IFU



Instructions for Use

BLOOD AGAR

Cat. no. A10	Blood Agar 5%, 15x100mm Plate, 19ml	10 plates/bag
Cat. no. A10BX	Blood Agar 5%, 15x100mm Plate, 19ml	100 plates/box
Cat. no. A17BX	Blood Agar 8%, 15x100mm Plate, 18ml	100 plates/box
<u>Cat. no. A71</u>	Blood Agar 10%, 15x100mm Plate, 18ml	10 plates/bag
Cat. no. A127	Blood Agar 5%, 86x128mm Omni Tray, 30ml	10 plates/bag
Cat. no. GA10	Blood Agar 5%, 15x100mm Plate, 19ml (reduced stacking ring)	10 plates/bag
Cat. no. H28	Blood Agar 5%, 15x150mm Plate, 70ml	10 plates/bag
Cat. no. J22	Blood Agar 5% / Eosin Methylene Blue (EMB), Levine Agar, 15x100mm Biplate, 10ml/10ml	10 plates/bag
Cat. no. J32	Blood Agar 5% / MacConkey Agar, 15x100mm Biplate, 10ml/10ml	10 plates/bag
Cat. no. J32BX	Blood Agar 5% / MacConkey Agar, 15x100mm Biplate, 10ml/10ml	100 plates/box
Cat. no. J42	Blood Agar 5% / Chocolate Agar, 15x100mm Biplate, 10ml/10ml	10 plates/bag
<u>Cat. no. J65</u>	Blood Agar 5% / CLED Agar with Bile, 15x100mm Biplate, 10ml/10ml	10 plates/bag
Cat. no. J71	Urine Quad Plate (Eosine Methylene Blue (EMB) Agar, Levine / Xylose Lysine Deoxycholate (XLD) Agar, Modified / Simmons Citrate / Blood Agar, 5%), 15x100mm Quadplate, 5ml/section	10 plates/bag
Cat. no. J79	All Purpose Quad Plate (Eosine Methylene Blue (EMB) Agar / Mannitol Salt Agar (MSA) / Mycobiotic Agar / Blood Agar, 5%), 15x100mm Quadplate, 5ml/section	10 plates/bag
<u>Cat. no. J92</u>	Blood Agar 5% / Group A Beta Strep Agar, 15x100mm Biplate, 10ml/10ml	10 plates/bag
Cat. no. J93	Blood Agar 5% / Blood Agar 5%, 15x100mm Biplate, 10ml/10ml	10 plates/bag
Cat. No. J315	TSA Blood / CLED / MacConkey, 15x100mm Triplate, 7ml/section	10 plates/bag
<u>Cat. no. L12</u>	Blood Agar 5%, 16x100mm Tube, 5.5ml Slant	20 tubes/box
<u>Cat. no. P33</u>	Blood Agar 5%, Contact Plate, 15ml	10 plates/bag

INTENDED USE

Hardy Diagnostics Blood Agar products are recommended for use as general purpose growth media for the isolation, cultivation, and differentiation of a wide variety of microorganisms.

Cat. no. P33 is not intended to be used for the diagnosis of human disease.

SUMMARY

Tryptic Soy Agar is the basal medium for the Blood Agar products. Sheep blood has been added, in various concentrations, to facilitate the growth of some organisms, and for the observation of hemolytic reactions. The absence of reducing sugars and carbohydrates allows the hemolysis to occur without hindrance.

Blood Agar 5% Contact Plate (Cat. no. P33), is recommended for use in the cultivation of microorganisms from environmental surfaces. The contact plate has a specified grid molded into the bottom of the plate. They are used primarily to monitor microbial contamination, for enumeration of microbial colonies growing on a variety of surfaces, and to assist in determining surface sanitation.

FORMULA

Ingredients per liter of deionized water:*

Pancreatic Digest of Casein	15.0gm
Peptic Digest of Soybean Meal	5.0gm
Sodium Chloride	5.0gm
Sheep Blood	50.0ml
Agar	12.0gm

Final pH 7.3 +/- 0.2 at 25°C.

In addition, Blood Agar 8% (Cat. no. A17BX) contains 8.0% sheep blood and Blood Agar 10% (Cat. no. A71) contains 10.0% sheep blood.

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-8°C. away from direct light. Media should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), hemolysis, 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

For Cat. nos. A10, A10BX, A17BX, A127, A71, GA10, H28, J22, J32, J32BX, J42, J65, J71, J79, J92, J93, J315, and L12.

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the

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

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.

For Cat. no. P33

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.

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 media and refrigerated until inoculation. Consult listed references for information on specimen collection. (1-5)

Prepared media should be inoculated, incubated, and results recorded according to accepted procedures described in the listed reference texts. (1-5)

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:

Took Oncomismo	Inoculation Method*	Incubation			Results			
Test Organisms		Time	Temperature	Atmosphere	Results			
Streptococcus pneumoniae ATCC® 6305	A	24hr	35°C	Aerobic or CO ₂ **	Growth; alpha-hemolysis			
Streptococcus pyogenes ATCC® 19615***	A	24hr	35°C	Aerobic or CO ₂ **	Growth; beta-hemolysis			
Staphylococcus aureus ATCC® 25923***	A	24hr	35°C	Aerobic or CO ₂ **	Growth; beta-hemolysis			
Escherichia coli ATCC® 25922	A	24hr	35°C	Aerobic or CO ₂ **	Growth			
Enterococcus faecalis ATCC® 29212	A	24hr	35°C	Aerobic or CO ₂ **	Growth			
CAMP Test:****								
Staphylococcus aureus ATCC® 33862	Н	18-24hr	35°C	Aerobic	Growth			
Streptococcus agalactiae ATCC® 12386	Н	18-24hr	35°C	Aerobic	Growth; positive (enhanced arrowhead hemolysis)			
Streptococcus pyogenes ATCC® 19615	Н	18-24hr	35°C	Aerobic	Growth; negative (no enhanced arrowhead hemolysis)			

^{*} 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

^{**} Atmosphere of incubation is enriched with 5-10% CO₂ for Cat. no. J92.

^{***} Recommended QC strainsfor User Quality Control according to the CLSI document M22 when applicable.

^{****} Cat. nos. J65, J71, and J79 are not tested for the CAMP reaction.

Blood Agar products should appear opaque, and cherry red in color.



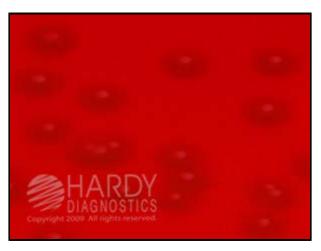
Streptococcus pyogenes (ATCC® 19615) colonies growing on Blood Agar, 5% Sheep (Cat. no. A10). Incubated aerobically for 24 hours at 35°C.



Staphylococcus aureus (ATCC® 25923) colonies growing on Blood Agar, 5% Sheep (Cat. no. A10). Incubated aerobically for 24 hours at 35°C.



Escherichia coli (ATCC[®] 25922) colonies growing on Blood Agar, 5% Sheep (Cat. no. A10). Incubated aerobically for 24 hours at 35°C.



Streptococcus pneumoniae (ATCC $^{\circledR}$ 6305) colonies growing on Blood Agar, 5% Sheep (Cat. no. A10). Incubated in CO $_2$ for 24 hours at 35°C.

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.

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



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:

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.

Copyright© 2020 by Hardy Diagnostics. All rights reserved.

HDQA 2207F [D]