



Instructions for Use

CRYOSAVER™, SKIM MILK MEDIA

Cat. no. CSM100	CryoSaver™, Skim Milk, 2ml Cryogenic Vial, 1.3 - 1.7ml Fill	100 vials/box
Cat. no. CSMG100	CryoSaver™, Skim Milk with Glycerol, 2ml Cryogenic Vial, 1.3 - 1.7ml Fill	100 vials/box
Cat. no. CSMG101	CryoSaver™, Skim Milk with Glycerol, Modified, 2ml Cryogenic Vial, 1.3 - 1.7ml Fill	100 vials/box

INTENDED USE

Hardy Diagnostics CryoSaver™, Skim Milk Media is recommended for the preservation of microorganisms by freezing.

This product is not intended to be used for the diagnosis of human disease.

SUMMARY

The use of Skim Milk Media for maintaining frozen stock cultures is common practice in the field of Microbiology. Isolated patient organisms and stock cultures have been known to survive many years in Skim Milk Media when stored at -70°C. One reference states that some strains may be kept indefinitely at -70°C and one year at -50°C.⁽⁵⁾

The CryoSaver™ system is designed for ease of use. Numbered compartments in a durable container protect the CryoSaver™ vials and saves space in the freezer. Each vial has an easy "write-on" label for specimen identification. Accessories include the workstation, which securely holds up to 40 vials for easy one-handed operation when screwing the caps on or off. Inoculation needles and spatulas are available to aid in specimen removal from the CryoSaver™ vial. Colored round cap inserts are available for color coding of the vials. These inserts are available in eleven colors. The caps themselves are available in five colors. See the "Materials Required But Not Provided" section for more information.

FORMULA

Ingredients per liter of deionized water:*

Skim Milk (Cat. no. CSM100):	
Skim Milk Powder	20.0gm

Ingredients per 850ml of deionized water:*

Skim Milk with Glycerol (Cat. no. CSMG100):	
Skim Milk Powder	100.0gm

Glycerol	150.0ml
----------	---------

Ingredients per 900ml of deionized water:*

Skim Milk with Glycerol, Modified (Cat. no. CSMG101):	
Skim Milk Powder	85.0gm
Glycerol	100.0ml

Final pH 6.3 +/- 0.3 at 25°C.

* Adjusted and/or supplemented as required to meet performance criteria.

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-8°C. away from direct light. Media should not be used if there are any signs of deterioration, contamination, or if the expiration date has passed. Product is light and temperature sensitive.

The expiration dating on the product label applies to the product in its intact packaging when stored as directed. The product may be used and tested up to the expiration date on the product label and incubated for the recommended quality control incubation times.

Refer to the document "[Storage](#)" for more information.

PRECAUTIONS

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious, and handle observing the usual universal blood precautions. Do not ingest, inhale, or allow to come into contact with skin.

This product is for laboratory use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." Refer to the document "[Guidelines for Isolation Precautions](#)" from the Centers for Disease Control and Prevention.

For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M-29: *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline*.

Sterilize all biohazard waste before disposal.

Refer to the document "[Precautions When Using Media](#)" for more information.

PROCEDURE

1. Stock cultures should be prepared as soon as the organism is isolated in pure culture in order to prevent genetic variation and inotation. Isolates can be preserved as stock cultures from a non-selective liquid or solid media. Cultures should be 18-24 hours old.
2. To inoculate from a broth, dispense 0.5ml of an 18-24 hour pure broth culture into the Skim Milk Media. Freeze and maintain the culture preferably at -70°C. Plate out a portion of the culture to check the purity of the isolate put into stock.

3. To inoculate from a solid media, suspend 3 to 4 well isolated colonies in the Skim Milk Media. Mix carefully to ensure an even suspension. Freeze and maintain the culture preferably at -70°C.

4. To retrieve the organism, thaw rapidly in a 37°C. waterbath. Using a sterile loop, transfer from the vial to an appropriate non-selective agar media. **Do not refreeze the vial.** Alternatively, a scraping may be taken from the frozen vial with a sterile spatula (Cat. no. 57949041) and streaked onto a non-selective media. When using this method, the vial should be returned immediately to the freezer before it thaws.

Frozen stock organisms should be subcultured twice before using them as controls.

LIMITATIONS

It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification.

Skim Milk Media is intended for maintenance of pure cultures. The purity of the culture can be checked by plating a portion of the culture onto an appropriate non-selective media.

