

CRITERION™ PHENOL RED BROTH BASE

Cat. no. C6590	CRITERION TM Phenol Red Broth Base	32gm
Cat. no. C6591	CRITERION TM Phenol Red Broth Base	500gm
Cat. no. C6592	CRITERION™ Phenol Red Broth Base	2kg
Cat. no. C6593	CRITERION TM Phenol Red Broth Base	10kg
Cat. no. C6594	CRITERION TM Phenol Red Broth Base	50kg

INTENDED USE

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Hardy Diagnostics CRITERIONTM Phenol Red Broth Base is intended to be used in the differentiation of microorganisms based on fermentation reactions.

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

Phenol Red Carbohydrate Test Media contains pancreatic digest of casein, sodium chloride, a carbohydrate, and phenol red. Pancreatic digest of casein provides the nutrients and growth factors necessary for growth. This media is low in carbohydrates which may interfere with the fermentation reactions of the media. The individual carbohydrates are added at a concentration of 1%. Phenol red is the acid-base indicator in the media. It is red at an alkaline pH, and shifts to yellow when acid is produced during carbohydrate fermentation. Durham tubes, also known as fermentation tubes, are added to visualize gas production produced during carbohydrate fermentation reactions. After incubation, yellow media with gas trapped in the durham tube is indicative of positive acid and gas fermentation reactions.

FORMULA*

Gram weight per liter:	16.0gm/L
Pancreatic Digest of Casein	10.0gm
Sodium Chloride	5.0gm
Phenol Red	18.0mg

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 pink.

Store the prepared culture medium 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. Dissolve 16.0gm in 1 liter of distilled or deionized water.

2. Distribute into tubes. To detect gas production, place inverted fermentation tubes (durham tubes) in the tubes of medium.

3. Sterilize in the autoclave at 121°C. for 15 minutes.

When preparing 0.5-1% carbohydrate fermentation broths, dissolve 5-10gm of the desired carbohydrate in the basal medium prior to sterilization, or dissolve 16.0gm of Phenol Red Broth Base in 900ml distilled or deionized water and aseptically add 100ml of a sterile 5-10% carbohydrate solution after sterilizing and cooling the basal medium.

PROCEDURE

Specimen Collection: This product is not intended for primary isolation of patient specimens. It should be used only with cultures of isolated organism. This product is used in conjunction with other biochemical tests to identify cultures of isolated organism.

Inoculate tubes with one drop of a diluted pure culture.

PROCEDURE AND INTERPRETATION OF RESULTS

For information on procedures and interpretation of results, consult listed references or refer to the prepared media

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:

Dextrose is added at a final concentration of 1% to the tubes of prepared Phenol Red Broth Base before QC testing.

Test Organisms	Inoculation Method*	Incubation			Results		
		Time	Temperature	Atmosphere	Kesuits		
Phenol Red Base:							
Escherichia coli ATCC [®] 25922	А	18-24hr	35°C	Aerobic	Growth; yellow color change and gas bubble in durham tube		
Shigella flexneri ATCC [®] 12022	В	18-24hr	35°C	Aerobic	Growth; yellow color change, no gas bubble in durham tube		

* 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 <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 Phenol Red Broth Base powder should appear homogeneous, free-flowing, and pink in color. The prepared media should appear clear, and 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. Koneman, E.W., et al. *Color Atlas and Textbook of Diagnostic Microbiology*, J.B. Lippincott Company, Philadelphia, PA.

5. MacFaddin, J.F. 1985. Media for Isolation, Cultivation, Identification, Maintenance of Bacteria, Vol. I. Williams &

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

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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.

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