Regenmedlab

USER MANUAL

Product: MSCCRYOSAVE OTS

Components: Human Serum Albumin (USP), Amino acid, Electrolytes.

Reference number: 182 (100 mL bottle); 185 (500 mL bottle).

Size: 100 mL bottle; 500 mL bottle

Intended Use:

For research or manufacturing use only.

MSCCryosave OTS is a medium for preserving mesenchymal stem cells at -86°C and -196°C. After thawing, mesenchymal stem cells preserved with MSCCryosave OTS can be directly used on humans without the need for washing to remove the MSCCryosave OTS solution.

MSCCryosave OTS is fully compatible with the production of off-the-shelf mesenchymal stem cell products.

Summary and Explanation:

MSCCryosave OTS is a complete cryopreservation medium for mesenchymal stem cells that does not require the addition of any other components to the medium before use. With our unique technology, MSCCryosave OTS does not contain any cryoprotectant and does not contain protein components of animal origin.

MSCCryosave OTS can maintain high viability of mesenchymal stem cells after thawing.

The medium has a low endotoxin level (≤ 0.25 EU/mL), is free from Mycoplasma contamination, meets the sterility requirements (0 CFU), and has a pH range of 6.5 - 7.4.

Known Applications:

MSCCryosave OTS has been evaluated for use on mesenchymal stem cells derived from adipose tissue, bone marrow, and umbilical cord. On these examined cell lines, the cell survival rate after cryopreservation is over 90% when stored at -196°C or -86°C for 6 months. The manufacturer is currently monitoring longer-term storage for extended preservation times.

Note: The viability of the cells depends on the state of the mesenchymal stem cells prior to preservation and the proper execution of the cryopreservation and thawing procedures.

Reconstitution, dilution, mixing:

The product is supplied in a 1X form and does not require any dilution or additional components before use.

Materials and chemicals required (but not provided):

AfterFreeze OTS.

Storage and Stability:

Transport at room temperature.

Storage: 2-8°C; avoid direct light. Do not freeze the product at temperatures below 0°C.

Expiry date: 24 months from the date of manufacture.

Instructions for Use:

1. The vial of MSCCryosave OTS should be stored at a temperature of 2-8°C overnight (for at least 12 hours) before use. Ensure that the MSCCryosave OTS has been properly cooled to a temperature of 2-8°C.
2. After centrifugation to collect the mesenchymal stem cell pellet, proceed with resuspending the cells in MSCCryosave OTS to achieve a cell density ranging from 5 to 10 million cells per milliliter.

To ensure that the concentration of MSCCryosave OTS is not diluted, it is necessary to carefully aspirate any remaining solution on top of the cell pellet after centrifugation.

3. Proceed to aspirate and aliquot the cell suspension into suitable containers such as cryovials, 2-cap bottles, or bags designed for cryopreservation.
4. Cool the cell containers by placing them in Mr. Frosty or using a programmed cooling device set at a rate of -1°C per minute until reaching -86°C. After reaching -86°C, store the samples at -86°C overnight (before transferring to -196°C if storing at -196°C).

To ensure a high cell viability after thawing, the time from contact with MSCCryosave OTS to cooling should not exceed 15 minutes. In cases where packaging the product requires more time, the contact time can be extended up to 45 minutes, but it is advised not to exceed this duration.

The cooling process using Mr. Frosty is carried out by placing the cell-containing tubes into the box and placing it in a minimum of -86°C freezer for at least 4 hours or overnight before transferring the cell tubes to another appropriate storage container. Afterward, the Mr. Frosty should be removed from the freezer and kept at room temperature when not in use (before and after cooling). It is recommended to replace the isopropanol every 5 freezing cycles.

5. Cells can be stored at either -86°C or -196°C, depending on the application and the specific production process.

Cell thawing

Scenario 1: Cells stored in the MSCCryosave OTS medium and frozen at -86°C.

1. Remove the cell-containing tubes/bags from the -86°C freezer and place them on a clean surface (such as wood or stone) for natural thawing.

Do not place the tubes/bags on a metal surface for thawing.

2. Allow the tubes/bags to thaw naturally. To aid in the thawing process, you can gently hold and swirl the tubes/bags occasionally.

Do not thaw the tubes/bags rapidly by placing them in a water bath or an incubator. The estimated natural thawing time for frozen 1.8 mL tubes is approximately 17 minutes, for 5 mL tubes is around 10 minutes, and for 20 mL bags is approximately 20 minutes.

3. When the ice is almost completely thawed, and there are still a few remaining ice crystals, proceed to mix the **AfterFreeze OTS** solution with MSCCryosave OTS in a 1:1 ratio.

The mixing ratio between AfterFreeze OTS and MSCCryosave OTS is 1:1 (v/v). For example, if you have 1 mL of cell solution, you would mix it with 1 mL of AfterFreeze. The AfterFreeze solution should be at room temperature and must not be refrigerated.

4. Thoroughly mix the AfterFreeze OTS and MSCCryosave OTS solutions. This cell suspension can be used directly without the need for further washing. At this step, you can take a sample to count the cell quantity and assess the viability. The cell suspension can be administered by diluting it with physiological saline, lactate Ringer's solution, Stem Cell Infusion Medium, or other isotonic infusion solutions.

To ensure a high cell viability, it is recommended to use the thawed cells within 45 minutes after thawing.

Scenario 2: Cells stored in the MSCCryosave OTS medium and frozen at -196°C.

Due to the absence of cryoprotectants in the MSCCryosave OTS medium, the thawing process needs to be conducted slowly. The cells stored at -196°C should be removed and placed in a -86°C freezer overnight (> 12 hours) to gradually bring them from -196°C to -86°C. The next day, the thawing process can be carried out following Scenario 1.

Note: To ensure high cell viability, the transfer of vials from the liquid nitrogen container to the -86°C freezer should be done expeditiously. The liquid nitrogen container holding the samples should be placed adjacent to the -86°C freezer for efficient and immediate transfer of the vials.

Precautions:

MSCCryosave OTS contains human serum albumin and some amino acids (USP). It is important to note that the use of human serum albumin should follow the recommendations and guidelines provided by regulatory authorities regarding its usage.

MSCCryosave OTS is not a medicine and is not used as a drug or infusion solution. MSCCryosave OTS is manufactured according to pharmaceutical-grade raw material standards. Therefore, the use of a

product containing these ingredients (MSCCryosave OTS) should be subject to quality control as regulated by the competent authorities and comply with their regulations.

To ensure high cell viability when thawing mesenchymal stem cells, it is a must to use the **AfterFreeze OTS** product (Product code 176) and follow the instructions provided with **AfterFreeze OTS** for proper usage.

Do not use this product if the packaging is damaged or cracked, and/or if the solution appears discolored or turbid.

Troubleshooting:

Not applicable

Explaination of symbols and warnings:

The symbols present on the kit are explained below:

			
Use By:	Batch code	Keep away from light	Catalog number
			
Temperature Limitation	Consult instructions for use	Caution, consult accompanying documents	Sterilized using aseptic processing techniques

Related-products

Product Name	Reference Number
AfterFreeze OTS	
100 mL	261
500 mL	176
Cryosave I	
100 mL	136
Cryosave II	
100 mL	138
MSCCryosave OTS	
100 mL	182
500 mL	185

To purchase other products, please visit: http://biomedmart.org; http://biomedmart.com.vn

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