

Instructions for Use

CRITERION[™] GROUP A BETA STREP AGAR BASE

Cat. no. C5110	CRITERION™ Group A Beta Strep Agar Base	85.9gm
Cat. no. C5111	CRITERION™ Group A Beta Strep Agar Base	500gm
Cat. no. C5112	CRITERION™ Group A Beta Strep Agar Base	2kg
<u>Cat. no. C5113</u>	CRITERION™ Group A Beta Strep Agar Base	10kg
Cat. no. C5114	CRITERION™ Group A Beta Strep Agar Base	50kg

INTENDED USE

IFU

Hardy Diagnostics CRITERION[™] Group A Beta Strep Agar Base is an enriched media for the selective isolation of group A *Streptococcus (Streptococcus pyogenes)* from clinical specimens.

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 Group A Beta Strep Agar Base is a selective media for isolation of group A streptococci from respiratory sources. This medium will inhibit most other oral flora including diptheroids, coliforms, staphylococci, *Micrococcusspp., Haemophilus spp., Neisseria spp., and S. viridans. Streptococcuspneumoniae* is also inhibited.

Tryptic Soy Agar is the basal medium for CRITERIONTM Group A Beta Strep Agar Base. Organic nitrogen, particularly amino acids and long-chained peptides, are supplied by the combination of casein and soy peptones. This combination renders the medium highly nutritious. Osmotic equilibrium is maintained by sodium chloride. Selective agents are present in the media to suppress much of the normal respiratory flora. Sheep blood (5%) is added to facilitate growth and to detect hemolytic activity. The addition of a Bacitracin Disk (Cat. no. Z7021), 0.04 units, aids in the presumptive identification of *S. pyogenes* from alternative group A strains or from other PYR-positive, beta-hemolytic species.

FORMULA

Gram weight per liter:	42.2gm/L
Casein Peptone	10.0gm
Proteose Peptone	4.0gm
Sodium Chloride	5.5gm
Selective Agents	10.2mg

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 "<u>Storage</u>" 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 42.95gm of the dehydrated culture media in 1 liter of distilled or deionized water. Stir to mix thoroughly.
- 2. Add 2.0mL of a 0.2mg/mL Crystal Violet solution.
- 3. Heat to boiling to dissolve completely.
- 4. Sterilize in the autoclave at 121°C. for 15 minutes.
- 5. Cool to 45-50°C.
- 6. Aseptically add 50ml of sterile defibrinated sheep blood. Stir gently while dispensing.

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. A72.

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.

Unless a provision is made to reduce oxygen tension, approximately 2% of group A streptococci may be missed if incubated aerobically. It is recommended that several stabs be made into the medium upon inoculation.⁽²⁾ Incubation increased CO_2 or anaerobically is recommended.

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
Streptococcus pyogenes ATCC [®] 19615	А	24hr	35°C	CO ₂ **	Growth with beta-hemolysis
Streptococcus mitis ATCC [®] 6249	В	24hr	35°C	CO ₂ **	Partial to complete inhibition
Escherichia coli ATCC [®] 25922	В	24hr	35°C	CO ₂ **	Partial to complete inhibition
Staphylococcus epidermidis ATCC [®] 12228	В	24hr	35°C	CO ₂ **	Partial to complete inhibition

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

** Atmosphere of incubation is enriched with 5-10% CO₂.

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 Group A Beta Strep Agar Base powder should appear homogeneous, free-flowing, and light beige in color. The prepared media should appear opaque, and cherry 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. Isenberg, H.D. *Clinical Microbiology Procedures Handbook*, Vol. I, II & III. American Society for Microbiology, Washington, D.C.

5. Koneman, E.W., et al. *Color Atlas and Textbook of Diagnostic Microbiology*, J.B. Lippincott Company, Philadelphia, PA.

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

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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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