IFU

Instructions for Use

HARDY DIAGNOSTICS
A Culture of Service™

MACCONKEY AGAR, USP

Cat. no. G35	MacConkey Agar, USP, 15x100mm Plate, 18ml	10 plates/bag
Cat. no. G35BX	MacConkey Agar, USP, 15x100mm Plate, 18ml	100 plates/box
Cat. no. P47	MacConkey Agar, USP, Contact Plate, 15ml	10 plates/bag

INTENDED USE

Hardy Diagnostics MacConkey Agar, USP is recommended for use as a selective and differential medium for the isolation of gram-negative bacilli on the basis of lactose fermentation. The *U.S. Pharmacopeia National Formulary <61>* describes the use of MacConkey Agar for growth promotion of specified microorganisms in the microbiological examination of nonsterile products.(1)

This product is not intended to be used for the diagnosis of human disease.

SUMMARY

MacConkey Agar, USP is prepared according to the U.S. Pharmacopoeia *<62>* standard formula for MacConkey Agar.(1) MacConkey Agar, USP contains peptones, which provide amino acids and other nitrogenous compounds to promote microbial growth. Sodium chloride is present to maintain osmotic equilibrium. Lactose is added as a possible carbon source for energy. Bile salts and crystal violet are added to inhibit the growth of most gram-positive organisms.

Differentiation of enteric microorganisms is achieved by the combination of the neutral red indicator and lactose. Lactose-fermenting organisms form pink colonies surrounded by a zone of bile salt precipitation. Color change is due to the production of acid, which changes the neutral red pH indicator from colorless to red. Acid production is also responsible for the formation of bile salt precipitation. Non-lactose-fermenters, such as *Salmonella* spp. and *Shigella* spp., develop transparent, colorless colonies with no precipitated zone.

FORMULA

Ingredients per liter of deionized water:*

Pancreatic Digest of Gelatin	17.0gm
Lactose Monohydrate	10.0gm
Sodium Chloride	5.0gm
Peptones (meat and casein)	3.0gm
Bile Salts	1.5gm
Neutral Red	30.0mg
Crystal Violet	1.0mg
Agar	13.5gm

Final pH 7.1 +/- 0.2 at 25ºC.

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

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 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

Catalog nos. G35 and G35BX

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 *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." 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.

Catalog no. P47

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

Specimen Collection: Consult listed reference for information on specimen collection.[1]

Method of Use:
Consult listed reference for the correct inoculation procedure.[1] Prior to inoculation, the medium should be brought to room temperature. The U.S. Pharmacopeoa recommends subculturing from MacConkey Broth, USP (Cat. no. U125). Streak to obtain isolated colonies. Incubate aerobically at 30-35ºC. for 18 to 72 hours. Examine plates for colony morphology.

Contact Plate Method of Use:
Allow plates to warm to room temperature. Select a surface to test. Sample the surface by firmly pressing the agar against the test area, using the thumb and second finger to hold the plate and the first finger to press firmly and evenly on the base. The same amount of pressure should be used for each sample. Do not move the plate laterally, as this spreads contaminants across the agar surface. A rolling motion may be used when slightly curved surfaces are sampled. Areas to be assayed may by divided into grids or sections, and samples may be taken from specific areas within the divisions. Incubate aerobically at 30-35ºC. for 18 to 72 hours. Examine plates for colony morphology.

INTERPRETATION OF RESULTS

Following incubation, the MacConkey Agar, USP is examined for typical colony morphology. Well isolated colonies of lactose-fermenting bacteria, such as *Escherichia coli,* appear pink to red in color and are surrounded by a zone of bile salt precipitation. Non-lactose-fermenting colonies, such as *Shigella* spp. and *Salmonella* spp., appear transparent and colorless, with no zone of bile salt precipitation. Consult the listed reference for further procedures for identification of isolates.[1]

LIMITATIONS

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

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 (Cat. no. U125), 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	
Escherichia coli ATCC® 8739**	J	18 hrs	30-35°C	Aerobic	Growth; pink to red colonies with bile precipitate surrounding colonies
Pseudomonas aeruginosa ATCC® 9027	J	18-24 hrs	30-35°C	Aerobic	Growth; colorless colonies
Salmonella enterica ATCC® 14028	J	18-24 hrs	30-35°C	Aerobic	Growth; colorless colonies
Staphylococcus aureus ATCC® 6538	B	72 hrs	30-35°C	Aerobic	Inhibited
Proteus mirabilis ATCC® 12453	A	24 hrs	35°C	Aerobic	Growth; colorless colonies, no swarming
Escherichia coli ATCC® 25922	A	24 hrs	35°C	Aerobic	Growth; pink to red colonies with bile precipitate surrounding colonies
Enterococcus faecalis ATCC® 29212	B	24 hrs	35°C	Aerobic	Partial to complete inhibition

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

**Tested in accordance with USP <62>.[1]

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

MacConkey Agar, USP should appear transparent, slightly opalescent, and pink in color.

REFERENCES

1. The Official Compendia of Standards. *USP-NF*. United States Pharmacopeial Convention, 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.

HDQA 2207H Rev. 101817gr