

**Mac Conkey Broth (MCK B-F)***For microbiological control only*Detection of *Escherichia coli* in non sterile pharmaceutical products.**SUMMARY AND EXPLANATION**

Mac Conkey broth is used for selective enrichment of *Escherichia coli* in non-sterile pharmaceutical products, prior to subculturing on Mac Conkey agar medium.

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 provided by bile which inhibits most Gram-positive micro-organisms.

Lactose fermentation by coliforms acidifies the MacConkey broth, which is revealed by the change in colour to yellow of the bromcresol purple used as a pH indicator.

**PRESENTATION****Ready-to-use medium**

REF 42 622 6 x 100 ml bottles

**COMPOSITION****Theoretical formula**

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

Hydrolyzed pancreatic gelatine (bovine)* .....	20 g
Monohydrated lactose (bovine) .....	10 g
Dehydrated bile (bovine)** .....	5 g
Bromcresol purple .....	0.01 g
Purified water .....	1 l

pH 7.3

\* other possible origin (porcine)

\*\* other possible origin (ovine)

**REAGENTS AND MATERIAL REQUIRED BUT NOT PROVIDED****Reagents:**

- Trypcase Soy Broth (Ref. 41 146).
- Mac Conkey agar (Ref. 43 141 and 43 149)

**Material:**

- Water baths.
- Bacteriology incubator.

**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/NCCLS M29-A, *Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue ; Approved Guideline - Current Revision*". For additional handling precautions, refer to "Biosafety in Microbiological and Biomedical Laboratories, CDC/NIH, Latest Edition", or to the regulations currently in use in each country.
- Culture media should not be used as manufacturing material or components.
- Do not use reagents after the expiry date.
- Do not use bottles which show signs of contamination.
- The presence at the bottom of the bottle of a slight white precipitate, easily resuspended by shaking, does not alter the performance of the broth.
- Before use, make sure the tamper-proof seal on the bottle screw-caps is intact.
- The medium must be used according to the procedure described in this package insert. Any change or modification in the procedure may affect the results.

**STORAGE CONDITIONS**

- **Store the bottles at 15-25°C in their box until the expiry date.**
- The bottles must not be frozen.

**SPECIMENS**

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

**INSTRUCTIONS FOR USE**

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 following the indications in the harmonised chapters of the Pharmacopoeia.

**QUALITY CONTROL**

Mac Conkey broth is designed and developed to meet the strictest quality requirements.

The quality control results of strains tested batch by batch are given on the quality control certificate available on request.

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.
- The pH of the medium may decrease during the product's shelf-life to as low as 7.0. It has been verified that this decrease in pH does not modify performance.

**WASTE DISPOSAL**







Dispose of used or unused 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 type 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. European Pharmacopoeia EP 5.
2. United States Pharmacopoeia USP 29.
3. Japanese Pharmacopoeia JP 15.

**INDEX OF SYMBOLS**

Symbol	Meaning
	Catalogue number
	Manufacturer
	Temperature limitation
	Use by
	Batch code
	Consult Instructions for Use

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