IFU

Instructions for Use

HARDY DIAGNOSTICS
A Culture of Service™

MACCONKEY BROTH, USP

Cat. no. U125	MacConkey Broth, USP, 180ml Wide Mouth Polycarbonate Jar, 100ml	12 jars/box

INTENDED USE

Hardy Diagnostics MacConkey Broth is recommended for cultivating gram-negative, lactose-fermenting bacilli from water and foods as a presumptive test for coliforms. MacConkey Broth can also be used for pre-enrichment of *E. coli* O157 for toxin testing.

Cat. no. U125 is not intended to be used for the diagnosis of human disease.

SUMMARY

MacConkey Broth is a modification of the original bile salt broth recommended by MacConkey, which contained 0.5% sodium taurocholate and litmus as an indicator.[1] MacConkey later suggested variations of this formulation using neutral red as an indicator instead of litmus.[2,3] Consequently, Childs and Allen demonstrated the inhibitory effect of neutral red and further revised the formula to include the less inhibitory bromcresol purple.[4] Bile salts in the growth medium replaced the original sodium taurocholate.

Gelatin peptone provides MacConkey Broth with nitrogen and vitamins to promote growth. Lactose is utilized by lactose-fermenting bacilli. Bile salts inhibit the growth of gram-positive microorganisms and bromcresol purple acts as the pH indicator.

FORMULA

Ingredients per liter of water:*

Gelatin Peptone	20.0gm
Lactose	10.0gm
Bile Salts	5.0gm
Bromcresol Purple	0.01gm

Final pH 7.3 +/- 0.2 at 25ºC.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-30ºC. away from direct light. Media should not be used if there are any signs of deterioration, 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 dating 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

quality control incubation times.

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.

PROCEDURE

1. Inoculate tubes with the test specimen. Incubate tubes at 42-44ºC. in an aerobic atmosphere with loose caps.

2. For toxin testing procedures, consult the manufacturer's technical insert.

INTERPRETATION OF RESULTS

Lactose-fermenting microorganisms grow well in MacConkey Broth and produce acid, causing the medium to turn yellow. Non-fermenting organisms produce excellent growth but will not produce acid or gas.

LIMITATIONS

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

Due to nutritional variation, some strains encountered may grow poorly or fail to grow on this medium.

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 loops, swabs, applicator sticks, other culture media, 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 Certificates of Analysis (CofA). The following organisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
MacConkey Broth (Cat. no. U125):					
Escherichia coli[b] ATCC® 8739	J	18-24hr	42 - 44°C	Aerobic	Growth; media turns yellow, gas production
Staphylococcus aureus[b] ATCC® 6538	B	48hr	42 - 44°C	Aerobic	Partial to complete inhibition; no color change, no gas production

* Refer to the document "Inoculation Procedures for Media QC" on the Hardy Diagnostics Technical Document website for more information.

[b] Tested in accordance with USP <62>.(14)

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 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

Hardy Diagnostics MacConkey Broth should appear clear, and reddish-purple in color.

REFERENCES

1. MacConkey. 1901. *Zentralbl. Bakteriol.*; 29:740.

2. MacConkey, A.T. 1905. Lactose-fermenting bacteria in faeces. *J. Hyg.*; 5:333-379.

3. MacConkey. 1908. *J. Hyg.*; 8:322.

4. Childs, Eileen and Allen, L.A. 1953. Improved methods for determining the most probable number of *Bacterium coli* and of *Streptococcus faecalis*. *J. Hyg.*; 51:468-477.

5. Anderson, N.L., et al. 2005. *Cumitech 3B; Quality Systems in the Clinical Microbiology Laboratory*, Coordinating ed., A.S. Weissfeld. American Society for Microbiology, Washington, D.C.

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

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

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

9. MacFaddin, J.F. 1985. *Media for Isolation*, *Cultivation*, *Identification*, *Maintenance of Bacteria*, Vol. I. Williams & Wilkins, Baltimore, MD.

10. *Quality Assurance for Commercially Prepared Microbiological Culture Media*. M22. Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS), Wayne, PA.

11. American Public Health Association. *Standard Methods for the Examination of Dairy Products,* APHA, Washington, D.C.

12. American Public Health Association. *Standard Methods for the Examination of Water and Wastewater,* APHA, Washington, D.C.

13. The Official Compendia of Standards. USP General Chapter <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests. *USP-NF*. United States Pharmacopeial Convention Inc., Rockville, MD

14. The Official Compendia of Standards. USP General Chapter <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms. *USP-NF*. United States Pharmacopeial Convention Inc., Rockville, MD

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Ordering Information

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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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