IFU

Instructions for Use

CRITERION™ BRUCELLA AGAR

Cat. no. C5300	CRITERION™ Brucella Agar	86gm
Cat. no. C5301	CRITERION™ Brucella Agar	500gm
Cat. no. C5302	CRITERION™ Brucella Agar	2kg
Cat. no. C5303	CRITERION™ Brucella Agar	10kg
Cat. no. C5304	CRITERION™ Brucella Agar	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Brucella Agar 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

Brucella Agar is prepared according to APHA formula for Albimi Broth, which is used for the isolation of *Brucella* species.[2] Brucellosis is a zoonotic disease with a domestic-animal reservoir. Transmission by milk, milk products, meat and direct contact with infected animals is the usual route of exposure.[1]

CRITERION™ Brucella Agar 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 and additives can be added aseptically to the media after it has been autoclaved. Adding hemin, vitamin K, sheep or horse blood, provide nutrients for more fastidious organisms. Antibiotics may be added to make the media selective.

Brucella Agar is also recommended for use in agar dilution susceptibility tests for anaerobes.[1] Additionally, *Standard Methods for the Examination of Dairy Products* recommends Brucella Agar for the cultivation of *Brucella* species from dairy samples.[2]

FORMULA

Gram weight per liter:	43.0gm/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
Agar	15.0gm

Final pH 7.0 +/- 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 culture media at 2-8ºC.

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 43.0gm of the dehydrated culture media in 1 liter of distilled or deionized water.

2. Heat to boiling and mix to dissolve completely.

3. Sterilize in the autoclave at 121ºC. for 15 minutes. Do not overheat.

4. Cool to 45-50ºC. and aseptically add enrichments, 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. H05 which contains sheep blood, hemin, and vitamin K.

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.

Brucella Agar is a general purpose growth media. Colonies growing on Brucella Agar will require further biochemical and/or serological testing for complete identification.

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

Hemolytic reactions of organisms may vary on this medium depending on the type of animal blood used.

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	
Bacteroides fragilis ATCC® 25285	A	24-72hr	35°C	Anaerobic	Growth
Clostridium perfringens ATCC® 13124	A	24-72hr	35°C	Anaerobic	Growth

* 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™ Brucella Agar powder should appear homogeneous, free-flowing, and light beige in color. The

prepared media should appear slightly hazy, and light amber in color.

REFERENCES

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

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

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

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

7. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22. Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS), Wayne, PA.

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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]