IFU

HARDY DIAGNOSTICS
A Culture of Service™

Instructions for Use

BRUCELLA BROTH

Cat. no. R18	Brucella Broth, 13x100mm Tube, 1ml	20 tubes/box

INTENDED USE

Hardy Diagnostics Brucella Broth is recommended for use as a general purpose growth media for the cultivation of a variety of fastidious organisms, such as *Streptococcus* and *Brucella* spp. in clinical and food samples.

SUMMARY

Brucella broth is rich in nutrients and growth factors making it very suitable to grow and isolate a wide variety of microorganisms. This medium is used extensively for the cultivation of *Brucella* species along with the cultivation of many anaerobes from diagnostic specimens. Brucella Broth can also be used as the liquid medium component in blood culture bottles.[2]

Brucella Broth supports the growth of fastidious microorganisms with peptones, dextrose and yeast extract. The peptones provide nitrogen, vitamins, minerals and amino acids promoting growth. Yeast extract is a source of the B-complex vitamins. Dextrose is an energy source as a fermentable carbohydrate. The sodium bisulfite is a reducing agent and sodium chloride maintains osmotic balance.

FORMULA

Ingredients per liter of deionized water:*

Pancreatic Digest of Casein	10.0gm
Peptic Digest of Animal Tissue	10.0gm
Sodium Chloride	5.0gm
Yeast Extract	2.0gm
Dextrose	1.0gm
Sodium Bisulfite	0.1gm

Final pH 7.0 +/- 0.2 at 25ºC.

* Adju sted and/or supplemented as required to meet performance criteria.

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-30ºC. away from direct light. Cat. no. R18 should be stored at 2-8ºC. away from direct light. Media should not be used if there are any signs of deterioration, discoloration, contamination, or if the expiration

date has passed. Product is light and temperature sensitive; protect from light, excessive heat, moisture, and freezing.

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

Brucella spp. are classified as Biosafety Level 3 pathogens. Procedures with live cultures and antigens must be confined to a Class II biological safety cabinet (BSC). Biosafety Level 2 practices, containment equipment and facilities are recommended for routine clinical specimens of human or animal origin that contains or is believed to contain pathogenic *Brucella* spp.[2,11]

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 Precautions for blood. Do not ingest, inhale, or allow to come into contact with skin.

This product is for *in vitro* diagnostic 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.

PROCEDURE

Specimen Collection: Consult listed references for information on specimen collection.[2-4,7-10] Infectious material should be submitted directly to the laboratory without delay and protected from excessive heat, cold, and oxygen exposure. If there is to be a delay in processing, the specimen should be inoculated onto an appropriate transport medium (Cat. no. S120D) and refrigerated until inoculation.

Method of Use: Consult the listed references for the appropriate cultivation techniques using this medium.[2-4,7-10]

1. The medium can be inoculated with a pure culture of an isolated colony, macerated tissue or liquid from a clinical specimen or a food sample.

2. For the cultivation of *Brucella* spp., incubate at 35ºC in duplicate. Incubate one set under aerobic conditions and another set at 5-10% CO_2.

3. For the cultivation of other organisms, incubate at 35 degrees with or without 5-10% CO_2 depending on the most suitable atmosphere to encourage growth.

INTERPRETATION OF RESULTS

Consult listed references for the interpretation of growth and other identification tests to identify growth of organism in this medium.[2-5, 8, 9 ,10]

The presence of growth is indicated by the appearance of turbidity.

LIMITATIONS

It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification of bacteria and/or fungi.

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 loops, swabs, applicator sticks, other culture media, incinerators, and incubators, etc., as well as serological and biochemical reagents, 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
Streptococcus pyogenes ATCC® 19615***	A	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% CO_2.

*** Recommended QC strains for User Quality Control according to the CLSI document M22 when applicable.

USER QUALITY CONTROL

End users of commercially prepared 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. Also refer to the document "Finished Product Quality Control Procedures," and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media* for more information on the appropriate QC procedures. See the references below.

PHYSICAL APPEARANCE

Brucella Broth should appear clear and light amber in color, with no precipitates or debris.

REFERENCES

1. Anderson, N.L., et al. *Cumitech 3B; Quality Systems in the Clinical Microbiology Laboratory*, Coordinating ed., A.S. Weissfeld. American Society for Microbiology, Washington, D.C.

2. Jorgensen., et al. *Manual of Clinical Microbiology*, American Society for Microbiology, 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. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22. Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS), Wayne, PA.

7. Association of Official Analytical Chemists. *Official Methods of Analysis*^{sm}, AOAC, Washington, D.C.

8. American Public Health Association. 1992. *Standard Methods for the Examination of Dairy Products*, 16th ed. APHA, Washington, D.C.

9. APHA Technical Committee on Microbiological Methods for Foods. 2001. *Compendium of Methods for the Microbiological Examination of Foods*, 4th ed. APHA, Washington, D.C.

10. U.S. Food and Drug Administration. *Bacteriological Analytical Manual*. AOAC, Arlington, VA. http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm.

11. U.S. Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health. 2007. *Biosafety in microbiological and biomedical laboratories*, 5th ed. HHS Publication No. (CDC) 93-8395. U.S. Government Printing Office, Washington, D.C.

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

IFU-10090[A]

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