

Instructions for Use

CRITERION™ CAMPYLOBACTER AGAR BASE

| Cat. no. C5330 | CRITERION TM Campylobacter Agar Base | 74gm |
|----------------|---|-------|
| Cat. no. C5331 | CRITERION™ Campylobacter Agar Base | 500gm |
| Cat. no. C5332 | CRITERION™ Campylobacter Agar Base | 2kg |
| Cat. no. C5333 | CRITERION TM Campylobacter Agar Base | 10kg |
| Cat. no. C5334 | CRITERION TM Campylobacter Agar Base | 50kg |

INTENDED USE

IFU

Hardy Diagnostics CRITERIONTM Campylobacter Agar Base is used for the selective isolation of *Campylobacter* species, particularly *C. jejuni* and *C. coli*, from clinical specimens and food samples. Campylobacter Agar Base is usually supplemented with sheep blood or lysed horse blood and selective agents such as Campylobacter Supplement by Oxoid - Skirrow formula, Cat. no. SR69E.

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

Campylobacter species are microaerophilic organisms that inhabitant the gastrointestinal tracts of various animals, including poultry, dogs, cats, sheep, and cattle. *C. jejuni* and *C. coli* are the most common *Campylobacter* species associated with gastrointestinal infection. Symptoms usually include fever, abdominal cramping, and diarrhea lasting for several days to more than 1 week. Symptomatic infections, such as gastroenteritis, are usually self-limiting and do not require antibiotic therapy, although relapses may occur in 5 to 10% of untreated patients. Deaths attributed to *C. jejuni* infection are uncommon.^(1,2,5,6)

Ingestion of improperly handled or undercooked food, primarily poultry products, raw milk, or contaminated water are common sources for human infections. The highest incidence of food borne illness occurs in infants and young children. Additionally, travelers to developing countries are also at risk for Campylobacter infections.^(1,2,4-6) Unpasteurized milk has been a commonly implicated vehicle in foodborne outbreaks of *C. jejuni* enteritis. Survival of many strains of *C. jejuni* in raw milk is poor, and typically small numbers of the organism are present. This may explain the low incidence and difficulty in recovering this organism from suspect milk samples. In general, *C. jejuni* grows poorly in food and dies rapidly when exposed to ambient temperatures and atmospheres. However, it takes relatively few Campylobacter cells to cause illness and or symptoms of gastroenteritis in humans.^(4,5,11)

CRITERION[™] Campylobacter Agar Base contains proteose peptone no. 3 as a nitrogen source. Yeast Extract supplies B vitamins and growth stimulation. Beef extract provides a source of vitamins, carbon, nitrogen and amino acids. The addition of blood supplements the medium with X-factor and other growth requirements. The Campylobacter Supplement (Cat. no. SR69E) provides the selective agents to suppress the growth of normal fecal flora.

FORMULA

| Gram weight per liter: | 37.0gm/L |
|------------------------|----------|
| | |
| Proteose Peptone No.3 | 12.5gm |
| Yeast Extract | 5.0gm |
| Sodium Chloride | 5.0gm |
| Beef Extract | 2.5gm |
| Agar | 12.0gm |

Final pH 7.4 +/- 0.2 at 25°C.

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

STORAGE AND SHELF LIFE

Store the sealed bottle(s) containing dehydrated culture medium at 2-30°C. 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 2-8°C.

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 "<u>Guidelines for Isolation</u> <u>Precautions</u>" 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 37.0gm 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 121°C. for 15 minutes.
- 4. Cool to 45-50°C.
- 5. Aseptically add animal blood and selective agents (Cat. no. SR69E) as desired.

PROCEDURE AND INTERPRETATION OF RESULTS

For information on procedures and interpretation of results, consult listed references or refer to the prepared media Instructions for Use (IFU) for Cat. No. A40.

