

# Instructions for Use

# CRITERION™ SF (STREPTOCOCCUS FAECALIS) BROTH

Cat. no. C6930	CRITERION™ SF Broth	72gm
Cat. no. C6931	CRITERION™ SF Broth	500gm
Cat. no. C6932	CRITERION™ SF Broth	2kg
Cat. no. C6933	CRITERION™ SF Broth	10kg
Cat. no. C6934	CRITERION™ SF Broth	50kg

# **INTENDED USE**

Hardy Diagnostics  $CRITERION^{TM}$  SF Broth is recommended for the cultivation and differentiation of group D enterococci from group D non-enterococci.

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

In general *Enterococcus* inhabit the intestinal tract of both warm and cold-blooded animals. *Enterococcus faecalis* and *E. faecium* are heat resistant and are able to survive milk pasteurization. *E. faecium* is especially heat tolerant. Other enterococci, especially those that are highly resistant to antibiotics, can cause serious illness to humans. Because enterococci have the ability to survive and grow in food processing plants they serve as a good index of sanitation<sup>(11)</sup>

CRITERION<sup>TM</sup> SF Broth is prepared according to the formulation developed by Hajna and Perry.<sup>(12)</sup> The medium contains 0.05% sodium azide, casein peptone, dextrose and bromcresol purple. Sodium azide acts as the selective agent by inhibiting the cytochrome oxidase enzyme in the electron transport chain. Casein peptone and dextrose supply necessary growth nutrients. Bromcresol purple serves as the color indicator.

Specimens containing group D enterococci result in the production of acid from dextrose-fermentation. Acid production is noted by a color change in the medium from purple to yellow by use of bromcresol as the pH indicator. Appearance of a yellow color change is indicative of the presence of group D enterococci.

# **FORMULA**

Gram weight per liter:	36.0gm/L
Pancreatic Digest of Casein	20.0gm
Dextrose	5.0gm

Sodium Chloride	5.0gm
Dipotassium Phosphate	4.0gm
Monopotassium Phosphate	1.5gm
Sodium Azide	0.5gm
Bromcresol Purple	32.0mg

Final pH 6.9 +/- 0.2 at 25°C.

#### 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 to gray.

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 36.0gm of the dehydrated culture media in 1 liter of distilled or deionized water. Stir to mix thoroughly.
- 2. Heat as necessary to dissolve completely.
- 3. Sterilize in the autoclave at 121°C. for 15 minutes.
- 4. Cool to 45-50°C.

<sup>\*</sup> Adjusted and/or supplemented as required to meet performance criteria.

# 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. K45.

# **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.

Enterococci will usually result in heavy growth and a color change within 24 hours; some strains, however, take 48 hours while others grow with no color change even after 72 hours. (4)

Refer to the document "Limitations of Procedures and Warranty" for more information.

# MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, other culture media, swabs, applicator sticks, incinerators and incubators, etc., as well as serological and biochemical reagents, 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	
Enterococcus faecalis ATCC® 29212	E	24-48hr	35°C	Aerobic	Growth; broth turns yellow
Streptococcus pyogenes ATCC® 19615	Е	24-48hr	35°C	Aerobic	Inhibited; broth remains purple

<sup>\*</sup> 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

CRITERION<sup>TM</sup> SF Broth powder should appear homogeneous, free-flowing, and light beige to gray in color. The prepared media should appear clear, and purple in color.

# **REFERENCES**

- 1. MacFaddin, J.F. 1985. *Media for Isolation, Cultivation, Identification, Maintenance of Bacteria*, Vol. I. Williams & Wilkins, Baltimore, MD.
- 2. Clinical Laboratory Standards Institute (CLSI formerly NCCLS). 1996. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22-A2, Vol. 16, No. 16, Clinical Laboratory Standards Institute (CLSI formerly NCCLS), Villanova, PA.
- 3. 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.
- 4. Jorgensen., et al. Manual of Clinical Microbiology, American Society for Microbiology, Washington, D.C.
- 5. Tille, P., et al. Bailey and Scott's Diagnostic Microbiology, C.V. Mosby Company, St. Louis, MO.
- 6. Isenberg, H.D. *Clinical Microbiology Procedures Handbook*, Vol. I, II & III. American Society for Microbiology, Washington, D.C.
- 7. Koneman, E.W., et al. *Color Atlas and Textbook of Diagnostic Microbiology*, J.B. Lippincott Company, Philadelphia, PA.
- 10. American Public Health Association. *Standard Methods for the Examination of Dairy Products*, APHA, Washington, D.C.
- 11. APHA Technical Committee on Microbiological Methods for Foods. *Compendium of Methods for the Microbiological Examination of Foods*, APHA, Washington, D.C.
- 12. Hajna and Perry. 1943. Am. Jour. Publ. Health.; 33:550.

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

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**Ordering Information** 

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

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