REF 51015

08509 **F** - en - 2015/01 EN

Mac Conkey Broth (MCK B-D)

For microbiological control only

Selective enrichment of *Escherichia coli*

SUMMARY AND EXPLANATION

Mac Conkey broth is used for the selective enrichment of *Escherichia coli* in non-sterile pharmaceutical products, prior to subculture on Mac Conkey agar.
This broth complies with the performance requirements of the European, United States, and Japanese Pharmacopoeia (1, 2, 3) in the harmonised chapters.

PRINCIPLE

Its composition favours the growth of *E. coli*.
The selectivity of the medium is achieved through the presence of bile which inhibits most Gram-positive micro-organisms.
Lactose fermentation by coliforms acidifies the Mac Conkey broth, which is revealed by the change in colour to yellow of the bromcresol purple used as a pH indicator.

CONTENT OF THE KIT

	Dehydrated medium:
REF 51015	500 g bottle

COMPOSITION

Theoretical formula after reconstitution of the medium.

This medium can be adjusted and/or supplemented according to the performance criteria required:

Bile (bovine or ovine)	5 g
Gelatin peptone (bovine or porcine)	20 g
Lactose (bovine)	10 g
Bromcresol purple	0.01 g
Purified water	1 l

pH 7.3

MATERIAL REQUIRED BUT NOT PROVIDED

- Autoclave.
- Autoclavable tubes.
- Autoclavable bottles.
- Bacteriology incubator.
- Water-baths.

POSSIBLE ADDITIONAL REAGENTS

- Mac Conkey agar (ref. 43141/43149)

WARNINGS AND PRECAUTIONS

- **For microbiological control only.**
- **For professional use only.**
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- All specimens, microbial cultures and inoculated products should be considered infectious and handled appropriately. Aseptic technique and usual precautions for handling the bacterial group studied should be observed throughout this procedure. Refer to "CLSI® M29-A, *Protection of Laboratory Workers from Occupationally Acquired Infections*; *Approved Guideline* – current revision." For further information on handling precautions, refer to "Biosafety in Microbiological and Biomedical Laboratories – CDC/NIH – Latest edition, or the current regulations in the country of use.
- Culture media should not be used as manufacturing material or components.
- Do not use reagents past the expiry date.
- Do not use media which are not homogeneous (presence of lumps).
- When the medium is used for the first time, make sure the tamper-proof seal of the bottle stopper is intact.
- Close the bottles correctly after use.
- Avoid opening bottles in a humid atmosphere (steam, condensation, etc.).
- The medium must be used according to the procedure indicated in this package insert. Any change or modification in the procedure may affect the results.
- Microscopic elements, possibly coming from dead micro-organisms, may be observed in the broth, but this does not alter the performance of the medium.

STORAGE CONDITIONS

- **Store the bottles at 2-30°C until the expiry date.**
- Store in a dry place.
- Bottles must be correctly sealed with stoppers after use.
- Performance is maintained for bottles which have been opened a maximum of 10 times.

SPECIMENS

Follow the recommendations in the harmonised chapters of the Pharmacopoiea to perform specimen preparation.

INSTRUCTIONS FOR USE

Preparation:

1. Suspend 38 g of powder in 1 litre of purified or demineralised water.
2. Mix carefully.
3. Bring to the boil.
4. Dispense into bottles or directly into tubes (9-10 ml per tube).
5. Autoclave for 15 minutes at 120°C.

Inoculation and incubation:

Refer to the method described in the harmonised chapters of the Pharmacopoeia:

The optimum incubation conditions are 24 hours at 44°C.

READING AND INTERPRETATION

After incubation, observe the sample as follows:
- The presence of turbidity indicates bacterial growth.
- The growth of a lactose-positive strain turns the broth yellow.

In all cases, subculture the broth on Mac Conkey agar (ref. 43141/43149) following the indications of the harmonised chapters of the Pharmacopoeia.

QUALITY CONTROL

Mac Conkey Broth is designed and developed to meet the strictest quality requirements.
The results of the strains tested in the batch by batch quality control are given on the quality control certificate available on the technical library that can be accessed via our corporate website (www.biomerieux.com).
The control complies with the recommendations in the harmonised chapters of the Pharmacopoeia.

LIMITATIONS OF THE METHOD

- Some strains of lactose-negative *E. coli* do not turn the broth yellow.
- Some strains of *E. coli* are not heat-tolerant and do not develop at 43-45°C in the broth.
- Some Gram-positive bacterial strains (in particular *Enterococcus faecalis*) may develop in the broth.
- Due to the diversity of tested samples, it is the responsibility of the user to validate this medium for its specific application.

WASTE DISPOSAL

Unused reagents may be considered as non-hazardous waste and disposed of accordingly. Dispose of all used reagents as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products.
It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

LITERATURE REFERENCES

1. American Pharmacopoeia USP *.
2. European Pharmacopoeia EP *.
3. Japanese Pharmacopoeia JP *.

* This document is in compliance with current version of Pharmacopoeias.

INDEX OF SYMBOLS

Symbol	Meaning
	Catalogue number
	Manufacturer
	Temperature limit
	Use by date
	Batch code
	Consult Instructions for Use
	Keep dry

WARRANTY

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REVISION HISTORY

Change type categories

N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user
Note:	*Minor typographical, grammar, and formatting changes are not included in the revision history*

Release date	Part Number	Change Type	Change Summary
2015/01	08509**F**	Administrative	Creation of revision history
		Technical	Summary and explanation, Possible additional reagents, Specimens, Instructions for use, Reading and interpretation, Quality control, Limitations of the method, Literature references.

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