

## MacConkey Broth - Instructions for Use

### *Intended Use*

BACGro™ MacConkey Broth, when prepared as directed, is used as a selective media for the growth of coliform bacteria. It is not intended for use in diagnosis, treatment, or prevention of disease in humans. BACGro™ MacConkey Broth conforms to harmonized USP/EP/JP requirements.

### *Product Summary*

The formulation of BACGro™ MacConkey Broth includes peptone for nutrient sources. Bile salts act as a selective agent to inhibit most gram-positive organisms. Bromocresol purple serves as a pH indicator. Coliforms will produce gas and acid when grown in MacConkey Broth, due to the fermentation of lactose.

MacConkey Broth conforms to the Harmonized United States Pharmacopeia (USP)<sup>1</sup>, European Pharmacopeia (EP)<sup>2</sup> and Japanese Pharmacopeia (JP)<sup>3</sup> Standards.

### *Formulation\* (per Liter)*

Gelatin Peptone	20.0 g
Lactose	10.0 g
Bile Salts	5.0 g
<u>Bromocresol Purple</u>	<u>0.01 g</u>
Total	35.01 g/L

\*Formula may be supplemented and/or adjusted as required to meet performance criteria

## Directions

1. Dissolve 35 g of MacConkey Broth powder in 1 L of deionized water.
2. Mix thoroughly.
3. Dispense into test tubes containing inverted Durham tubes.
4. Autoclave at 121 degrees Celsius for 15 minutes.

## Precautions

This product is for laboratory use only and should only be used by qualified, trained laboratory personnel. Personnel should always use proper aseptic technique and observe all biohazardous precautions. All microbiological cultures should be presumed to be infectious.

Avoid ingestion, inhalation, or contact with skin and mucous membranes. If contact occurs, flush the area with clean water.

## Quality Control Specifications

Gold Standard Diagnostics tests each lot of manufactured BACGro™ culture media utilizing appropriate control organisms and specifications as documented on the Certificate of Analysis. End users should perform quality control testing in accordance with government regulatory requirements and accreditation guidelines. The following specifications are routinely used for testing:

Appearance (dehydrated): Light beige, homogenous, free flowing powder, free of debris.

Appearance (prepared): Purple, may be slightly hazy.

pH (prepared): 7.1 – 7.5 at 25°C

Organism Performance:

Strain ID	Inoculum	Incubation			Result
		Time	Temp.	Environment	
<i>E. coli</i> (ATCC® 8739)	<100 CFU	18 – 48 hr.	42°C	Aerobic	Growth, Yellow, Gas
<i>S. enterica</i> ser. Typhimurium (ATCC® 14028)	<100 CFU	18 – 48 hr.	42°C	Aerobic	Growth, Purple, No Gas
<i>S. aureus</i> (ATCC® 6538)	>10,000 CFU	18 – 48 hr.	42°C	Aerobic	No Growth, Purple, No Gas
<i>E. faecalis</i> (ATCC® 29212)	>10,000 CFU	18 – 48 hr.	42°C	Aerobic	No Growth, Purple, No Gas

## ***Limitations of the Procedure***

This product is not labeled for use as a medical device, and is not intended to diagnose, treat, or prevent disease.

Due to variation in nutritional requirements, some species or strains may be encountered that grow poorly in this medium.

Further biochemical or serological testing is required for the identification of organisms grown in this medium.

## ***Storage and Expiration***

BACGro™ MacConkey Broth should be stored at 2 – 30 degrees Celsius. Because of the hygroscopic nature of dehydrated culture media, it should be stored in a dry place and the lid should remain tightly sealed. Media should be discarded if it is not free flowing or shows discoloration.

The expiration date printed on the label is applicable to media stored as directed.

## ***Catalog Numbers***

DCM4401 – MacConkey Broth, 500g

DCM4405 – MacConkey Broth, 5kg

<sup>1</sup> United States Pharmacopoeial Convention. *United States Pharmacopoeia and National Formulary (USP-NF)*.

<sup>2</sup> Directorate for the Quality of Medicines and the Council of Europe. *The European Pharmacopoeia*.

<sup>3</sup> Pharmaceuticals and Medical Devices Agency, Ministry of Health, Labor, and Welfare. *Japanese Pharmacopoeia*.

Revision History:

<b>Revision</b>	<b>Description</b>	<b>Effective Date</b>
03	Added part number DCM4405	23-AUG-2023
02	Periodic review. No changes required.	07-MAR-2023
01	Document creation	11-DEC-2020