

Instructions for Use

CRITERION™ TRYPTOSE PHOSPHATE BROTH

Cat. no. C7210	CRITERION™ Tryptose Phosphate Broth	59gm
Cat. no. C7211	CRITERION TM Tryptose Phosphate Broth	500gm
Cat. no. C7212	CRITERION™ Tryptose Phosphate Broth	2kg
<u>Cat. no. C7213</u>	CRITERION™ Tryptose Phosphate Broth	10kg

INTENDED USE

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Hardy Diagnostics CRITERIONTM Tryptose Phosphate Broth is recommended for use as a general purpose growth media for the isolation, cultivation, and differentiation of a wide variety of fastidious 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

CRITERIONTM Tryptose Phosphate Broth is an infusion-free buffered medium recommended for the cultivation of fastidious, pathogenic microorganisms. Tryptose Phosphate Broth is valuable in tissue culture procedures, as shown by Ginsberg, Gold, and Jordan. The peptone content of Tryptose Phosphate Broth is considered to be a stimulating factor for cells. Tryptose Phosphate Broth is specified for cell culture procedures.^(1,2)

Nitrogen, vitamins, and carbon sources are provided by peptones. Dextrose in the carbohydrate source. Sodium chloride maintains the osmotic environment and disodium phosphate is the buffering agent.

The addition of 0.1-0.2% agar to Tryptose Phosphate Broth facilitates anaerobic growth, and aids in dispersion of reducing substances and CO_2 formed in the environment.⁽³⁾ The low agar concentration provides suitable conditions for aerobic growth in the upper zone, and microaerophilic and anaerobic growth in the lower zone.

FORMULA*

Gram weight per liter:	29.5gm/L
Pancreatic Digest of Casein	10.0gm
Peptic Digest of Animal Tissue	10.0gm
Sodium Chloride	5.0gm
Disodium Phosphate	2.5gm
Dextrose	2.0gm

Final pH 7.3 +/- 0.2 at 25°C.

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

STORAGE AND SHELF LIFE

Store the sealed bottle(s) containing dehydrated culture medium at 2-30°C. 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 beige.

Store the prepared culture media at 2-8°C.

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 "<u>Guidelines for Isolation</u> <u>Precautions</u>" 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 29.5gm of the dehydrated culture media in one liter of distilled or deionized water. Stir to mix thoroughly.
- 2. Heat as necessary to dissolve completely.
- 3. Sterilize in the autoclave at 121°C. for 15 minutes.
- 4. Cool to 45-50°C.

PROCEDURE AND INTERPRETATION OF RESULTS

For information on procedures and interpretation of results, consult listed references.

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.

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	Kesuits
Neisseria meningitidis ATCC [®] 13090	А	18-48hr	35°C	Aerobic	Growth
Staphylococcus epidermidis ATCC [®] 12228	А	18-48hr	35°C	Aerobic	Growth
Streptococcus pneumoniae ATCC [®] 6305	А	18-48hr	35°C	Aerobic	Growth
Streptococcus pyogenes ATCC [®] 19615	А	18-48hr	35°C	Aerobic	Growth

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

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 <u>Certificate of Analysis</u> website. In addition, refer to the following document "<u>Finished Product</u> <u>Quality Control Procedures</u>," for more information on QC or see the reference(s) for more specific information.

PHYSICAL APPEARANCE

CRITERIONTM Tryptose Phosphate Broth powder should appear homogeneous, free-flowing, and beige in color. The prepared media should appear clear and golden in color.

REFERENCES

1. Ginsberg, Gold, and Jordan. 1955. Proc. Soc. Exp. Bio. Med.; 89:66.

2. U.S. Food and Drug Administration. *Bacteriological Analytical Manual*. AOAC, Arlington, VA. http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm.

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

4. Vanderzant, C. and D. R. Splittstoesser, (ed). 1992. *Compendium of Methods for the Microbiological Examination of Foods*, 3rd ed. APHA, Washington, D.C.

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

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1430 West McCoy Lane, Santa Maria, CA 93455, USA Phone: (805) 346-2766 ext. 5658 Fax: (805) 346-2760 Website: <u>HardyDiagnostics.com</u> <u>Email: TechnicalServices@HardyDiagnostics.com</u> <u>Ordering Information</u>

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.

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