LIMITATIONS

Campylobacters are not easily visualized with the safranin counterstain normally used in the Gram stain procedure; therefore carbol fuchsin or 0.1% aqueous basic fuchsin can be used as the counterstain, or extending the staining time of the safranin to at least 10 minutes can improve the intensity of the stain.^(1,6)

Most *Campylobacter* species require a microaerophilic atmosphere containing approximately 5% O_2 , 10% CO_2 , and 85% N_2 for optimal recovery. The concentration of oxygen generated in candle jars is not optimal for the isolation of *Campylobacter* spp. and should not be used.⁽¹⁾

Certain *Campylobacter* species, such as *C. sputorum*, *C. concisus*, *C. mucosalis*, etc., may require hydrogen for primary isolation and growth.⁽¹⁾

The antimicrobial agents that are present in some Campylobacter Selective media, such as cephalothin, colistin, and polymyxin B, may be inhibitory to some strains of *C. jejuni* and *C. coli*, and are inhibitory to *C. fetus*. Furthermore, *C. jejuni* subsp. *doylei* and *C. upsaliensis* generally do not grow on cephalothin-containing media.⁽¹⁾

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.

Campylobacter Agar Base prepared with either Campylobacter Antimicrobic Supplement S or Campylobacter Supplement B is selective primarily for *Campylobacter* species. Biochemical testing using a pure culture is necessary for complete identification.

Some strains of normal enteric organisms may be encountered that are not inhibited or only partially inhibited on Campylobacter selective agents.

Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Blood products and Campylobacter Supplements must be purchased separately. Standard microbiological supplies and equipment such as loops, other culture media, slides, staining reagents, pasteur pipettes, microaerophilic atmosphere packets, incubation jars, catalysts, 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 | | | Bamilta | | | |
|---|------------------------|------------|-------------|-------------------|-----------|--|--|--|
| | | Time | Temperature | Atmosphere | Results | | | |
| Campylobacter Agar Base with Supplement (Cat. no. SR69E): | | | | | | | | |
| Campylobacter jejuni ATCC [®] 33291 | А | 24-48hr | 37°C | Microaerophilic** | Growth | | | |
| Escherichia coli ATCC [®] 25922 | В | 24-48hr | 37°C | Aerobic | Inhibited | | | |

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

** Atmosphere of incubation is enriched with 5% O_2 , 10% CO_2 and 85% N_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 <u>Certificate of Analysis</u> website. In addition, refer to the following document "<u>Finished Product</u> <u>Quality Control Procedures</u>," for more information on QC or see the reference(s) for more specific information.

PHYSICAL APPEARANCE:

CRITERIONTM Campylobacter Agar Base powder should appear homogeneous, free-flowing, and beige in color. The prepared media, after the addition of animal blood, should appear opaque with no hemolysis, and cherry red 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. Marshall, R.T., ed. 1992. *Standard Methods for the Examination of Dairy Products*, 16th ed. APHA, Washington, D.C.

5. Vanderzant, C. and D.F. Splittstoesser, (ed.). 1992. *Compendium of Methods for the Microbiological Examination of Foods*, 3rd ed. APHA, Washington, D.C.

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

7. Isenberg, H.D. 1998. *Essential Procedures for Clinical Microbiology*. American Society for Microbiology, Washington, D.C.

8. Gun-Munro, J., R.P. Rennie, J.H. Thornley, H.L. Richardson, D. Hodge, and J. Lynch. 1987. Laboratory and clinical evaluation of isolation media for *Campylobacter jejuni*. J. Clin. Microbiol.; 25: 2274-2277.

9. Karmali, M.A., A.E. Simor, M. Roscoe, P.C. Fleming, S.S. Smith, and J. Lane. 1986. Evaluation of a blood-free, charcoal-based, selective medium for the isolation of *Campylobacter* organisms from feces. *J. Clin. Microbiol.*;

23:456-459.

10. Centers for Disease Control and Prevention. 2001. Campylobacter infections. *www.cdc.gov/ncidod/dbmd/diseaseinfo/campylobacter_g.*

11. Hunt, J.M., C. Abeyta and T. Tran. 1998. Chap. 7 Campylobacter. *Bacteriological Analytical Manual*, 8th ed., Rev. A. *vm.cfsan.fda.gov/~ebam/bam-7.html*.

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

IFU-10135[A]



1430 West McCoy Lane, Santa Maria, CA 93455, USA Phone: (805) 346-2766 ext. 5658 Fax: (805) 346-2760 Website: <u>HardyDiagnostics.com</u> <u>Email: TechnicalServices@HardyDiagnostics.com</u> <u>Ordering Information</u>

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 2207B [D]