Aseptic methods should be used to insure continued quality of the stored microorganism without contamination.

CryoSaver™, Skim Milk Media is formulated for the long-term storage of bacteria. It is not suitable for use in the identification of microorganisms.

This media should not be used if any of the following conditions are present before inoculation:

- the vial shows any evidence of leakage (loss of broth)
- the vial shows any evidence of turbidity, which suggests contamination
- the expiration date has elapsed

Refer to the document "[Limitations of Procedures and Warranty](#)" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

The following accessories are available for use with this system:

802501	CryoSaver™ Workstation, securely holds 40 vials	1 workstation
57949041	Spatula, stainless steel, 16.8cm long	1 spatula
T3121	CryoSaver™ Cap Insert, White	500 caps/bag
T3122	CryoSaver™ Cap Insert, Blue	500 caps/bag
T3123	CryoSaver™ Cap Insert, Red	500 caps/bag
T3124	CryoSaver™ Cap Insert, Green	500 caps/bag
T3125	CryoSaver™ Cap Insert, Yellow	500 caps/bag
T3128	CryoSaver™ Cap Insert, Tan	500 caps/bag
T3129	CryoSaver™ Cap Insert, Gray	500 caps/bag
T31210	CryoSaver™ Cap Insert, Lilac	500 caps/bag
T31211	CryoSaver™ Cap Insert, Orange	500 caps/bag
T31213	CryoSaver™ Cap Insert, Violet	500 caps/bag
T31214	CryoSaver™ Cap Insert, Pink	500 caps/bag
T3127	CryoSaver™ Cap Insert, Assorted	1,000 caps/bag

Standard microbiological supplies and equipment such as loops, swabs, applicator sticks, other culture media, incinerators, incubators, etc., as well as serological and biochemical reagents, are not provided.

QUALITY CONTROL

Hardy Diagnostics tests each lot of commercially manufactured media using appropriate quality control microorganisms and quality specifications as outlined on the Certificates of Analysis (CofA). The following organisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
<i>Escherichia coli</i> ATCC® 25922	E	24hr	35°C	Aerobic	Growth**
<i>Streptococcus pyogenes</i> ATCC® 19615	E	24hr	35°C	Aerobic	Growth**

* Refer to the document "[Inoculation Procedures for Media QC](#)" for more information.

** 3 to 4, 18-24 hour old isolated colonies are inoculated into the CryoSaver™, frozen, thawed and streaked onto a non-selective media to check for viability.

USER QUALITY CONTROL

End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction, if applicable. Hardy Diagnostics quality control testing is documented on the certificates of analysis (CofA) available from Hardy Diagnostics [Certificates of Analysis](#) website. In addition, refer to the following document "[Finished Product Quality Control Procedures](#)," for more information on QC or see reference(s) for more specific information.

PHYSICAL APPEARANCE

CryoSaver™, Skim Milk Media should appear opaque, and milky white to light tan in color.

REFERENCES

1. Tille, P., et al. *Bailey and Scott's Diagnostic Microbiology*, C.V. Mosby Company, St. Louis, MO.
2. Howard, B.J., et al. 1987. *Clinical and Pathogenic Microbiology*. C.V. Mosby Company, St. Louis, MO.
3. Isenberg, H.D. *Clinical Microbiology Procedures Handbook*, Vol. I, II & III. American Society for Microbiology, Washington, D.C.
4. Anderson, N.L., et al. *Cumitech 3B; Quality Systems in the Clinical Microbiology Laboratory*, Coordinating ed., A.S. Weissfeld. American Society for Microbiology, Washington, D.C.
5. Sutter, V.L., D.M. Citron, M.A.C. Edelstein and S.M. Finegold. 1992. *Wadsworth Anaerobic Bacteriology Manual*, 5th ed. Star Publishing Company.

ATCC is a registered trademark of the American Type Culture Collection.



1430 West McCoy Lane, Santa Maria, CA 93455, USA

Phone: (805) 346-2766 ext. 5658

Fax: (805) 346-2760

Website: HardyDiagnostics.com

Email: TechnicalServices@HardyDiagnostics.com

[Ordering Information](#)

Distribution Centers:

California · Washington · Utah · Arizona · Texas · Ohio · New York · Florida · North Carolina

The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.

Copyright © 2020 by Hardy Diagnostics. All rights reserved.

HDQA 2207D [C]