IFU

HARDY DIAGNOSTICS
A Culture of Service™

Instructions for Use

CRITERION™ FLUID THIOGLYCOLLATE MEDIUM, USP

Cat. no. C7500	CRITERION™ Fluid Thioglycollate Media	59.6gm
Cat. no. C7501	CRITERION™ Fluid Thioglycollate Media	500gm
Cat. no. C7502	CRITERION™ Fluid Thioglycollate Media	2kg
Cat. no. C7503	CRITERION™ Fluid Thioglycollate Media	10kg
Cat. no. C7504	CRITERION™ Fluid Thioglycollate Media	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Thioglycollate medium are recommended for the cultivation of aerobic, microaerophilic, and anaerobic microorganisms.

This dehydrated culture medium is a raw material intended to be used in the making of prepared media products, which will require further processing, additional ingredients, or supplements.

SUMMARY

The Fluid Thioglycollate Medium formulation was first described in 1940 by Brewer.[1] This medium demonstrated that combining a small amount of agar and a reducing substance initiated the growth of anaerobic bacteria. The Fluid Thioglycollate Medium formulation is the standard medium recommended by the Food and Drug Administration, National Institute of Health, the National Formulary, and the U.S. Pharmacopeia for sterility testing of clear fluid biologics and other sterile products.[2,4,5,7] Alternatively, Fluid Thioglycollate Medium is used for sterility testing of turbid biological specimens.

The addition of a small amount of agar in Thioglycollate Medium aids in the initiation and growth of small inocula and anaerobes by impeding the diffusion of oxygen into the medium. It also retards the dispersion of CO_2 and the reducing substance from the microenvironment surrounding the inoculum. Sodium thioglycollate is a reducing agent which maintains a low oxygen tension by removing molecular oxygen from the environment. Peroxides, which may be lethal to many anaerobic organisms, are not formed under this condition. Cystine and casein supply carbon and nitrogenous compounds, dextrose is added as another energy source, and sodium chloride maintains osmotic equilibrium.

Certain additives can be incorporated into the Thioglycollate Medium as desired. Yeast extract or papaic digest of soybean meal can be added as growth enhancers.

FORMULA

Gram weight per liter:	29.8gm/L
Agar	0.75gm

Pancreatic Digest of Casein	15.0gm
Yeast Extract	5.0gm
Dextrose	5.5gm
Sodium Chloride	2.5gm
Sodium Thioglycollate	0.5gm
L-Cystine	0.5gm
Resazurin	1.0mg

Final pH 7.1 +/- 0.2 at 25ºC.

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

STORAGE AND SHELF LIFE

Store the sealed bottle(s) containing dehydrated culture medium at 2-30ºC. Dehydrated culture medium is very hygroscopic. Keep lid tightly sealed. Protect dehydrated culture media from moisture and light. The dehydrated culture media should be discarded if it is not free-flowing or if the color has changed from its original light beige.

Store the prepared culture media at 2-30ºC.

The expiration date 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 incubation times as stated below.

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 M29: *Protection of Laboratory Workers from Occupationally Acquired Infections.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

METHOD OF PREPARATION FOR DEHYDRATED CULTURE MEDIA

1. Suspend 29.8gm of the dehydrated culture media in 1 liter of distilled or deionized water.

2. Heat to boiling and mix to dissolve completely.

3. Sterilize in the autoclave at 121ºC. for 15 minutes.

PROCEDURE AND INTERPRETATION OF RESULTS

For information on procedures and interpretation of results, consult listed references or refer to the prepared media Instructions for Use (IFU) for Cat. No. K84.

LIMITATIONS

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

Some formulations may require a settling period before pH testing of the prepared medium. If the pH is tested immediately after preparation and is out of specification, retest the medium after 24 hours to obtain final pH results. Always take pH reading at room temperature.

In test samples, the proper surface to volume ratio of the Thioglycollate Medium must be maintained to avoid oxidation of the medium, making it unsuitable for microaerophilic and anaerobic growth.

A slight turbidity or haziness may be present due to the small amount of agar in the medium. When the media has been boiled it appears clear.

Do not boil media more than once, as frequent boiling may lead to toxic products forming in the medium.[(3)] If it is suspected that the medium has more than 30% oxidation **after** boiling, it should be discarded.

Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as autoclaves, incinerators, and incubators, etc., 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 Certificate of Analysis (CofA) and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media*. The following microorganisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
Staphylococcus aureus ATCC® 6538	J	1-3 days	35°C	Aerobic	Growth
Pseudomonas aeruginosa ATCC® 9027	J	1-3 days	35°C	Aerobic	Growth
Clostridium sporogenes ATCC® 19404	J	1-3 days	35°C	Aerobic**	Growth

* Refer to the document "Inoculation Procedures for Media QC" for more information.

** Tubes are incubated in an aerobic incubator with the caps screwed down tightly to create an atmosphere of low oxygen tension within the tube.

USER QUALITY CONTROL

Users of dehydrated 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 certificate of analysis (CofA) available from Hardy Diagnostics Certificate of Analysis website. In addition, refer to the following document "Finished Product Quality Control Procedures," for more information on QC or see the reference(s) for more specific information.

Note: Thioglycollate with Indicator Media contains a resazurin indicator which will cause the upper layer of this broth to be pink, due to the exposure to oxygen. Containers that have been agitated recently will turn pink throughout. This can be reversed by allowing the container to stand still for a few hours or by putting the containers in a boiling waterbath for 10 minutes with loosened caps. The caps are then tightened firmly before the media cools. Also note that it is common for a whitish precipitate to form in this medium due to the agar content. This does not effect the performance of this medium.

PHYSICAL APPEARANCE

CRITERION™ Fluid Thioglycollate Media, USP powder should appear homogeneous, free-flowing, and light beige in color. The prepared media should appear translucent, and amber in color. Those formulations with an indicator added will have a pink layer at the medium-air interface. If the media appears pink in color, follow the instructions given above to restore and reduce the media.

REFERENCES

1. Brewer, J.H. 1940. *J. Amer. Med. Assoc.*; 115:598.

2. Federal Security Agency, Food and Drug Administration, Compilation of Regulations for Test and Methods of Assay and Certification of Antibiotic Drugs.

3. MacFaddin, J.F. 1985. *Media for Isolation, Cultivation, Identification, Maintenance of Bacteria*, Vol. I. Williams & Wilkins, Baltimore, MD.

4. American Public Health Association. *Standard Methods for the Examination of Dairy Products*, APHA, Washington, D.C.

5. National Institutes of Health Circular: *Culture Media for the Sterility Test*, 2nd rev. Feb. 5, 1946.

6. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22. Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS), Wayne, PA.

7. *U.S. Pharmacopeia*, 23rd rev. 1995. U.S. Pharmacopeial Convention, Rockville, MD.

8. Jorgensen., et al. *Manual of Clinical Microbiology*, American Society for Microbiology, Washington, D.C.

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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.

HDQA 2207B [D]