IFU

Instructions for Use

CRITERION™ MYP AGAR BASE

Cat. no. C7400	CRITERION™ MYP Agar Base	89gm
Cat. no. C7401	CRITERION™ MYP Agar Base	500gm
Cat. no. C7402	CRITERION™ MYP Agar Base	2kg
Cat. no. C7403	CRITERION™ MYP Agar Base	10kg
Cat. no. C7404	CRITERION™ MYP Agar Base	50kg

INTENDED USE

Hardy Diagnostics' CRITERION™ MYP Agar Base supplemented with egg yolk emulsion and polymyxin B sulfate is recommended for the isolation and identification of *Bacillus* spp. It is also recommended by the American Public Health Association (APHA) for the isolation and presumptive identification of *Bacillus cereus* in foods.

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

Mossel et al., formulated Mannitol Egg Yolk Polymyxin (MYP) Agar to isolate and enumerate *Bacillus cereus* from foods. This medium can differentiate *B. cereus* from other types of bacteria present in a sample based on typical biochemical reactions.

B. cereus is commonly found in nature, on vegetables and in some processed foods. Under favorable conditions, the organism can grow to sufficient numbers and cause gastrointestinal illness. Outbreaks of foodborne illness have been associated with the ingestion of boiled and cooked rice, cooked meats, cooked vegetables and a variety of other food types.

B. cereus is the etiological agent in two distinct types of food-poisoning: (1) diarrheal type, characterized by abdominal pain with diarrhea 8 to 16 hours after ingestion of the contaminated food, and (2) the emetic type, characterized by nausea and vomiting 1 to 5 hours after eating the contaminated meal. *B. cereus* spores can survive normal cooking procedures and when the cooked food is stored improperly, the spores germinate and vegetative cells multiply. As of yet, the toxin or other virulence factor responsible for the different syndromes has not been identified.

Hardy Diagnostics' CRITERION™ MYP Agar Base contains meat extract and peptones that supply nitrogen, vitamins and minerals. Mannitol is the carbohydrate source and phenol red is the pH indicator; thus, bacterial colonies capable of fermenting mannitol will appear yellow. Sodium chloride aids cells in maintaining osmotic equilibrium. When supplemented with polymyxin B and egg yolk emulsion, the medium can be used for the isolation and identification of *Bacillus* species, particularly *B. cereus*. Polymyxin B helps restrict the growth of gram-negative microorganisms present in the sample, while egg yolk emulsion helps differentiate lecithinase producing colonies. The insoluble products of egg yolk lecithin accumulate around colonies that produce lecithinase to form a zone of white precipitate.

FORMULA*

Gram weight per liter:	46.0gm/L
Peptone	10.0gm
Mannitol	10.0gm
Sodium Chloride	10.0gm
Meat Extract	1.0gm
Phenol Red	0.025gm
Agar	15.0gm

Final pH 7.2+/- 0.1 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 pink.

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 44.5gm of the dehydrated culture media in 1 liter of distilled or deionized water. Stir to mix thoroughly.

2. Heat to boiling for one minute to dissolve completely.

3. Sterilize in the autoclave at 121ºC. for 15 minutes.

4. Cool to 45-50ºC.

5. Aseptically add 25ml of sterile egg yolk emulsion and 0.1ml of polymyxin B and mix thoroughly.

6. Aseptically dispense desired volume into sterile containers.

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. G147.

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.

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	
Bacillus cereus ATCC® 13061	A	18-48hr	35°C	Aerobic	Growth; pink to red colonies with zone of whitish precipitate
Bacillus subtilis ATCC® 6633	A	18-48hr	30-35°C	Aerobic	Growth; yellow colonies with no zone of precipitate
Pseudomonas aeruginosa ATCC® 27853	B	18-48hr	30-35°C	Aerobic	Partial to complete inhibition

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

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™ MYP Agar Base powder should appear homogeneous, free-flowing, and pink in color. The prepared media should appear opaque, and orange in color.

REFERENCES

1. American Public Health Association. *Standard Methods for the Examination of Dairy Products,* APHA, Washington, D.C.

2. 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.

3. APHA Technical Committee on Microbiological Methods for Foods. *Compendium of Methods for the Microbiological Examination of Foods*, APHA, Washington, D.C.

4. Association of Official Analytical Chemists. *Official Methods of Analysis*^{sm}, AOAC, Washington, D.C.

5. Coliner, A.R. 1948. The action of *Bacillus cereus* and related species on the lecithin complex of egg yolk. *J. Bacteriol.*; 55:777-785.

6. U.S. Food and Drug Administration. *Bacteriological Analytical Manual.* AOAC, Arlington, VA. http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm.

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

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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]