

Instructions for Use

CRITERION™ TODD HEWITT BROTH

Cat. no. C7090	CRITERION™ Todd Hewitt Broth	60gm
Cat. no. C7091	CRITERION™ Todd Hewitt Broth	500gm
Cat. no. C7092	CRITERION™ Todd Hewitt Broth	2kg
Cat. no. C7093	CRITERION™ Todd Hewitt Broth	10kg
Cat. no. C7094	CRITERION™ Todd Hewitt Broth	50kg

INTENDED USE

Hardy Diagnostics CRITERIONTM Todd Hewitt Broth is recommended for the production of antigenic streptococcal hemolysin and the cultivation of streptococci prior to serological grouping. It is also recommended for the cultivation of beta-hemolytic streptococci, pneumococci and other fastidious organisms.

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

Todd Hewitt Broth was originally developed in 1932 by Todd and Hewitt. Elliot found the medium to be useful in growing group A streptococci for the production of the type specific M protein antigen. (1) Later, the formula was modified by Updyke and Nickel who found the medium to be particularly useful for growing group A streptococci for serological typing. (2)

CRITERIONTM Todd Hewitt Broth follows the formula developed by Updyke and Nickel. (2) The medium is composed of beef heart infusion, peptones and yeast extract which all supply necessary growth nutrients. Dextrose is added as an energy source and stimulates streptococcal antigen production. Sodium carbonate and disodium phosphate are included as buffers which serve to protect the hemolysin from inactivation by acid produced from dextrose fermentation.

FORMULA

Gram weight per liter:	30.0gm/L
Pancreatic Digest of Casein	10.0gm
Yeast Extract	10.0gm
Beef Heart Infusion	3.1gm
Sodium Carbonate	2.5gm
Dextrose	2.0gm

Sodium Chloride	2.0gm
Disodium Phosphate	0.4gm

Final pH 7.8 +/- 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 light beige.

Store the prepared culture media at 2-30°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 "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 30.0gm 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 121°C. for 15 minutes.
- 4. Dispense into sterile tubes.

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. K79.

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.

Streptococcus spp. grown in Todd Hewitt Broth and harvested as antigen to raise antibodies may carry antigenic material from the broth.

Todd Hewitt Broth is nonselective. Additional tests including subculture to an appropriate agar media, as well as biochemical and/or serological tests, should be performed for complete identification of pure cultures. For more information, consult appropriate references.

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	Incubation			Results
Test Organisms	Method*	Time	Temperature	Atmosphere	Results
Streptococcus pyogenes ATCC® 19615	A	24hr	35°C	Aerobic	Growth
Streptococcus agalactiae ATCC® 12386	A	24hr	35°C	Aerobic	Growth

^{*} Refer to the document "Inoculation Procedures for Media OC" 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 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.

PHYSICAL APPEARANCE

CRITERIONTM Todd Hewitt Broth powder should appear homogeneous, free-flowing, and light beige in color. The prepared media should appear clear, and medium amber in color.

REFERENCES

- 1. Elliott, S.D. 1945. J. Exp. Med.; 81:573.
- 2. Applied Microbiol.; 2:117, 1954.
- 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. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22. Clinical and Laboratory Standards Institute (CLSI formerly NCCLS), Wayne, PA.

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

IFU-10279[A]



1430 West McCoy Lane, Santa Maria, CA 93455, USA Phone: (805) 346-2766 ext. 5658 Fax: (805) 346-2760

Website: <u>HardyDiagnostics.com</u>

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 2207B [D]