

Instructions for Use

CRITERION™ NUTRIENT GELATIN

Cat. no. C6480	CRITERION™ Nutrient Gelatin	256gm
Cat. no. C6481	CRITERION™ Nutrient Gelatin	500gm
Cat. no. C6482	CRITERION™ Nutrient Gelatin	2kg
Cat. no. C6483	CRITERION™ Nutrient Gelatin	10kg
Cat. no. C6484	CRITERION™ Nutrient Gelatin	50kg

INTENDED USE

Hardy Diagnostics CRITERIONTM Nutrient Gelatin is used to aid in classification of the *Enterobacteriaceae* by determining an organism's ability to liquify gelatin.

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

Gelatin was the substance originally used to gel culture media. However, gelatin is liquid at 35°C., the optimum temperature for many bacteria. In addition, some bacteria are capable of liquifying the gelatin, making it an unsuitable solidifying agent. Agar, gelatin's replacement, has neither of these drawbacks.

The breakdown of gelatin is a result of the production of the enzyme gelatinase by an organism. The purpose of this proteolytic enzyme is to break down large molecules so that they can be brought into the cell to be metabolized. This ability to liquify gelatin is characteristic of certain *Enterobacteriaceae* such as *Proteus* species and *Serratia* species.

Nutrient Gelatin contains peptone and beef extract as carbon and nitrogen sources for general growth requirements. Gelatin is the Substrate for determining of the microorganism has the proteolytic enzyme to hydrolyze (liquify) the gelatin.

FORMULA

Gram weight per liter:	128.0gm/L				
Gelatin	120.0gm				
Peptone	5.0gm				
Beef Extract	3.0gm				

* 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 tan.

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 "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 128.0gm of the dehydrated culture media in 1 liter of distilled or deionized water.
- 2. Warm to 50-55°C. to dissolve completely.
- 3. Dispense required amount in test tubes and place caps on tubes.
- 4. Sterilize in the autoclave at 121°C. for 15 minutes.

PROCEDURE AND INTERPRETATION OF RESULTS

For information on procedures and interpretation of results, refer to the prepared media Instructions for Use (IFU) for Cat. No. O23.

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.

A control tube must be run in parallel with each test. One control tube can be used for all organisms being tested, if all tubes are inoculated at the same time. (2)

If the tubes are incubated at temperatures of greater than 20 degrees C., the tubes must be chilled below 20 degrees C before reactions can be determined. (2)

Do not shake the tubes after incubation, as some positive liquifaction reactions will be missed. (2)

Fastidious bacteria may not grow in Nutrient Gelatin.

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
Test Organisms		Time	Temperature	Atmosphere	Results
Staphylococcus aureus ATCC® 25923	D	up to 14 days	35°C	Aerobic	Growth; positive liquifaction
Clostridium perfringens ATCC® 13124	D	up to 14 days	35°C	Aerobic	Growth; positive liquifaction
Bacillus subtilis ATCC® 6633	D	up to 14 days	35°C	Aerobic	Growth; positive liquifaction
Escherichia coli ATCC® 25922	D	up to 14 days	35°C	Aerobic	Growth; negative liquifaction

^{*} 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

CRITERIONTM Nutrient Gelatin powder should appear homogeneous, free-flowing, and tan in color. The prepared

media should appear clear and colorless.

REFERENCES

- 1. Baron, E.J., L.R. Peterson and S.M. Finegold. 1994. *Bailey & Scott's Diagnostic Microbiology*, 10th ed. Mosby, St. Louis, MO.
- 2. MacFaddin, J.F. 1985. *Media for Isolation, Cultivation, Identification, Maintenance of Bacteria*, Vol. I. Williams & Wilkins, Baltimore, MD.
- 3. Howard, B.J., et al. 1997. Clinical and Pathogenic Microbiology. 2nd ed. Mosby, St. Louis, MO.
- 4. Isenberg, H.D. *Clinical Microbiology Procedures Handbook*, Vol. I, II & III. American Society for Microbiology, Washington, D.C.

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IFU-10218[A]



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Ordering Information

Distribution Centers:

California · Washington · Utah · Arizona · Texas · Ohio · New York · Florida · North Carolina

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