sterilization validity is three years. Do not use if the sterile packaging has been compromised or expiry date has been exceeded.
This product is intended to be used by staff who have obtain the relevant qualifications.

Warnings

Law restricts this device to sale by or on the order of a physician.
Before use the product, please read the instruction for use carefully.
Waste should be disposed in according to the regulations of hospital or environmental protection department.
During use the product, Please do not try to change its structure.

Storage Condition

Avoid sunshine, water, high temperature and weight, store in a dry and ventilated place.

ISO Notation



Rx Only This product should be purchased by a doctor (or a licensed operator)

Registrant/ Manufacturer name: **REPROBIOTECH CORP CHINA LTD**

Registrant/ Manufacturer address: Gyeonggi Industrial Park No.103, Hunan East Road ,High-tech Zone, Liaocheng, Shandong , China

Registrant/ Manufacturer telephone: 400-002-0926

After-sales centers: **REPROBIOTECH CORP CHINA LTD**

Product Address: Gyeonggi Industrial Park No.103, Hunan East Road ,High-tech Zone, Liaocheng, Shandong , China

Production license number: 鲁食药监械生产许 20190034 号

Registration certificate number: 鲁械注准 20192180478

Product standard number: 鲁械注准 20192180478

Web: www.ruibaichina.com

Date of instruction preparation: September 03,2019