



Instructions for Use

CRITERION™ LACTOSE BROTH

Cat. no. C5940	CRITERION™ Lactose Broth	26gm
Cat. no. C5941	CRITERION™ Lactose Broth	500gm
Cat. no. C5942	CRITERION™ Lactose Broth	2kg
Cat. no. C5943	CRITERION™ Lactose Broth	10kg
Cat. no. C5944	CRITERION™ Lactose Broth	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Lactose Broth is used to detect coliforms in food, dairy products, and water, and to preenrich samples for the recovery of *Salmonella* species.

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 processed foods, *Salmonella* species can be present in low concentrations and in debilitated condition. Lactose Broth provides a environment favorable for the recovery of *Salmonella*. The media provides for the repair of cell damage, dilutes toxic substances that may be present, and favors growth of *Salmonella* over other species.⁽²⁾

Lactose Broth is also used to detect coliforms in food, dairy products, and water. The concentration of ingredients in Lactose Broth, when used to detect coliforms in samples, must remain the same after addition of the sample being tested.

FORMULA

Gram weight per liter:	13.0gm/L
Pancreatic Digest of Gelatin	5.0gm
Lactose	5.0gm
Beef Extract	3.0gm

Final pH 6.9 +/- 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 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. See chart below for amount of the dehydrated culture media to suspend in 1 liter of distilled or deionized water.

Lactose Broth Preparation:^(4,7)

Inoculum (ml)	Amount of Medium in Tube (ml)	Amount of Medium and Inoculum (ml)	Dehydrated Lactose Broth (grams/liter)
1	10 or >	11 or >	13.0
10	10	20	26.0
10	20	30	19.5
100	50	150	39.0
100	35	135	49.4
100	20	120	78.0

2. Heat to boiling and mix to dissolve completely.

3. Sterilize in the 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. K137.

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.

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	
<i>Escherichia coli</i> ATCC® 25922	A	18-48hr	35°C	Aerobic	Growth; gas production
<i>Salmonella enterica</i> subsp. <i>enterica</i> serovar <i>typhimurium</i> ATCC® 14028	A	18-48hr	35°C	Aerobic	Growth; 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 certificates of analysis (CofA) available from Hardy Diagnostics [Certificates of Analysis](#) website. In addition, refer to the following document "[Finished Product Quality Control Procedures](#)," for more information on QC or see reference(s) for more specific information.

PHYSICAL APPEARANCE

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

REFERENCES

1. American Public Health Association. *Standard Methods for the Examination of Dairy Products*, APHA, Washington, D.C.
2. APHA Technical Committee on Microbiological Methods for Foods. *Compendium of Methods for the Microbiological Examination of Foods*, APHA, Washington, D.C.
3. U.S. Food and Drug Administration. *Bacteriological Analytical Manual*. AOAC, Arlington, VA.
<http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm>.
4. American Public Health Association. *Standard Methods for the Examination of Water and Wastewater*, APHA, Washington, D.C.
5. *U.S. Pharmacopeia*, 22nd rev. 1990. U.S. Pharmacopeial Convention, Rockville, MD.
6. Jorgensen., et al. *Manual of Clinical Microbiology*, American Society for Microbiology, Washington, D.C.
7. MacFaddin, J.F. 1985. *Media for Isolation, Cultivation, Identification, Maintenance of Bacteria*, Vol. I. Williams & Wilkins, Baltimore, MD.
8. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22. Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS), Wayne, PA.

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

IFU-10184[A]



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[Ordering Information](#)

Distribution Centers:

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

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