IFU

Instructions for Use

CRITERION™ TSA BLOOD AGAR BASE

Cat. no. C5220	CRITERION™ TSA Blood Agar Base	77gm
Cat. no. C5221	CRITERION™ TSA Blood Agar Base	500gm
Cat. no. C5222	CRITERION™ TSA Blood Agar Base	2kg
Cat. no. C5223	CRITERION™ TSA Blood Agar Base	10kg
Cat. no. C5224	CRITERION™ TSA Blood Agar Base	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ TSA Blood Agar Base is used with blood for isolation of fastidious microorganisms when hemolytic reactions are important. 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

TSA Blood Agar Base is typically supplemented with sheep, rabbit, or horse blood, in various concentrations, to facilitate the growth of some organisms, and for the observation of hemolytic reactions. The absence of reducing sugars and carbohydrates allows the hemolysis to occur without hindrance.

TSA Blood Agar Base 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. 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:	38.5gm/L
Pancreatic Digest of Casein	15.0gm
Peptic Digest of Soybean Meal	5.0gm
Sodium Chloride	5.0gm
Agar	13.5gm

Final pH 7.3 +/- 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 38.5gm 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.

For use with blood:

1. Prepare media as above.

2. Cool to 45-50ºC. and aseptically add defibrinated blood with thorough mixing.

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. A10.

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.

Neisseria gonorrhoeae may grow on this media with added blood due to the highly enriched nature of the formula.

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	
Streptococcus pyogenes ATCC® 19615	A	18-24hr	35°C	Aerobic	Growth; beta-hemolysis
Streptococcus pneumoniae ATCC® 6305	A	18-24hr	35°C	Aerobic	Growth; alpha-hemolysis
Staphylococcus aureus ATCC® 25923	A	18-24hr	35°C	Aerobic	Growth; white colonies
Escherichia coli ATCC® 25922	A	18-24hr	35°C	Aerobic	Growth; off-white colonies
Enterococcus faecalis ATCC® 29212	A	18-24hr	35°C	Aerobic	Growth; non-hemolytic

* 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.

** Expected results when prepared with the addition of 5% sheep blood.

PHYSICAL APPEARANCE

CRITERION™ Tryptic Soy Blood Agar Base powder should appear homogeneous, free-flowing, and light beige in

color. The prepared basal media should appear slightly opalescent, and light amber in color. The prepared media, with the addition of blood, should appear opaque, and red 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.

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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]