IFU

Instructions for Use

CRITERION™ LAURYL TRYPTOSE BROTH

Cat. no. C5980	CRITERION™ Lauryl Tryptose Broth	69.4gm
Cat. no. C5981	CRITERION™ Lauryl Tryptose Broth	500gm
Cat. no. C5982	CRITERION™ Lauryl Tryptose Broth	2kg
Cat. no. C5983	CRITERION™ Lauryl Tryptose Broth	10kg
Cat. no. C5984	CRITERION™ Lauryl Tryptose Broth	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Lauryl Tryptose Broth is used for detecting coliform organisms in water, wastewater, and foods.

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

Lauryl Tryptose Broth is prepared according to the formulation of Mallmann and Darby.[5] Sodium lauryl sulfate, by inhibiting most gram-positive microorganisms, serves as a selective agent for coliforms. The addition of lactose to the medium allows for detection of rapid lactose-fermentation by coliforms. Essential growth ingredients are provided by casein peptone which is composed of nitrogen, carbon compounds, sulfur and trace ingredients. Potassium phosphate acts as a buffer while sodium chloride serves to maintain osmotic equilibrium. A durham tube is present in order to detect the production of gas.

Coliforms grown in Lauryl Tryptose Broth ferment lactose and produce gas. Other bacteria are either inhibited or grow without producing gas.

FORMULA

Gram weight per liter:	35.6gm/L
Tryptose	20.0gm
Lactose	5.0gm
Sodium Chloride	5.0gm
Monopotassium Phosphate	2.75gm
Dipotassium Phosphate	2.75gm
Sodium Lauryl Sulfate	0.1gm

Final pH 6.8 +/- 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 media at 2-30ºC.

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

2. Warm slightly to dissolve completely.

3. Dispense into tubes containing inverted fermentation vials.

4. Autoclave at 121ºC. 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. K33.

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.

Turbidity without gas production is not indicative of a positive test.

A precipitate or cloudiness may form in refrigerated broth. Media will become clear when warmed to room temperature.

Prior to inoculation of the medium, it may be necessary to invert the tube in order to release any bubbles that may be trapped in the durham tube. Bubbles that are not removed before inoculation may lead to false-positive results.

Since the nutritional requirements of organisms vary, some strains may be encountered that fail to grow or grow poorly on this medium.

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	
Escherichia coli ATCC® 25922	A	24hr	35°C	Aerobic	Growth; gas bubble in durham tube
Enterococcus aerogenes ATCC® 13048	A	24hr	35°C	Aerobic	Growth; weak gas bubble in durham tube at 48 hours
Salmonella enterica ATCC® 14028	A	48hr	35°C	Aerobic	Growth; no gas production
Serratia marcescens ATCC® 8100	A	48hr	35°C	Aerobic	Growth; no gas production
Staphylococcus aureus ATCC® 25923	B	48hr	35°C	Aerobic	Partial to complete inhibition; no gas production

* 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.

PHYSICAL APPEARANCE

CRITERION™ Lauryl Tryptose Broth powder should appear homogeneous, free-flowing, and light beige in color. The prepared media should appear clear, and amber in color.

REFERENCES

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

2. *The United States Pharmacopeia*. U.S. Pharmacopeial Convention Inc., Rockville, MD.

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

4. Greenberg, et al. *Standard Methods for the Examination of Water and Wastewater*. APHA, Washington, D.C.

5. Mallmann, W.L. and C.W. Darby. 1941. *Am. J. Publ. Health;* 31:127.

6. Williams, ed. *Official Methods of Analysis of the Association of Official Analytical Chemists*. AOAC, Arlington, VA.

7. FDA. *Bacteriological Analytical Manual*. AOAC, Gaithersburg, MD.

8. Greenberg, et al. *Standard Methods for the Examination of Water and Wastewater*. APHA, Washington, D.C.

IFU-10186[B]

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Ordering Information

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.

HDQA 2207B [D]