IFU

Instructions for Use

CARBON UTILIZATION MEDIA - FOR IDENTIFICATION OF MYCOBACTERIA

Cat. no. Y125	Carbon Utilization Base, 20x125mm Tube, 8ml Slant	20 tubes/box
Cat. no. Y126	Carbon Utilization with Inositol, 20x125mm Tube, 8ml Slant	20 tubes/box
Cat. no. Y127	Carbon Utilization with Mannitol, 20x125mm Tube, 8ml Slant	20 tubes/box
Cat. no. Y128	Carbon Utilization with Citrate, 20x125mm Tube, 8ml Slant	20 tubes/box

INTENDED USE

Hardy Diagnostics Carbon Utilization Media with added carbon sources are recommended for use in the cultivation and differentiation of a wide variety of rapidly growing mycobacteria.

SUMMARY

Once an acid-fast isolate has been assigned to a specific subgroup on the basis of pigment and growth rate, species identification can be accomplished by the performance of a battery of *in vitro* tests.[6] Carbon source testing is a biochemical test that assists in the detection of subtle differences between thirty or more species of rapidly growing *Mycobacterium*.[1-3,6]

This test is significant as at least three of the rapidly growing *Mycobacterium* have been associated with disease in humans. *M. fortuitum*, *M. chelonae*, and *M. abscessus* can cause cutaneous, pulmonary, and nosocomial infections while *M. smegmatis*, *M. peregrinum*, and *M. mucogenicum* have also been associated with rare disease in humans.[2,3,6]

This media measures the ability of certain rapid growers to metabolize several carbon sources in the presence of ammoniacal nitrogen: inositol, mannitol, and citrate. The test is run on the desired carbon source media as well as on the basal control medium, which lacks an available carbon source. Growth on the test medium and not on the basal control confirms a positive finding and demonstrates that the organism is capable of utilizing the carbon source. The absence of growth on both the test slant and the control slant indicate a negative finding.[1-3,6,11]

FORMULA

Ingredients per liter of deionized water:*

Carbon Source**	5.0-5.6gm
Ammonium Sulfate	2.4gm
Monopotassium Phosphate	0.5gm
Magnesium Sulfate	0.5gm
Agar	20.0gm

Final pH 6.9 +/- 0.2 at 25ºC.

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

** 5.0gm, 5.0gm, and 5.6gm of the appropriate carbon source are added to the Mannitol, Inositol and Citrate Media, respectively. There is no carbon source addition to the Basal Control Media.

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-8ºC. away from direct light. Media should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), contamination, or if the expiration date has passed. Product is light and temperature sensitive; protect from light, excessive heat, moisture and freezing.

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 Precautions for blood. Do not ingest, inhale, or allow to come into contact with skin.

This product is for *in vitro* diagnostic 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.

PROCEDURE[6]

Specimen Collection: Infectious material should be submitted directly to the laboratory without delay and protected from excessive heat and cold. Consult listed references for information on specimen collection.[1-3,6,7]

1. Perform serial dilutions with deionized water on a seven day old 7H9 Broth culture of the test organism until turbidity is no longer visible.

2. Inoculate 0.1ml of this last suspension onto the carbon source media and to the control slant.

3. All slants should be incubated at 28ºC. aerobically for two weeks before interpreting the results.

INTERPRETATION OF RESULTS

Growth on the carbon source slant but not on the control slant is indicative of a positive finding. A negative finding can only be noted when there is no growth on the carbon source media and simultaneously no growth on the control slant.

LIMITATIONS

It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification of bacteria and/or fungi.

Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, other culture media, swabs, applicator sticks, incinerators, and incubators, etc., as well as serological and biochemical reagents, 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
Basal Control:			
Mycobacterium peregrinum ATCC® 14467	*	14 days	No growth
Mycobacterium fortuitum subsp. *fortuitum* ATCC® 6841	*	14 days	No growth
Mycobacterium chelonae ATCC® 14472	*	14 days	No growth
Mycobacterium neworleansense Group III ATCC® 49404**	*	14 days	No growth
Carbon Utilization with Inositol:			
Mycobacterium neworleansense Group III ATCC® 49404**	*	14 days	Growth
Mycobacterium chelonae ATCC® 14472	*	14 days	Partial to complete inhibition
Mycobacterium peregrinum ATCC® 14467**	*	14 days	Partial to complete inhibition
Carbon Utilization with Mannitol:			
Mycobacterium peregrinum ATCC® 14467**	*	14 days	Growth
Mycobacterium chelonae ATCC® 14472**	*	14 days	Partial to complete inhibition
Mycobacterium fortuitum subsp. *fortuitum*	*	14 days	Partial to complete inhibition

ATCC® 6841			
Carbon Utilization with Citrate:			
Mycobacterium chelonae ATCC® 14472**	*	14 days	Growth
Mycobacterium fortuitum subsp. *fortuitum* ATCC® 6841**	*	14 days	Partial to complete inhibition
Mycobacterium peregrinum ATCC® 14467	*	14 days	Partial to complete inhibition

* Refer to the above "Procedure" section for a detailed explanation of the inoculation method.

** Recommended QC strains for User Quality Control according to the CLSI document M22 when applicable.

USER QUALITY CONTROL

End users of commercially prepared 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. Also refer to the document "Finished Product Quality Control Procedures," and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media* for more information on the appropriate QC procedures. See the references below.

PHYSICAL APPEARANCE

Carbon Utilization Media should appear opaque and colorless.

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. Kubica, G.P., et al. 1985. *Public Health Mycobacteriology: A Guide For The Level III Laboratory*. Centers for Disease Control. Atlanta, GA.

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

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