IFU

Instructions for Use

CRITERION™ OXIDATIVE-FERMENTATIVE MEDIUM (OF BASAL MEDIUM)

Cat. no. C6500	CRITERION™ OF Basal Medium	18.8gm
Cat. no. C6501	CRITERION™ OF Basal Medium	500gm
Cat. no. C6502	CRITERION™ OF Basal Medium	2kg
Cat. no. C6503	CRITERION™ OF Basal Medium	10kg
Cat. no. C6504	CRITERION™ OF Basal Medium	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ OF Basal Medium is used with added carbohydrates for the differentiation of gram-negative bacteria based on oxidation-fermentation patterns.

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

OF Basal Medium was developed by Hugh and Leifson to aid in the identification of gram-negative bacteria on the basis of their ability to oxidize or ferment a specific carbohydrate.[6]

As compared to other OF Media, Hugh and Leifson's formula employs a low peptone/carbohydrate ratio and a minimal amount of agar. The decreased amount of peptone reduces the formation of alkaline amines which can ultimately mask the small quantities of acid that may be produced from oxidative metabolism.[5] The increased carbohydrate results in an increase in the amount of acid that may be formed. The small amount of agar added to the medium provides a semi-solid structure which concentrates the acid at the point of reaction, thereby facilitating visual interpretation of the pH shift.

Proper performance of the OF test requires an organism to be inoculated to two tubes of each OF Medium. Once inoculated, one tube is overlaid with mineral oil or melted paraffin. The other tube is left open to the air.

Oxidative utilization of the carbohydrate will result in acid production (yellow) in the open tube only. Fermentative utilization of the carbohydrate will result in acid production (yellow) in both the open and closed tubes. Acidic changes in the overlaid tubes are considered to be a result of true fermentation, while acidic development in the open tubes are due to oxidative utilization of the carbohydrate present. Asaccharolytic organisms will not produce acid in either tube.

FORMULA

Gram weight per liter:	9.4gm/L

Sodium Chloride	5.0gm
Pancreatic Digest of Casein	2.0gm
Dipotassium Phosphate	0.3gm
Bromothymol Blue	0.08gm
Agar	2.0gm

OF Media with carbohydrates require an addition of 10.0gm of specific carbohydrate.

Final pH 6.8 +/- 0.2 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 beige with a greenish tinge.

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. Combine 9.4gm of medium with one liter of deionized water. Stir to mix thoroughly.

2. Boil to dissolve completely. Do not overheat.

3. Autoclave at 121ºC. for 15 minutes.

4. Add 1% carbohydrate before or after sterilization, depending on heat lability.

5. Dispense into test tubes.

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. Y51.

LIMITATIONS

Organisms that only oxidize dextrose will not ferment any other carbohydrate. Other carbohydrates will only be oxidized. The overlaid (closed) tube, therefore, may be omitted when determining other carbohydrate utilization of such organisms.

Some microorganisms do not grow in OF Basal Medium. It may be necessary to use another basal medium containing dextrose to confirm the negative reaction.

Some mineral oils are acidic and may result in erroneous results.

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, incubators and mineral oil, 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	
OF Base Medium:					
Escherichia coli ATCC® 25922	D	18-48hr	35°C	Aerobic	Growth; no color change (top may turn blue at 48 hours) in open tube and in oil overlaid tube
OF Dextrose:					
Escherichia coli ATCC® 25922	D	18-24hr	35°C	Aerobic	Growth; acid (yellow) reaction and gas in open tube and in oil overlaid tube

Shigella flexneri ATCC® 12022	D	18-24hr	35°C	Aerobic	Growth; acid (yellow) reaction in open tube and in oil overlaid tube
Pseudomonas aeruginosa ATCC® 27853	D	18-24hr	35°C	Aerobic	Growth; acid (yellow) reaction in open tube; no change in oil overlaid 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 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™ OF Basal Medium powder should appear homogeneous, free-flowing, and light beige with a greenish tinge in color. The prepared media should appear slightly opalescent, and green in color.

REFERENCES

1. 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.

2. Jorgensen., et al. *Manual of Clinical Microbiology*, American Society for Microbiology, Washington, D.C.

3. Tille, P., et al. *Bailey and Scott's Diagnostic Microbiology*, C.V. Mosby Company, St. Louis, MO.

4. Isenberg, H.D. *Clinical Microbiology Procedures Handbook*, Vol. I, II & III. American Society for Microbiology, Washington, D.C.

5. Koneman, E.W., et al. *Color Atlas and Textbook of Diagnostic Microbiology*, J.B. Lippincott Company, Philadelphia, PA.

6. Hugh, R. and Leifson, E. 1953. *J. Bacteriol.*; 66:24-26.

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The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.

HDQA 2207B [D]