

CRITERION™ MACCONKEY AGAR WITHOUT CRYSTAL VIOLET

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| Cat. no. C6120 | CRITERION™ MacConkey Agar without Crystal Violet | 104gm |
| Cat. no. C6121 | CRITERION™ MacConkey Agar without Crystal Violet | 500gm |
| Cat. no. C6122 | CRITERION™ MacConkey Agar without Crystal Violet | 2kg |
| Cat. no. C6123 | CRITERION™ MacConkey Agar without Crystal Violet | 10kg |
| Cat. no. C6124 | CRITERION™ MacConkey Agar without Crystal Violet | 50kg |

INTENDED USE

Hardy Diagnostics CRITERION™ MacConkey Agar without Crystal Violet is recommended for the detection of coliforms and enteric pathogens in water, waste water, and foods, as well as for differentiating *Mycobacterium* spp.

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

CRITERION™ MacConkey Agar without Crystal Violet is a modification of the formula originally developed by MacConkey in 1905.(11) The modified medium contains a higher concentration of bile salts and does not contain crystal violet. The exclusion of crystal violet renders the medium less selective than the original formula and permits growth of staphylococci, enterococci, mycobacteria, and the Enterobacteriaceae.

The selective/differential characteristics of the medium make it useful in determining the fecal contamination of food and water. Lactose-fermenting microorganisms produce pink to red colored colonies while non-lactose-fermenters appear colorless.

The medium is especially useful in differentiating *Mycobacterium fortuitum-chelonae* complex from other rapidly growing acid-fast bacilli.(1-3) Common saprophytic species of acid-fast bacilli are inhibited on the medium while the potentially pathogenic rapid growers of the *Mycobacterium fortuitum-chelonae* complex grow within 5-11 days and usually produce a color change in the medium.

FORMULA

Gram weight per liter: 52.0gm/L

Pancreatic Digest of Casein 10.0gm

Peptic Digest of Animal Tissue 10.0gm

Lactose 10.0gm

Bile Salts No. 3 5.0gm

Sodium Chloride 5.0gm

Neutral Red 30.0mg

Agar 12.0gm

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 beige.

Store the prepared culture media at 2-8°C.

The expiration dating on the product label applies to the product in its intact packaging when stored as directed.

Refer to the document "Storage" on the Hardy Diagnostics Technical Document website 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." The "Guidelines for Isolation Precautions" is available from the Centers for Disease Control and Prevention at www.cdc.gov/ncidod/dhqp/gl_isolation.html.

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 M-29: Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline.

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" on the Hardy Diagnostics Technical Document website for more information.

Refer to the document SDS Search instructions on the Hardy Diagnostics website for more information.

METHOD OF PREPARATION FOR DEHYDRATED CULTURE MEDIA

1. Suspend 52.0gm of the dehydrated culture media in 1 liter of distilled or deionized water.
2. Heat to boiling and mix to dissolve completely.
3. Sterilize in the autoclave at 121°C. for 15 minutes.
4. Dispense into sterile containers as desired.

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. G99.

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.

Most gram-positive microorganisms, with the exception of fecal streptococci and some staphylococci, are inhibited on MacConkey Agar without Crystal Violet.

Approximately 25% of *M. smegmatis* strains grown on MacConkey Agar without Crystal Violet.(5) The 3-day arylsulfatase test may be performed to aid in the differentiation of *M. smegmatis* (arylsulfatase-negative) from mycobacteria belonging to the *M. fortuitum*-*chelonae* complex (arylsulfatase-positive).(5)

M. fortuitum may or may not produce a color change in the medium, however the extent of growth is more important than the development of a color change.

Refer to the document "Limitations of Procedures and Warranty" on the Hardy Diagnostics Technical Document website 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 Certificates of Analysis (CofA). The following organisms are routinely used for testing at Hardy Diagnostics:

| Test Organisms | Inoculation Method* | Incubation Time | Temperature | Atmosphere | Results |
|-----------------------|---------------------|-----------------|-------------|------------|------------------------------|
| Escherichia coli | | | | | |
| ATCC® 25922 | | | | | |
| A | | 24hr | 35°C | Aerobic | Growth; pink to red colonies |
| Proteus mirabilis | | | | | |
| ATCC® 12453 | | | | | |
| A | | 24hr | 35°C | Aerobic | Growth; clear colonies |
| Enterococcus faecalis | | | | | |
| ATCC® 29212 | | | | | |
| A | | 24hr | 35°C | Aerobic | Growth; clear colonies |

* Refer to the document "Inoculation Procedures for Media QC" on the Hardy Diagnostics Technical Document website 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 certificates of analysis (CofA) available from Hardy Diagnostics Certificates of Analysis website. In addition, refer to the following documents on the Hardy Diagnostics Technical Document website for more information on QC: "Introduction to Quality Control" and "Finished Product Quality Control Procedures," or see reference(s) for more specific information.

PHYSICAL APPEARANCE

CRITERION™ MacConkey Agar without Crystal Violet powder should appear homogeneous, free-flowing, and beige in color. The prepared media should appear clear, and reddish-orange in color.

REFERENCES

1. Gordon, R.E. and Mihm, J.M 1959.. J. Gen. Microbiol.; 21:736-748.
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3. Kubica, G.P. and Vitvitsky, J. 1974. Trudeau Institute, Inc. Saranac Lake, N.Y., Applied Microbiology; 917-919.
4. Kent, P.T. and Kubica, G.P. 1985. Public Health Mycobacteriology, U.S. Dept. of Health and Human Services, Public Health Service, Center for Disease Control, Atlanta, GA.
5. Koneman, E.W., et al. Color Atlas and Textbook of Diagnostic Microbiology, J.B. Lippincott Company, Philadelphia, PA.
6. Tille, P., et al. Bailey and Scott's Diagnostic Microbiology, C.V. Mosby Company, St. Louis, MO.
7. Jorgensen., et al. Manual of Clinical Microbiology, American Society for Microbiology, Washington, D.C.
8. Isenberg, H.D. Clinical Microbiology Procedures Handbook, Vol. I, II & III. American Society for Microbiology, Washington, D.C.
9. 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.
10. Quality Assurance for Commercially Prepared Microbiological Culture Media, M22. Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS), Wayne, PA.
11. MacConkey, A.T. 1905. J. Hyg.; 5:333.

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

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