IFU

Instructions for Use

CRITERION™ AZIDE DEXTROSE BROTH

| <u>Cat. no. C5050</u> | CRITERION™ Azide Dextrose Broth | 69.4gm |
|-----------------------|---------------------------------|--------|
| Cat. no. C5051 | CRITERION™ Azide Dextrose Broth | 500gm |
| Cat. no. C5052 | CRITERION™ Azide Dextrose Broth | 2kg |
| Cat. no. C5053 | CRITERION™ Azide Dextrose Broth | 10kg |
| Cat. no. C5054 | CRITERION™ Azide Dextrose Broth | 50kg |

INTENDED USE

Hardy Diagnostics CRITERION[™] Azide Dextrose Broth is used to detect the presence of streptococci in water, shellfish, sewage, and milk.

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

Azide Dextrose Broth is recommended by the APHA for the isolation of fecal streptococci.⁽²⁾ Various workers indicated that sodium azide could be used to inhibit gram-negative microorganisms while allowing the growth of gram-positive microorganisms, particularly *Streptococcus* spp. Azide Dextrose Broth has also been used for isolation of streptococci in foodstuffs and other specimens of sanitary significance as an indication of contamination.

Beef extract and tryptose serve as sources of carbon, nitrogen, vitamins and minerals. Dextrose serves as an energy source and sodium chloride is added to maintain the osmotic equilibrium. Sodium azide inhibits cytochrome oxidase in gram-negative bacteria.

FORMULA

| Gram weight per liter: | 34.7gm/L | | | | |
|------------------------|----------|--|--|--|--|
| | | | | | |
| Casein Peptone | 7.5gm | | | | |
| Animal Tissue Peptone | 7.5gm | | | | |
| Dextrose | 7.5gm | | | | |
| Sodium Chloride | 7.5gm | | | | |
| Beef Extract | 4.5gm | | | | |
| Sodium Azide | 0.2gm | | | | |

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 light beige.

Store the prepared media at 2-8°C.

The expiration dating 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 quality control incubation times.

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." The "Guidelines for Isolation Precautions" is available from the Centers for Disease Control and Prevention at www.cdc.gov/ncidod/dhqp/gl_isolation.html.

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 M-29: *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

Refer to the document SDS Search instructions on the Hardy Diagnostics' website for more information.

METHOD OF PREPARATION FOR DEHYDRATED CULTURE MEDIA

1. Suspend 34.7gm of the dehydrated culture media in 1 liter of distilled or deionized water.

2. Heat as needed to dissolve completely.

3. 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. K87.

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.

CRITERIONTM Azide Dextrose Broth is used to detect presumptive evidence of fecal contamination. Further biochemical testing must be done for confirmation.

For inoculum sizes of 10ml or larger, use double strength medium to prevent dilution of ingredients.

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 Certificates of Analysis (CofA). The following organisms are routinely used for testing at Hardy Diagnostics:

| Test Organisms | Inoculation Method* | Incubation | | | Results |
|---|------------------------|------------|-------------|------------|--------------|
| | | Time | Temperature | Atmosphere | Results |
| <i>Enterococcus faecalis</i> ATCC [®] 29212 | А | 24-48hr | 35°C | Aerobic | Heavy growth |
| <i>Escherichia coli</i> ATCC [®] 25922 | В | 24-48hr | 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 certificates of analysis (CofA) available from Hardy Diagnostics <u>Certificates of Analysis</u> website. In addition, refer to the following document "<u>Finished</u> <u>Product Quality Control Procedures</u>," for more information on QC or see reference(s) for more specific information.

PHYSICAL APPEARANCE

CRITERION[™] Azide Dextrose Broth powder should appear homogeneous, free-flowing, and light beige in color. Visually the single strength prepared broth should appear clear, and light to medium amber in color; double strength should appear clear, and medium to dark amber in color.

REFERENCES

1. MacFaddin, J.F. 1985. *Media for Isolation, Cultivation, Identification, Maintenance of Bacteria*, Vol. I. Williams & Wilkins, Baltimore, MD.

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

3. APHA Technical Committee on Microbiological Methods for Foods. *Compendium of Methods for the Microbiological Examination of Foods*, APHA, Washington, D.C.

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

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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