

Fluid D Rinsing solution (FLUID D-ST)*For microbiological control only*

Sterility testing by membrane filtration

SUMMARY AND EXPLANATION

Fluid D Rinsing solution is a diluent for rinsing membranes during sterility testing by filtration.

Its use is described in the United-States (1), European (2) and Japanese (3) Pharmacopoeias.

PRINCIPLE

The pharmacopoeia recommend the use of low concentrations of peptones.

The polysorbate 80 in the medium improves the solubility of the lipidic products and is recommended by the different pharmacopoeia (1, 2, 3).

PRESENTATION**Ready-to-use medium**

REF 42 624 4 x 300 ml bottles

1 Package insert provided in the kit or downloadable from www.biomerieux.com/techlib

COMPOSITION**Theoretical formula**

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

Meat peptone (bovine or porcine)	1 g
Polysorbate 80	1 ml
Purified water	1 l

pH 7.1

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

- Trypcase Soy Broth (Ref. 44 011)
- Thioglycollate broth with resazurin (Ref. 44 001)

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.
- Rinsing solutions should not be used as manufacturing material or components.
- Do not use reagents past the expiration date.
- Do not use bottles which show signs of contamination.
- 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.
- According to the European Pharmacopoeia, the medium must be handled either under Class A conditions (which should be situated within a class B environment) or in an isolator.
- Bottles must be equipped with a grey injectable stopper, covered with a transparent cap. This protective cap is not hermetic. For this reason, the stoppers must be thoroughly decontaminated prior to perforation:
 - Remove the cap and disinfect the grey part of the stopper using a sterile gauze impregnated with alcohol.
 - Leave to dry.
 - Follow the recommendations indicated for your filtration control device.
- Special recommendation if an insulator is used:
 - The outside of the bottles is not sterile. The bottle must be thoroughly cleaned. The transparent cap must be removed and the grey part of the stopper disinfected (see protocol described above), **before** the bottle is placed in the insulator.

STORAGE CONDITIONS

- **The bottles should be stored in their box at 2-25°C until the expiration date.**
- Use immediately after perforating the stopper.

SPECIMENS

Specimens for testing should be collected from sterile products.

Follow the recommendations of the pharmacopoeia to establish a sampling plan.

INSTRUCTIONS FOR USE

1. Allow the bottles to come to room temperature.
2. Remove the transparent cap and carefully disinfect the grey part of the stopper.
3. Perform filtration and rinsing test according to the method currently used in the laboratory.
4. After specimen filtration and rinsing, pour 100 ml of Trypcase Soy Broth onto one membrane and 100 ml of Thioglycollate broth with resazurin onto the other.
5. Incubate for a minimum of 14 days:
 - Trypcase Soy Broth at 20-25°C.
 - Thioglycollate broth with resazurin at 30-35°C.
 Refer to the package inserts for Trypcase Soy Broth and Thioglycollate broth with resazurin. Incubation conditions may vary depending on the protocols validated by the laboratory.

READING

Refer to the package inserts for Trypcase Soy Broth and Thioglycollate broth with resazurin.

QUALITY CONTROL

Fluid D Rinsing solution was 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 the Technical Library that can be accessed via our corporate website (www.biomerieux.com).

LIMITATIONS OF THE METHOD

- Given the wide variety of specimens tested, it is the responsibility of the user to validate this medium in 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. United States Pharmacopoeia USP 33.
2. European Pharmacopoeia EP 6.
3. Japanese Pharmacopoeia JP 15.

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INDEX OF SYMBOLS

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

WARRANTY

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