IFU

Instructions for Use

CRITERION™ CHARCOAL AGAR

Cat. no. C7600	CRITERION™ Charcoal Agar	133gm
Cat. no. C7601	CRITERION™ Charcoal Agar	500gm
Cat. no. C7602	CRITERION™ Charcoal Agar	2kg
Cat. no. C7603	CRITERION™ Charcoal Agar	10kg
Cat. no. C7604	CRITERION™ Charcoal Agar	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Charcoal Agar is recommended for the cultivation and isolation of *Bordetella pertussis*.

SUMMARY

Charcoal Agar is formulated according to the method described by Mishulow, Sharpe and Cohen. They found Charcoal Agar to be an efficient substitute for the Bordet-Gengou Agar in the production of *B. pertussis* vaccines.[3]

The four *Bordetella* species, *B. pertussis*, *B. parapertussis*, *B. bronchiseptica*, and *B. avium*, are all respiratory pathogens that reside on the mucous membranes of the respiratory tract.[4] *B. pertussis* is the major cause of whooping cough or pertussis. *B. parapertussis* is associated with a milder form of whooping cough.[4] *B. bronchiseptica* is an opportunistic human pathogen, often occurring in patients having close contact with animals.[4] *B. avium* has not been reported in humans.

CRITERION™ Charcoal Agar contains beef extract, meat peptone, proteose peptone, and yeast extract as sources of nutrients. Sodium chloride is added to maintain osmotic balance and the starch is added to absorb toxic by-products. Nicotinic acid and charcoal provides selective properties and growth requirements.

Charcoal Agar can be supplemented with horse blood for use in the cultivation and isolation of *Haemophilus influenzae*.[2]

FORMULA

Gram weight per liter:	66.5gm/L
Beef Extract	10.0gm
Peptic Digest of Animal Tissue	10.0gm
Proteose Peptone	10.0gm
Starch	10.0gm

Yeast Extract	5.0gm
Sodium Chloride	5.0gm
Charcoal	4.0gm
Nicotinic Acid	0.001gm
Agar	12.0gm

Final pH 7.4 +/- 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 gray.

Store the prepared media in plates 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 66.5gm 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. Mix thoroughly during dispensing to uniformly distribute the charcoal.

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 regarding the processing and inoculation of specimens.[2-6,9]

The medium should be brought to room temperature prior to inoculation. Prepared media should be inoculated as to produce isolated colonies. Incubate aerobically in a humidified atmosphere with CO_2 at 35ºC. Incubate up to 96 hours and examine daily for growth.

INTERPRETATION OF RESULTS

Refer to appropriate references and procedures for results.[1-4]

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.

Charcoal has a tendency to settle out of the medium. Swirl the flask gently when dispensing to obtain a uniform charcoal suspension.

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	
Bordetella pertussis ATCC® 9340	A	48-96hr	35°C	CO_2**	Growth
Bordetella parapertussis ATCC® 15311	A	18-72hr	35°C	Aerobic	Growth

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

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

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™ Charcoal Agar powder should appear homogeneous, free-flowing, and gray in color. The prepared media should appear opaque with no chips or debris, and black in color.

REFERENCES

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

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

3. Mishulow, L., L.S. Sharpe and L.L. Cohen. 1953. Beef-heart charcoal agar for the preparation of *pertussis* vaccines. *Am. J. Public Health*; 43:1466.

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

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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.

HDQA 2207B [D]