IFU

Instructions for Use

CRITERION™ ANTIBIOTIC MEDIUM #19

Cat. no. C8321	CRITERION™ Antibiotic Medium #19	500gm

INTENDED USE

Hardy Diagnostics CRITERION™ Antibiotic Medium #19 is recommended for determining antibiotic potency by the microbiological assay technique as described by the United States Pharmacopeia (USP <81>).[4,6,8]

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

Microbial and biological assays to establish the inhibitoryeffect on microorganisms remain the gold standard for determining antibiotic potency. Subtle changes in potency may be undetectible by chemical means; consequently, evaluating antimicrobial efficacy by microbial methods may resolve concerns related to potential loss of activity. Two methods are outlined by the United States Pharmacopeia (USP) General Chapter <81>: the cylinder-plate or "plate" assay and the turbidimetric or "tube" assay.[8]

The cylinder plate method was first described by Abraham et al. for the determination of penicillin and was later modified by Foster and Woodruff and Schmidt and Moyer.[1,3,7] This method employs diffusion of an antibiotic solution from a cylinder through a solid agar medium to produce a "zone" of inhibited growth around the region of the medium containing the antibiotic. The cylinder plate method is useful for determining commercial preparations of antibiotics, in addition to quantitative determination of antibiotics in bodily fluids, animal feeds and other materials.

In contrast, the turbidimetric method depends on the inhibition of growth of a culture in a uniform solution of antibiotic, which is added to a growth promoting broth medium. Turbidimetric methods have an advantage over the cylinder plate method by providing results after three to four hours. However, this method is prone to interference from solvents or other inhibitory materials that may also influence turbidimetric assays. Thus, turbidimetric methods are most appropriate when the test sample is initially optically clear. However, with either method, the use of standardized culture media and careful and consistent control of all test conditions is essential in order to achieve satisfactory and meaningful results.

CRITERION™ Antibiotic Medium #19 was originally described by Kirshbaum and Arret and is prepared according to the specifications set forth by the USP, European Pharmacopeia (EP) and AOAC International.[2,5,8] Antibiotic Assay Media are traditionally identified numerically as assigned by Grove and Randall, with the exception of Antibiotic Medium #19 which was described by Kirshbaum and Arret.[4,6] The formulation contains peptone, yeast and animal extracts, and dextrose (D-glucose) to provide essential nutrients and other factors required for growth. Agar is the solidifying agent.

FORMULA*

Gram weight per liter:	60.0gm/L
Dextrose	10.0gm
Sodium Chloride	10.0gm
Peptone	9.4gm
Yeast Extract	4.7gm
Beef Extract	2.4gm
Agar	23.5gm

Final pH 6.1 +/- 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 light tan.

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 60.0gm of the dehydrated culture media in one 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 and pour desired volume into pre-sterilized petri dishes.

PROCEDURE AND INTERPRETATION OF RESULTS

For information on procedures and interpretation of results, consult listed references.

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	
Saccharomyces kudriavzevii ATCC® 2601	A	48hr	30°C	Aerobic	Growth

* 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.

REFERENCES

1. Abraham, E.P., E. Chain, C.M. Fletcher, A.D. Gardner, N.G. Heatley, M.A. Jennings, and H.W. Florey. 1941. Further Observations on Penicillin. *Lancet* 2:177-188.

2. Council of Europe. 2002. European Pharmacopeia, 4th ed. Council of Europe. Strasbourgh, France.

3. Foster, J.W. and H.B. Woodruff. 1943. Microbiological Aspects of Penicillin; Methods of Assay. *J. Bacteriol*.

46:187-202.

4. Grove, D.C. and W.A. Randall. 1955. *Assay Methods of Antibiotics.* New York, NY. Medical Encyclopedia, Inc.

5. Horwitz, W. (ed.). 2005. *Official Methods of Analysis,* 18th ed. Association of Analytical Communities (AOAC) International, Gaithersburg, MD.

6. Kirshbaum, A. and B. Arret. 1967. Outline of detail for official microbiological assays of antibiotics. *J. Pharm. Sci.* 56(4):511-515.

7. Schmidt, W.H. and A.J. Moyer. 1944. Penicillin; Methods of Assay. *J. Bacteriol.* 47:199-209.

8. The Official Compendia of Standards. 2008. USP General Chapter <81> Antibiotics - Microbial Assays. *USP27-NF22*. United States Pharmacopeial Convention, Rockville, MD.

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

IFU-10109[B]

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