IFU



Instructions for Use

BHI BROTH

Cat. no. R10	BHI Broth, 13x100mm Tube,0.5ml	20 tubes/box
Cat. no. R15	BHI Broth, 13x100mm Tube, 2ml	20 tubes/box
Cat. no. R20	BHI Broth, 13x100mm Tube, 5ml	20 tubes/box
Cat. no. K110	BHI Broth, 13x100mm Tube, 1ml	20 tubes/box
<u>Cat. no. K27</u>	BHI Broth, 16x100mm Glass Tube, 5ml	20 tubes/box
Cat. no. K25	BHI Broth, 16x125mm Tube, 10ml	20 tubes/box
Cat. no. K08	BHI Broth with Fildes, 16x125mm Tube, 10ml	20 tubes/box
Cat. no. K75	BHI Broth with Hemin and Vitamin K, 16x125mm Tube, 10ml	20 tubes/box

INTENDED USE

Hardy Diagnostics Brain Heart Infusion (BHI) Broth is a general purpose nutrient medium recommended for the cultivation and isolation of a variety of fastidious and nonfastidious microorganisms, including bacteria, yeast, and mold. Brain Heart Infusion (BHI) Broth enriched with Fildes is useful for cultivating capsular strains of *Haemophilusinfluenzae*. Brain Heart Infusion (BHI) Broth enriched with Hemin and Vitamin K is recommended for the cultivation and isolation of aerobic and anaerobic microorganisms.

SUMMARY

Rosenow discovered a medium useful in the cultivation of streptococci by adding brain tissue to Dextrose Broth. (8) Formula modifications were made by various researchers who found the medium effective in the recovery of dental pathogens. (4,5,8)

The formulation presently in use employs calf brain, which is equivalent in nutritional value to beef heart infusion but provides a more optically clear medium. Additionally, a variety of supplements have been added to further enhance the recovery of fastidious microorganisms.

BHI with Fildes is used for organisms requiring blood derivatives, especially *Haemophilus* spp. Fildes is a peptic digest of sheep blood which is rich in X- and V-factors. (11,12)

Hardy Diagnostics BHI Broth, 0.5ml (Cat. no. R10) is used to prepare suspensions for microdilution minimal inhibitory concentration (MIC) inocula.

BHI with Hemin and Viatmin K is primarily used for anaerobic organism cultivation and the recovery of fastidious anaerobic organisms.

FORMULA

Ingredients per liter of deionized water:*

Calf Brain-Beef Heart Infusion	17.5gm
Pancreatic Digestion of Gelatin	10.0gm
Sodium Chloride	5.0gm
Disodium Phosphate	2.5gm
Dextrose	2.0gm

In addition, BHI Broth with Fildes (Cat. no. K08) contains:

Fildes Enrichment	50.0ml
Fildes Emichinent	30.0111

BHI Broth with Hemin and Vitamin K (Cat. no. K75) contains:

Hemin	5.0mg
Vitamin K	0.1mg

Final pH 7.4 +/- 0.3 at 25°C.

STORAGE AND SHELF LIFE

Storage: Upon receipt store BHI Broth at 2-30°C. away from direct light. BHI Broth, 0.5ml (Cat. no. R10), BHI Broth with Fildes (Cat. no. K08), and BHI Broth with H&K (Cat. no. K75) should be stored at 2-8°C away from direct light. Media should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), contamination, or if the expiration date has passed. Product is light and temperature sensitive; protect from light, excessive heat 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

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.

^{*} Adjusted and/or supplemented as required to meet performance criteria.

Refer to the document "Precautions When Using Media" for more information.

PROCEDURE

Specimen Collection: Infectious material should be submitted directly to the laboratory without delay and protected from excessive heat and cold. If there is to be a delay in processing, the specimen should be inoculated onto an appropriate transport medium and refrigerated until inoculation. Consult listed references for information on specimen collection. (1-3,6)

Method of Use: It is recommended that liquid media for anaerobic incubation should be reduced prior to inoculation by placing tubes (with loosened caps) under anaerobic conditions for 18-24 hours. Alternatively, the media may be reduced by bringing the media up to 100°C. in a boiling waterbath. Loosen screw caps slightly before heating, and tighten during cooling to room temperature. Consult listed references for the appropriate cultivation techniques using this medium.^(1-3,6)

Inoculate broth using aseptic techniques. Swab specimens may be inserted into the medium after plated media has been inoculated. Medium should be incubated at 35-37°C., checking daily, as needed. Growth or turbidity should be confirmed by Gram stain and subculture onto an appropriate solid medium.

