

Instructions for Use

CRITERION™ TRYPTIC SOY AGAR (TSA)

| Cat. no. C7120 | CRITERION™ Tryptic Soy Agar | 80gm |
|----------------|-----------------------------|-------|
| Cat. no. C7121 | CRITERION™ Tryptic Soy Agar | 500gm |
| Cat. no. C7122 | CRITERION™ Tryptic Soy Agar | 2kg |
| Cat. no. C7123 | CRITERION™ Tryptic Soy Agar | 10kg |
| Cat. no. C7124 | CRITERION™ Tryptic Soy Agar | 50kg |

INTENDED USE

Hardy Diagnostics CRITERIONTM Tryptic Soy Agar is recommended for use as a general growth medium for the isolation and cultivation of microorganisms. This medium is also recommended for use in the cultivation, storage, and transportation of pure cultures of bacteria.

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 formulation of Tryptic Soy Agar is prepared according to the United States Pharmacopeia (USP) standard formula for Soybean-Casein Digest Agar Medium. (9) It is also included in approved procedures in the *Compendium of Methods for the Microbiological Examination of Foods* and in *Standard Methods for the Examination of Water and Wastewater*. (4,8)

CRITERIONTM Tryptic Soy Agar contains digests of soybean meal and casein which provides amino acids and other nitrogenous compounds making it a nutritious medium for many microorganisms. Sodium chloride is added to maintain the osmotic equilibrium. Dextrose is added to serve as an energy source. This medium may be supplemented with blood to provide a more nutritious medium for fastidious organisms, or with antimicrobials to provide a selective medium for specific organisms out of a mixed flora sample.

FORMULA

| Gram weight per liter: | 40.0gm/L |
|-------------------------------|----------|
| Pancreatic Digest of Casein | 15.0gm |
| Peptic Digest of Soybean Meal | 5.0gm |
| Sodium Chloride | 5.0gm |
| Agar | 15.0gm |

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 light 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 "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 40.0gm 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.

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. G60.

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 | | | D |
|--------------------------------------|------------------------|------------|-------------|------------|---------|
| | | Time | Temperature | Atmosphere | Results |
| Staphylococcus aureus** ATCC® 6538 | J | 1-3 days | 35°C | Aerobic | Growth |
| Escherichia coli** ATCC® 8739 | J | 1-3 days | 35°C | Aerobic | Growth |
| Candida albicans ATCC® 10231 | J | 1-5 days | 35°C | Aerobic | Growth |
| Bacillus subtilis ATCC® 6633 | J | 1-3 days | 35°C | Aerobic | Growth |
| Salmonella enterica ATCC® 14028 | J | 1-3 days | 35°C | Aerobic | Growth |
| Staphylococcus aureus ATCC® 25923 | A | 1-3 days | 35°C | Aerobic | Growth |
| Escherichia coli ATCC® 25922 | A | 1-3 days | 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 Tryptic Soy Agar powder should appear homogeneous, free-flowing, and light beige in color. The

^{**} Tested in accordance with USP <61> and <62>.(10,11)

prepared media should appear translucent, slightly opalescent, and light amber in color.

REFERENCES

- 1. 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.
- 2. Jorgensen., et al. Manual of Clinical Microbiology, American Society for Microbiology, Washington, D.C.
- 3. Tille, P., et al. Bailey and Scott's Diagnostic Microbiology, C.V. Mosby Company, St. Louis, MO.
- 4. Greenberg, A.E., et al. (ed.). 1992. *Standard Methods for the Examination of Water and Wastewater*, 18th ed. APHA, Washington, D.C.
- 5. Isenberg, H.D. *Clinical Microbiology Procedures Handbook*, Vol. I, II & III. American Society for Microbiology, Washington, D.C.
- 6. MacFaddin, J.F. 1985. *Media for Isolation, Cultivation, Identification, Maintenance of Bacteria*, Vol. I. Williams & Wilkins, Baltimore, MD.
- 7. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22. Clinical and Laboratory Standards Institute (CLSI formerly NCCLS), Wayne, PA.
- 8. Vanderzant, C. and D.F. Splittstoesser, (ed.). 1992. *Compendium of Methods for the Microbiological Examination of Foods*, 3rd ed. APHA, Washington, D.C.
- 9. U.S. Pharmacopeia, 22nd rev. 1990. U.S. Pharmacopeial Convention, Rockville, MD.
- 10. The Official Compendia of Standards. USP General Chapter <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests. *USP-NF*. United States Pharmacopeial Convention Inc., Rockville, MD.
- 11. The Official Compendia of Standards. USP General Chapter <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms. *USP-NF*. United States Pharmacopeial Convention Inc., Rockville, MD.

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IFU-10269[A]



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Ordering Information

Distribution Centers:

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

HDQA 2207B [D]