

Instructions for Use

CRITERION™ BRILLIANT GREEN BILE BROTH

| Cat. no. C5250 | CRITERION™ Brilliant Green Bile Broth | 80gm |
|-----------------------|--|-------|
| Cat. no. C5251 | CRITERION TM Brilliant Green Bile Broth | 500gm |
| <u>Cat. no. C5252</u> | CRITERION™ Brilliant Green Bile Broth | 2kg |
| <u>Cat. no. C5253</u> | CRITERION TM Brilliant Green Bile Broth | 10kg |
| Cat. no. C5254 | CRITERION™ Brilliant Green Bile Broth | 50kg |

INTENDED USE

IFU

Hardy Diagnostics CRITERIONTM Brilliant Green Bile Broth is recommended for the detection of coliforms in water and other samples.

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 for Brilliant Green Bile Broth was developed by the Association of Official Analytical Chemistry and the American Public Health Association.^(3,5) The basal medium is composed of peptone, which contains 2% bile, and brilliant green dye. The bile is inhibitory to gram-positive flora while the brilliant green dye inhibits selected gram-negative bacilli. Lactose-fermenting organisms that are resistant to the inhibitors are detected by the production of gas. Gas production is noted by the appearance of bubbles in the durham tube.

FORMULA

| Gram weight per liter: | 40.0gm/L |
|------------------------------|----------|
| | |
| Oxbile (Oxgall) | 20.0gm |
| Pancreatic Digest of Gelatin | 10.0gm |
| Lactose | 10.0gm |
| Brilliant Green | 13.3mg |

Final pH 7.2 +/- 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 greenish-beige.

Store the prepared culture media at 2-30°C. Tubed media with slips caps are stored 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 40.0gm of the dehydrated culture media in 1 liter of distilled or deionized water. Stir to mix thoroughly.

- 2. Heat as necessary to dissolve completely. Avoid overheating.
- 3. Dispense into tubes containing durham tubes.

4. Sterilize in the autoclave at 121°C for 12-15 minutes. Heat sensitive product. Depending on autoclave used, time or temperature adjustment may be necessary.

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. K09.

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.

It may be necessary to invert the tube prior to inoculation if bubbles are trapped in the durham tube. Trapped bubbles that are not released may lead to false-positive results.

Turbidity alone is not indicative of a positive test for the presence of coliforms; turbidity with gas production is considered a positive test.

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 |
| Escherichia coli ATCC [®] 25922 | А | 18-48hr | 35°C | Aerobic | Growth; gas bubble in durham tube |
| Salmonella enterica ATCC [®] 14028 | А | 18-48hr | 35°C | Aerobic | Growth; no gas bubble in durham tube |
| Enterococcus faecalis ATCC [®] 29212 | В | 18-48hr | 35°C | Aerobic | Inhibited |

* 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 <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 Brilliant Green Bile Broth powder should appear homogeneous, free-flowing, and greenish-beige in color. The prepared media should appear clear, and light green in color.

REFERENCES

1. *Compendium of Methods for the Microbiological Examination of Food*. American Public Health Association, Washington, D.C.

2. American Public Health Association. *Standard Methods for the Examination of Dairy Products*, APHA, Washington, D.C.

3. American Public Health Association. *Standard Methods for the Examination of Water and Wastewater*, APHA, Washington, D.C.

4. "Public Health Service Drinking Water Standards," Publication No. 956. 1962. U.S. Government Printing Office, Washington, D.C.

5. Williams, ed. 1984. Official Methods of Analysis of the Association of Official Analytical Chemists, 14th ed., AOAC, Arlington, VA.

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

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