INTERPRETATION OF RESULTS

Consult listed references for the interpretation of growth and other biochemical tests needed to identify organisms grown in this medium. (1-3,6)

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.

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, other culture media, swabs, applicator sticks, 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 Ouganisms	Inoculation Method*	Incubation			Results
Test Organisms		Time	Temperature	Atmosphere	Kesuits
BHI Broth**:					
Escherichia coli ATCC® 25922	A	18-24hr	35°C	Aerobic	Growth; broth becomes turbid
Staphylococcus aureus ATCC® 25923	A	18-24hr	35°C	Aerobic	Growth; broth becomes turbid
BHI Broth with Fildes:					

Haemophilus influenzae ATCC® 10211	A	24-48hr	35°C	Aerobic	Growth; broth becomes turbid	
Staphylococcus epidermidis ATCC® 12228	A	24-48hr	35°C	Aerobic	Growth; broth becomes turbid	
BHI Broth with Hemin and Vitamin K:						
Streptococcus pyogenes ATCC® 19615	Е	24-48hr	35°C	Aerobic	Growth; broth becomes turbid	
Bacteroides fragilis ATCC® 25285	Е	24-48hr	35°C	Aerobic	Growth; broth becomes turbid	
Clostridium perfringens ATCC® 13124	E	24-48hr	35°C	Aerobic	Growth; broth becomes turbid	
Clostridioides difficile/i> ATCC [®] 9689	Е	24-48hr	35°C	Aerobic	Growth; broth becomes turbid	

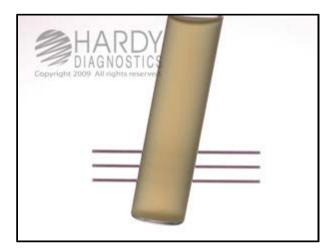
^{*} Refer to the document "Inoculation Procedures for Media OC" for more information.

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

- BHI Broth and BHI Broth with H&K should appear clear, and medium amber in color.
- BHI Broth with Fildes should appear clear, and reddish-brown in color.



Escherichia coli (ATCC® 25922) growing in BHI Broth (Cat. no. R20). Incubated aerobically for 24 hours at 35°C.



Uninoculated tube of BHI Broth (Cat. no. R20).

REFERENCES

^{**} Refer to guidelines for testing in the CLSI publication M22-A. (10)

- 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. Versalovic, J., et al. Manual of Clinical Microbiology. American Society for Microbiology, Washington, D.C.
- 3. Tille, P.M., et al. Bailey and Scott's Diagnostic Microbiology, C.V. Mosby Company, St. Louis, MO.
- 4. Falk, C.R., et al. 1939. J. Bacteriol.; 37:121.
- 5. Haden, R.L. 1932. Arch. Internal Med.; 32:828.
- 6. Isenberg, H.D. *Clinical Microbiology Procedures Handbook*, Vol. I, II & III. 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. Hitchens, A.P. 1921. J. Infect. Disease; 29:390.
- 9. Rosenow, E.C. 1919. J. Dental Research; 1:205.
- 10. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22. Clinical and Laboratory Standards Institute (CLSI formerly NCCLS), Wayne, PA.
- 11. Fildes, P. 1920. Br. J. Exp. Pathol.; 1:129.
- 12. Fildes, P. 1921. Br. J. Exp. Pathol.; 2:16.

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

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1430 West McCoy Lane, Santa Maria, CA 93455, USA Phone: (805) 346-2766 ext. 5658 Fax: (805) 346-2760

Website: <u>HardyDiagnostics.com</u>

Email: TechnicalServices@HardyDiagnostics.com

Ordering Information

Distribution Centers:

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