REF 42 609

10636 **D** - en - 2010/08 EN

Peptoned Buffer Solution pH 7.0 (PH7 - F)

For microbiological control only

Diluent for the detection and enumeration of microorganisms

SUMMARY AND EXPLANATION

Peptoned Buffer solution with sodium chloride pH 7.0 is used as a diluent for the detection and enumeration of micro-organisms in non-sterile pharmaceutical products.
It is described in the harmonised chapters of the European, United States and Japanese Pharmacopoeia (1, 2, 3).

PRINCIPLE

The use of a low concentration of peptones is recommended by the Pharmacopoeia.
The pH is maintained at 7.0 by the presence of a phosphate buffer.
Peptoned Buffer Solution can be supplemented with tensio-active agents or inactivators of antimicrobial agents, such as polysorbate 80.

CONTENT OF THE KIT

	Ready-to-use medium
REF 42 609	6 x 90 ml bottles

COMPOSITION

Theoretical formula.

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

Monopotassium phosphate	3.6 g
Disodium hydrogen phosphate dihydrate, $2H_2O$	7.2 g
Sodium chloride	4.3 g
Meat peptone (bovine or porcine)	1 g
Purified water	1 l

pH 7.0

REAGENTS AND MATERIAL REQUIRED BUT NOT PROVIDED

Reagents

- Enrichment broths such as: Mossel (Ref. 42 621), Mac Conkey (Ref. 42 622), Trypcase-Soy (Ref. 41 146 or 42 614).
- Selective agar: Mac Conkey (Ref. 43 141 / 43 149), VRBG (Ref. 42 601), XLD (Ref. 43 563 / 43 564).

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® M29-A, *Protection of Laboratory Workers From occupationally Acquired Infections*; Approved Guideline – Current Revision". For additional 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 should be used according to the procedure indicated in this package insert. Any change or modification in the procedure may affect the results.

STORAGE CONDITIONS

- **Store the bottles in their boxes at 2-25°C until the expiry date.**

SPECIMENS

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

INSTRUCTIONS FOR USE

Allow the bottles to come to room temperature.
Refer to the procedure described in the harmonised chapters of the Pharmacopoeia.

Notes:

- Polysorbate 80 may need to be added to certain products which are insoluble in water, to make preparation of the suspension easier.
- To neutralize the inhibitory effect of preservatives in some products, inactivators such as polysorbate 80 and/or lecithin must be added, otherwise, Peptoned Buffer Solution pH 7.0 with Neutralizers (Ref. 42 623) can be used.

READING AND INTERPRETATION

- Refer to the package inserts for the culture media used.

QUALITY CONTROL

Peptoned Buffer Solution pH 7.0 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.

LIMITATIONS OF THE METHOD

- Given the wide variety of specimens tested, it is the responsibility of the user to validate this medium for its specific intended use.
- After mixing the sample, contact must not exceed 30 minutes if the presence of anaerobic bacteria is suspected.
- The addition of tensio-active agents or inactivators may slow down the growth of some organisms.

WASTE DISPOSAL

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

INDEX OF SYMBOLS

Symbol	Meaning
REF	GB : Catalogue number US : Catalog number
	Manufacturer
	Temperature limitation
	Use by
LOT	Batch code
	Consult Instructions for Use

WARRANTY

bioMérieux disclaims all warranties, express or implied, including any implied warranties of MERCHANTABILITY AND FITNESS FOR A PARTICULAR USE. bioMérieux shall not be liable for any incidental or consequential damages. IN NO EVENT SHALL BIOMERIEUX'S LIABLITY TO CUSTOMER UNDER ANY CLAIM EXCEED A REFUND OF THE AMOUNT PAID TO BIOMERIEUX FOR THE PRODUCT OR SERVICE WHICH IS THE SUBJECT OF THE CLAIM.

bioMérieux SA
376 Chemin de l'Orme
69280 Marcy-l'Etoile - France

673 620 399 RCS LYON
Tél. 33 (0)4 78 87 20 00
Fax 33 (0)4 78 87 20 90
www.biomerieux.com