

CM 21091 - MacConkey AGAR (as per USP/EP/BP/JP)

INTENDED USE

for selective isolation and differentiation of *E. coli* and other enteric bacteria from pharmaceutical products in accordance with the microbial limit testing by harmonized method

PRODUCT SUMMARY AND EXPLANATION

MacConkey Agar is the earliest selective and differential medium for cultivation of coliform organisms. Subsequently MacConkey Agar and Broth have been recommended for use in microbiological examination of foodstuffs and for direct plating / inoculation of water samples for coliform counts. This medium is also accepted by the Standard Methods for the Examination of Milk and Dairy Products. It is recommended in pharmaceutical preparations and is in accordance with the harmonized method of USP/EP/BP/JP.

After enrichment of *Escherichia coli* in MacConkey Broth, it is then subcultured on MacConkey Agar. Gram-negative bacteria usually grow well on the medium and are differentiated by their ability to ferment lactose. Lactose fermenting strains grow as red or pink and may be surrounded by a zone of acid precipitated bile. The red colour is due to production of acid from lactose, absorption of neutral red and a subsequent colour change of the dye when the pH of medium falls below 6.8. Lactose non-fermenting strains, such as *Shigella* and *Salmonella* are colourless and transparent and typically do not alter appearance of the medium. *Yersinia enterocolitica* may appear as small, non-lactose fermenting colonies after incubation at room temperature.

COMPOSITION

Ingredients	Gms / Ltr
Pancreatic digest of gelatin	17.000
Peptones (meat and casein)	3.000
Lactose monohydrate	10.000
Sodium chloride	5.000
Bile salts	1.500
Neutral red	0.030
Crystal violet	0.001
Agar	13.500

PRINCIPLE

Pancreatic digest of gelatin and Peptones (meat and casein) provide the essential nutrients, vitamins and nitrogenous factors required for growth of microorganisms. Lactose monohydrate is the fermentable source of carbohydrate. The selective action of this medium is attributed to crystal violet and bile salts, which are inhibitory to most species of gram-positive bacteria. Sodium chloride maintains the osmotic balance in the medium.

INSTRUCTION FOR USE

- Dissolve 50.03 grams in 1000 ml distilled water. Boil for 1 minute with constant stirring.
- Sterilize by autoclaving at 15 psi (121°C) for 15 minutes or as per validated cycle.
- Avoid overheating. Cool to 45-50°C.
- Mix well before pouring into sterile Petri plates.
- The surface of the medium should be dry when inoculated.

QUALITY CONTROL SPECIFICATIONS



Appearance of Powder : Light yellow to pink homogeneous free flowing powder
 Appearance of prepared medium : Red with purplish tinge coloured clear to slightly opalescent gel forms in Petri plates.
 pH (at 25°C) : 7.1±0.2

INTERPRETATION

Cultural characteristics observed after an incubation.

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Recovery	Colour of colony	Incubation Temperature	Incubation Period
Escherichia coli	8739	50-100	Luxuriant	≥70%	Pink-red with bile precipitate	30-35°C	18 -72 Hours
Escherichia coli	25922	50-100	Luxuriant	≥70%	Pink-red with bile precipitate	30-35°C	18-24 Hours
Klebsiella aerogenes	13048	50-100	Luxuriant	≥70%	Pink to red	30-35°C	18-24 Hours
Enterococcus faecalis	29212	50 -100	None-poor	0-10 %	Colourless pale pink	30-35°C	18-24 Hours
Salmonella Typhimurium	14028	50-100	Luxuriant	≥70%	Colourless	30-35°C	18-24 Hours
Staphylococcus aureus subsp. aureus	6538	≥10 ³	Inhibited	0%	-	30-35°C	≥24 Hours
Staphylococcus aureus subsp. aureus	25923	≥10 ³	Inhibited	0%	-	30-35°C	≥24 Hours
Salmonella Enteritidis	13076	50 -100	Luxuriant	≥70%	Colourless	30-35°C	18-24 Hours
Salmonella Paratyphi A	9150	50 -100	Luxuriant	≥70%	Colourless	30-35°C	18-24 Hours



Salmonella Paratyphi B	8759	50 -100	Luxuriant	>=70%	Colourless	30-35°C	18-24 Hours
Salmonella Typhi	6539	50 -100	Luxuriant	>=70%	Colourless	30-35°C	18-24 Hours
Proteus vulgaris	13315	50 -100	Luxuriant	>=70%	Colourless	30-35°C	18-24 Hours
Shigella flexneri	12022	50 -100	Fair-good	20 -40 %	Colourless	30-35°C	18-24 Hours
Staphylococcus epidermidis	12228	>=10 ³	Inhibited	0%	-	30-35°C	>=24 Hours

PACKAGING:

In pack size of 100 gm and 500 gm bottles.

STORAGE

Dehydrated powder, hygroscopic in nature, store in a dry place, in tightly-sealed containers between 10-25°C and protect from direct sunlight. Under optimal conditions, the medium has a shelf life of 4 years. When the container is opened for the first time, note the time and date on the label space provided on the container. After the desired amount of medium has been taken out replace the cap tightly to protect from hydration.

Product Deterioration: Do not use if they show evidence of microbial contamination, discoloration, drying or any other signs of deterioration.

DISPOSAL

After use, prepared plates, specimen/sample containers and other contaminated materials must be sterilized before discarding.

REFERENCES

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11. The United States Pharmacopoeia, 2019, The United States Pharmacopoeial Convention. Rockville, MD.
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 GMP Good Manufacturing Practices Certified	 IVD For In Vitro Diagnostic Use	 QTY. Quantity	 LOT/ B. NO. Lot / Batch Number	 REF Catalogue Number	 Manufacturer
 Temperature Unit	 EC REP Authorized Representative MedNet GmbH Buckensee 10, 48163 Münster, Germany	 European Conformity	 QR Code	 Consults Instructions for Use	 Best Before

NOTE: Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

*ForLabUse Only