

Instructions for Use

CRITERION™ BRUCELLA BROTH

Cat. no. C5310	CRITERION™ Brucella Broth	56gm
<u>Cat. no. C5311</u>	CRITERION™ Brucella Broth	500gm
Cat. no. C5312	CRITERION™ Brucella Broth	2kg
Cat. no. C5313	CRITERION™ Brucella Broth	10kg
Cat. no. C5314	CRITERION™ Brucella Broth	50kg

INTENDED USE

Hardy Diagnostics CRITERION[™] Brucella Broth is used for the cultivation of *Brucella* species, and other fastidious organisms.

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

CRITERIONTM Brucella Broth, used for cultivation of *Brucella* and other fastidious organisms, is based upon the APHA formulation for Albimi Broth.⁽³⁾ Brucella Broth is recommended for the isolation of *Brucella* species from blood cultures.^(1,4) Additionally, Brucella Broth is specified in the *Compendium of Methods for the Microbiological Examination of Food*.⁽¹⁰⁾

CRITERIONTM Brucella Broth contains pancreatic digest of casein, peptic digest of animal tissue, and yeast extract as sources of nutrients. Dextrose is added as a carbon source in the media. Various growth factors, such as hemin and vitamin K, can be added aseptically to the medium after it has been autoclaved, to provide additional nutrients for more fastidious organism. Antibiotics can also be added to make the medium more selective.

FORMULA

Gram weight per liter:	28.0gm/L				
Pancreatic Digest of Casein	10.0gm				
Peptic Digest of Animal Tissue	10.0gm				
Yeast Extract	2.0gm				
Sodium Chloride	5.0gm				
Dextrose	1.0gm				
Sodium Bisulfite	0.1gm				

Final pH 7.0 +/- 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 28.0gm of the dehydrated culture media in 1 liter of distilled or deionized water.
- 2. Heat as necessary to dissolve completely.
- 3. Sterilize in the autoclave at 121°C. for 15 minutes.
- 4. Cool to 45-50°C. and aseptically add enrichments or antibiotics, if desired.

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. K218.

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.

Brucella Broth is a general purpose growth media. Organisms growing in Brucella Broth will require further biochemical and/or serological testing for complete identification.

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, 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>Bacteroides fragilis</i> ATCC [®] 25285	А	24-72hr	35°C	Anaerobic	Growth
<i>Clostridium perfringens</i> ATCC [®] 13124	А	24-72hr	35°C	Anaerobic	Growth
Streptococcus pyogenes ATCC [®] 19615	А	24-72hr	35°C	CO 2 **	Growth

* Refer to the document "Inoculation Procedures for Media QC" for more information.

** Atmosphere of incubation is enriched with 5-10% CO2.

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

CRITERIONTM Brucella Broth powder should appear homogeneous, free-flowing, and light beige in color. The prepared media should appear clear to slightly hazy, and light amber in color.

REFERENCES

1. Baron, E.J., L.R. Peterson and S.M. Finegold. 1994. *Bailey and Scott's Diagnostic Microbiology*, 9th ed. Mosby-Year Book, Inc., St. Louis, MO.

2. Tille, P., et al. Bailey and Scott's Diagnostic Microbiology, C.V. Mosby Company, St. Louis, MO.

3. Hausler, W.J. 1976. *Standard Methods for the Examination of Dairy Products*, 14th ed. American Public Health Association, Washington, D.C.

4. Isenberg, H.D. *Clinical Microbiology Procedures Handbook,* Vol. I, II & III. American Society for Microbiology, Washington, D.C.

5. Koneman, E.W., et al. *Color Atlas and Textbook of Diagnostic Microbiology*, J.B. Lippincott Company, Philadelphia, PA.

6. Marshall, R.T., ed. 1992. *Standard Methods for the Examination of Dairy Products*, 16th ed. APHA, Washington, D.C.

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

8. Jorgensen., et al. Manual of Clinical Microbiology, American Society for Microbiology, Washington, D.C.

9. Vanderzant, C. and D.F. Splittstoesser. 1992. Compendium of Methods for the Microbiological Examination of Food, 3rd ed. APHA, Washington, D.C.

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

IFU-10130[A]



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Distribution Centers:

 $California \cdot Washington \cdot Utah \cdot Arizona \cdot Texas \cdot Ohio \cdot New York \cdot Florida \cdot North Carolina$

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