IFU

Instructions for Use

CRITERION™ TRYPTOSE AGAR

Cat. no. C7170	CRITERION™ Tryptose Agar	80gm
Cat. no. C7171	CRITERION™ Tryptose Agar	500gm
Cat. no. C7172	CRITERION™ Tryptose Agar	2kg
Cat. no. C7173	CRITERION™ Tryptose Agar	10kg
Cat. no. C7174	CRITERION™ Tryptose Agar	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Tryptose Agar is recommended for use in cultivating a wide variety of fastidious microorganisms, particularly *Brucella* spp., but also streptococci, pneumococci, meningococci, *Listeria* spp., *Pasteurellae* and other microorganisms from mixed cultures. Additional enrichment or selective ingredients may be added to the prepared medium, as needed.

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

Tryptose media prepared with or without meat extract or infusion are commonly recommended for the cultivation and isolation of pathogenic and saprophytic bacteria. It was traditionally considered crucial to include the use of meat extract or infusion as a nutritional supplement in culture media. While studying the growth requirements of *Brucella*, Huddleson found tryptose media to be equivalent or far better at providing uniformity for the cultivation and differentiation of fastidious microorganisms than meat infusion media.[(1)] Moreover, Castañeda and McCullough also found media containing tryptose, and supplemented with additional nutrients, particularly useful for isolating *Brucella* spp. from other cultures.[(2,3)]

The increased productivity of tryptose media in the isolation and cultivation of fastidious microorganisms, particularly *Brucella* spp., supports the use of this formulation as a general, all-purpose growth medium; tryptose is also useful when avoiding animal tissue products is desired. Media such as tryptose agar may be further enriched by the addition of 5% sterile, defibrinated sheep, horse or rabbit blood or 5% bovine serum to support the growth of more fastidious microorganisms. Other nutrients to further enrich the medium and selective agents such as crystal violet and varying concentrations of antibiotics may be added to suppress the growth of undesirable microorganisms.[(6)]

Hardy Diagnostics CRITERION™ Tryptose Agar contains tryptose as the nitrogen and carbon source. Dextrose is the energy source for metabolism. Sodium chloride is added to maintain osmotic balance and agar is the solidifying agent.

FORMULA*

Gram weight per liter:	41.0gm/L

Tryptose	20.0gm
Sodium Chloride	5.0gm
Dextrose	1.0gm
Agar	15.0gm

Final pH 7.2 +/- 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 2-8ºC.

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 40gm of the dehydrated culture media in one liter of distilled or deionized water. Stir to mix thoroughly.

2. Heat to boiling for one minute to dissolve completely.

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

4. Cool to 45-50ºC.

Note: Additional nutritional or selective ingredients may be aseptically added prior to dispensing media.

5. Aseptically dispense desired volume into sterile containers.

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.

1. Certain diagnostic tests may be performed directly on this medium. Tryptose Agar is a general, non-selective medium that may support the growth of a wide variety of microorganisms. It is therefore recommended that biochemical and/or serological tests be performed on colonies from pure culture for complete identification.

2. Hemolytic reactions of some strains of group D streptococci may be affected by differences in animal blood. Prior knowledge of these differences may be needed before use, and care should be taken in preparing blood agar from this medium.

3. The atmospheric condition of incubation is known to influence the hemolytic reaction of beta-hemolytic streptococci.[9] Incubate tryptose media supplemented with blood under anaerobic or increased CO_2 conditions for best performance.

4. Some organisms may show a decrease in hemolysin production when grown on media containing dextrose.

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, animal blood, antimicrobial agents, 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	
Bacteroides fragilis ATCC® 25285	A	24-72hr	35°C	Anaerobic	Growth
Clostridium perfringens ATCC® 13124	A	24-72hr	35°C	Anaerobic	Growth
Streptococcus pyogenes ATCC® 19615	A	24-72hr	35°C	CO_2**	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 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.

** Atmosphere of incubation is enriched with 5-10% CO_2.

PHYSICAL APPEARANCE

CRITERION™ Tryptose Agar powder should appear homogeneous, free-flowing, and light beige in color. The prepared media should appear slightly opalescent, and light amber in color.

REFERENCES

1. Huddleson, I.F. 1943. *Brucellosis in Man and Animals*, rev. ed. The Commonwealth Fund, New York, NY.

2. Castañeda, M.R. 1947. A Practical Method for Routine Blood Cultures in Brucellosis. *Proc. Soc. Exp. Biol. Med.*; 64:114-115.

3. McCullough, W.G., et al. 1947. Studies in the Nutritional Requirements of *Brucella suis*. *J. Bacteriol.*; 53:5-15.

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

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

6. Moyer, N.P., et al. 1995. *Brucella*. In Murray, P.R., et al. *Manual of Clinical Microbiology*, 6th ed. American Society for Microbiology, Washington, D.C.

7. Harmon, S.M., et al. 1995. *Bacteriological Analytical Manual*, 8th ed. FDA. AOAC International, Washington, D.C.

8. Ruoff, K.L. 1995. *Streptococcus*. In Murray, P.R., et al. *Manual of Clinical Microbiology*, 6th ed. American Society for Microbiology, Washington, D.C.; p. 299-305.

9. Atlas, R.M. 1995. *Handbook of Microbiology Media for the Examination of Food*. CRC Press, Boca Raton, FL; p. 266-268.

10. Marshall, Robert T. 1992. *Standard Methods for the Examination of Dairy Products.* 16th ed. APHA, Washington, D.C.

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

HDQA 2207B [D]