

Instructions for Use

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* <62> describes the use of MacConkey Agar for growth promotion of specified microorganisms in the microbiological examination of nonsterile products.⁽¹⁾

SUMMARY

MacConkey Agar, USP is prepared according to the U.S. Pharmacopeia <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 25°C.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-8°C. 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

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 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.

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." 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

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. Pharmacopeia recommends subculturing from MacConkey Broth, USP (Cat. no. U125). Streak to obtain isolated colonies. Incubate aerobically at 30-35°C. 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 be divided into grids or sections, and samples may be taken from specific areas within the divisions. Incubate aerobically at 30-35°C. 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 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, 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 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	
<i>Escherichia coli</i> ATCC® 8739**	J	18 hrs	30-35°C	Aerobic	Growth; pink to red colonies with bile precipitate surrounding colonies
<i>Pseudomonas paraeruginosa</i>	J	18-24 hrs	30-35°C	Aerobic	Growth; colorless colonies

ATCC® 9027					
<i>Salmonella enterica</i> ATCC® 14028	J	18-24 hrs	30-35°C	Aerobic	Growth; colorless colonies
<i>Staphylococcus aureus</i> ATCC® 6538	B	72 hrs	30-35°C	Aerobic	Inhibited
<i>Proteus mirabilis</i> ATCC® 12453	A	24 hrs	35°C	Aerobic	Growth; colorless colonies, no swarming
<i>Escherichia coli</i> ATCC® 25922	A	24 hrs	35°C	Aerobic	Growth; pink to red colonies with bile precipitate surrounding colonies
<i>Enterococcus faecalis</i> ATCC® 29212	B	24 hrs	35°C	Aerobic	Partial to complete inhibition

* Refer to the document "[Inoculation Procedures for Media QC](#)" 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 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

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.

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

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[Ordering Information](#)

Distribution Centers:

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

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