

**Mossel Broth (MOSSEL-F)***For microbiological control only*

Enrichment medium for the detection of bile-resistant Gram-negative bacteria in non-sterile pharmaceutical products.

**SUMMARY AND EXPLANATION**

Mossel broth is used for the detection of bile-resistant Gram-negative bacteria during the microbiological control of non-sterile products. This broth complies with the performance requirements of the European, United States, and Japanese Pharmacopoeia (1, 2, 3) in the harmonised chapters.

**PRINCIPLE**

The Mossel medium contains a mixture of peptone and glucose which favour the growth of Gram-negative bacteria.

The selectivity of the medium is provided by brilliant green and bile which inhibit most micro-organisms other than Gram-negative bacteria (4).

**CONTENT OF THE KIT**

	<b>Ready-to-use medium</b>
<b>REF 42 621</b>	6 x 100 ml bottles

**COMPOSITION****Theoretical formula.**

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

Pancreatic digest of gelatin (bovine)*.....	10 g
Glucose monohydrate.....	5 g
Dehydrated bile (bovine)**.....	20 g
Monopotassium phosphate.....	2 g
Sodium phosphate dihydrate.....	8 g
Brilliant green.....	0.015 g
Purified water.....	1 l

pH 7.2

\* other possible origin (porcine)

\*\* other possible origin (ovine)

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

- Trypcase Soy broth (Ref. 41 146 / 42 614)
- VRBG agar (Ref. 42 601)

**Material:**

- 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 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 after the expiry date.
- Do not use bottles which show signs of contamination.
- 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 2-8°C in their box until the expiry date.**

**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 temperature is 35°C.

## QUALITY CONTROL

Mossel 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 request.

The control complies with the recommendations in the harmonised chapters of the Pharmacopoeia.

## LIMITATIONS OF THE METHOD

- The presence of fine particles in suspension in the broth does not affect its performance.
- Due to the diversity of tested samples, it is the responsibility of the user to validate this medium for its specific application.
- Growth depends on the requirements of each individual micro-organism. It is therefore possible that certain strains which have specific requirements (substrate, temperature, etc.) may not develop, such as *Proteus mirabilis* when the inoculum is weak.








## 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.
4. MOSSEL D.A.A., VISSAR M. and CORNELLISEN A.M.R. – The examination of foods for *Enterobacteriaceae* using a test of the type generally adopted for the detection of *Salmonellae*. - *J. Appl. Bact.* - 1963, vol. 26, p. 444-452.

## INDEX OF SYMBOLS

Symbol	Meaning
	GB : Catalogue number US : Catalog number
	Manufacturer
	Temperature limitation
	Use by
	Batch code
	Consult Instructions for Use
	Contains sufficient for <n> tests

## WARRANTY

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