IFU

Instructions for Use

CRITERION™ YM-11 AGAR BASE

Cat. no. C8890	CRITERION™ YM-11 Agar Base	132g
Cat. no. C8891	CRITERION™ YM-11 Agar Base	500g
Cat. no. C8892	CRITERION™ YM-11 Agar Base	2kg
Cat. no. C8893	CRITERION™ YM-11 Agar Base	10kg

INTENDED USE

Hardy Diagnostics CRITERION™ YM-11 Agar Base is recommended for the cultivation of yeast and mold.

Dehydrated culture media is a raw material not intended for use in the diagnosis of human disease. For implementation, this product requires additional processing and supplementation of ingredients before use.

SUMMARY

Yeast and mold are chemoorganoheterotrophs that consume organic compounds as their primary energy source, and do not require sunlight to grow. Their primary carbon source is obtained from hexose sugars such as dextrose, glucose, and fructose. Hardy Diagnostics CRITERION™ YM-11 Agar Base is prepared according to the formula published by Wickerham, who suggested that the selectivity of the medium may be enhanced through acidification or addition of selective agents.[6]

Hardy Diagnostics CRITERION™ YM-11 Agar Base contains soy peptone, casein peptone, and dextrose, which provide a rich source of trace elements, vitamins, amino acids, and carbon for optimum growth of yeast and mold. Sodium chloride helps maintain osmotic balance, while dipotassium phosphate (synonymous with potassium phosphate, dibasic) acts as a buffering agent and provides electrolytes. CRITERION™ YM-11 Agar Base also contains trypan blue, which is a non-toxic ingredient used to stain yeast and mold colonies blue to enhance visibility. Chloramphenicol is a selective agent that inhibits unwanted bacteria. Chlortetracycline HCl can also be added to the medium when prepared to further inhibit unwanted bacteria. Agar is the gelling agent.

FORMULA*

Gram weight per liter:	66.03g/L
Soy Peptone	20.0g
Casein Peptone	20.0g
Dextrose	5.0g
Sodium Chloride	5.0g
Dipotassium Phosphate	2.4g

Trypan Blue	0.03g
Chloramphenicol	0.1g
Agar	13.5g

Final pH 7.0 +/- 0.2 at 25ºC.

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

STORAGE AND SHELF LIFE

Store the sealed bottle(s) that contain dehydrated culture medium at 2-30ºC. Dehydrated culture medium is very hygroscopic and will clump when exposed to moisture and air. Keep lid tightly sealed. Protect dehydrated culture media from moisture and light. Dehydrated culture media should be discarded if clumped, if the media is not free-flowing or if the color has changed from its original beige with a few blue specks.

Store the prepared culture media at 2-8ºC and do not remove the container desiccant, if applicable.

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 66.0g of the dehydrated culture media in one liter of distilled or deionized water. Stir to mix thoroughly.

2. Heat as needed to dissolve completely.

3. Autoclave at 121ºC. for 15 minutes.

4. Allow media to cool to 45-50ºC. and dispense as desired.

5. If desired, aseptically add 20ml of a 0.5% (wt/V) aqueous solution of Chlortetracycline HCl. Mix thoroughly.

Note: The shelf life of in-house prepared media from dehydrated culture media is dependent upon preparation methods, container quality, equipment, storage conditions, and batch testing criteria and must be validated by the end user. Refer to *USP Microbiological Best Laboratory Practices <1117>* for more information on validation procedures.[1]

PROCEDURE

Refer to listed references for specific procedures.[1-5]

1. Prepare a sample homogenate or dilution series according to laboratory procedure.

2. Using a loop, streak the sample to obtain isolated colonies. Alternatively, using 1ml use the spread plate or membrane filtration technique.

    2a. If performing membrane filtration, place the filter on the surface of agar, remove any bubbles, and make sure the filter is in full contact with the agar surface.[3-5]

3. Incubate plates inverted at 15-30°C for 7 days, or according to laboratory procedure as dictated by the test.

4. Count the number of blue or blue-gray colonies.

INTERPRETATION OF RESULTS

Yeast colonies typically appear blue in color, whereas mold colonies are usually more blue-gray. If positive colonies are observed, count the number of colonies and report as the number of yeast and mold per gram or milliliter of sample. Consult laboratory procedures for additional testing or confirmatory methods.

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.

Accurate counting may be difficult with molds or spreading colonies.

Selective ingredients in the medium may also inhibit certain strains of pathogenic fungi. It is recommended users parallel test using a nonselective medium for comparison to ensure the presence of these types of strains.

Rare, fastidious microorganisms may not grow on selective media formulations.

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, incubators, tubes, bottles, petri dishes, 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	
Trichophyton mentagrophytes ATCC® 9533	A	7 days	15-30°C	Aerobic	Growth
Candida albicans ATCC® 10231	A	7 days	15-30°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.

PHYSICAL APPEARANCE

CRITERION™ YM-11 Agar Base powder should appear homogeneous, free-flowing, and beige with a few blue specks in color. The prepared medium should appear clear and light gray in color.

REFERENCES

1. Association of Official Analytical Chemists. *Official Methods of Analysis*. AOAC, Washington, D.C.

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

3. Entis, P. 1996. Two-day hydrophobic grid membrane filter method for yeast and mold enumeration in food using YM-11 Agar collaborative study. *J. AOAC Int.* 79:1069-108.

4. Entis, P. and I. Lerner. 1996. Two-day yeast and mold enumeration using the ISO-GRID membrane filter system in conjunction with YM-11 Agar. *J. Food. Prot*. 59:416-419.

5. Lin. C.C.S., D.Y.C. Fung, and P. Entis. 1984. Growth of yeast and mold on Trypan Blue Agar in conjunction with the ISO-GRID system. *Can. J. Microbiol*. 30:1405-1407.

6. Wickerham. 1939. *J. Tropical Med. Hyg*. 42:176.

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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]