IFU

Instructions for Use

CRITERION™ COLUMBIA AGAR BASE

Cat. no. C5450	CRITERION™ Columbia Agar Base	85gm
Cat. no. C5451	CRITERION™ Columbia Agar Base	500gm
Cat. no. C5452	CRITERION™ Columbia Agar Base	2kg
Cat. no. C5453	CRITERION™ Columbia Agar Base	10kg
Cat. no. C5454	CRITERION™ Columbia Agar Base	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Columbia Agar Base is used for cultivating fastidious and non-fastidious microorganisms with or without the addition of blood. It is an enriched agar medium.

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

Columbia Agar Base media can be prepared as Blood Agar or Chocolate Agar. It is typically supplemented with 5-10 % sheep, rabbit or horse blood. Columbia Blood Agar is used for isolating, cultivating and determining the hemolytic reactions of fastidious pathogenic microorganisms. Without enrichment, Columbia Agar Base can be used as a general purpose medium.

Columbia Agar Base media employs specially selected raw materials to support growth of fastidious microorganisms. Columbia Agar Base supplemented with 5 or 10% sheep blood derives its superior growth-supporting properties from the combination of peptones prepared from pancreatic digest of casein, peptic digest of animal tissue and beef extract. Yeast extract and corn starch are also included in the formulation and serve as energy sources with yeast extract supplying B-complex vitamins. Columbia Agar Base has a relatively high carbohydrate content and therefore beta-hemolytic streptococci may produce a greenish hemolytic reaction (on media containing blood) that may be mistaken for alpha-hemolysis.

FORMULA

Gram weight per liter:	40.0gm/L
Pancreatic Digest of Casein	12.0gm
Peptic Digest of Animal Tissue	5.0gm
Sodium Chloride	5.0gm
Yeast Extract	3.0gm

Beef Extract	3.0gm
Corn Starch	1.0gm
Agar	11.0gm

Final pH 7.3 +/- 0.2 at 25ºC.

* Adjusted and/or supplemented as required to meet performance standards.

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 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 40.0gm 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.

4. Cool to 45-50ºC. and aseptically add enrichments, if desired. Blood is generally added at a concentration of 5-10%.

PROCEDURE AND INTERPRETATION OF RESULTS

For information on procedures and interpretation of results,consult listed references or refer to the prepared media

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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.

Columbia Agar Base is intended for use with blood supplementation. Although certain diagnostic tests may be performed directly on these media, biochemical and, if indicated, immunological testing using pure cultures is recommended 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 some strains of group D streptococci have been shown to be affected by differences in animal blood. Such strains are beta-hemolytic in horse, human and rabbit blood agar and alpha-hemolytic on sheep blood agar.

Colonies of *Haemophilus haemolyticus* are beta-hemolytic on horse and rabbit blood agar and must be distinguished from colonies of beta-hemolytic streptococci using other criteria. The use of sheep blood has been suggested to eliminate this problem since sheep blood is deficient in pyridine nucleotides and does not support growth on *H. haemolyticus*.

The atmosphere of incubation has been shown to influenced hemolytic reactions of beta-hemolytic streptococci. For optimal performance, incubate blood agar media under increased CO_2 anaerobic conditions.

Columbia Agar has a relatively high carbohydrate content and therefore beta-hemolytic streptococci may produce a greenish hemolytic reaction (on media containing blood) that may be mistaken for alpha-hemolysis.

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	
With addition of blood:					
Streptococcus pyogenes ATCC® 19615	A	18-48hr	35°C	Aerobic**	Growth; beta-hemolysis
Streptococcus pneumoniae ATCC® 6305	A	18-48hr	35°C	Aerobic**	Growth; alpha-hemolysis

Staphylococcus aureus ATCC® 25923	A	18-48hr	35°C	Aerobic	Growth; beta-hemolysis
Escherichia coli ATCC® 25922	A	18-48hr	35°C	Aerobic	Growth
Peptostreptococcus anaerobius ATCC® 27337	A	24-48hr	35°C	Anaerobic	Growth
Without addition of blood:					
*Clostridium sporogenes*** ATCC® 19404	J	48hr	35°C	Anaerobic	Growth
Clostridium perfringens ATCC® 13124	J	48hr	35°C	Anaerobic	Growth

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

**Atmosphere of incubation is enriched with 5-10% CO_2.

***Tested in accordance with USP <61> and <62>.[6,7]

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™ Columbia Agar Base powder should appear homogeneous, free-flowing, and beige in color. The prepared medium should appear opalescent to opaque, and beige in color.

REFERENCES

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

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

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

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

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

6. The Official Compendia of Standards. USP General Chapter <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests. *USP-NF*. United States Pharmacopeial Convention Inc., Rockville, MD.

7. The Official Compendia of Standards. USP General Chapter <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms. *USP-NF*. United States Pharmacopeial Convention Inc., Rockville, MD.

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IFU-10139[B]

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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]