CLEAR - THIO (THIOC-ST)

For microbiological control only

Sterility testing by membrane filtration.

SUMMARY AND EXPLANATION

CLEAR - THIO, Thioglycollate broth with resazurin, is intended for the detection of anaerobic bacteria but it also enables the detection of aerobic bacteria.
This medium complies with the European, American, and Japanese pharmacopoeias (1, 2, 3) for sterility testing by membrane filtration.

PRINCIPLE

The broth contains a mixture of peptones which encourage the growth of most microorganisms.
The reducing agents (L-cystine and sodium thioglycollate) and yeast extract included in the medium, favor the growth of anaerobic bacteria.
The redox indicator (Resazurin) reveals the presence of oxygen (pink to mauve color).

CONTENT OF THE KIT

	Ready-to-use medium
REF 44021	12 x 100 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:

Pancreatic digest of casein (bovine)	15 g
L-cystine	0.5 g
Monohydrated/anhydrous dextrose	5.5 g / 5.0 g
Yeast extract	5 g
Sodium chloride	2.5 g
Sodium thioglycollate	0.5 g
or Thioglycolic acid	0.3 ml
Resazurin	0.001 g
Agar	0.75 g
Purified water	1 l

pH 7.1

REAGENTS AND MATERIAL REQUIRED BUT NOT PROVIDED

Reagents:

- Fluid A Rinsing Solution (Ref. 42044 or 42616).
- Fluid D Rinsing Solution (Ref. 42624).
- Trypcase Soy broth (Ref. 44011).

Material:

- Bacteriology incubator

POSSIBLE ADDITIONAL REAGENTS

- Sterile venting needles
- Filtration unit

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 expiration date.
- Do not use bottles which show signs of contamination.
- Do not use bottles which have a pink-mauve halo greater than 1 cm on the surface (observe on media which has been left to stand).
- Do not use bottles if the broth is any color other than pale yellow.
- According to the European Pharmacopoeia, the broth must be handled either under Class A conditions (which should be situated within a class B environment) or in an isolator.
- **The outside of the bottles is not sterile.** It is therefore necessary to take the following precautions:
  - for sterility testing by membrane filtration:
    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 top part of the stopper using a sterile gauze impregnated with a disinfectant.
    - Leave to dry.
    - Follow the recommendations indicated for your filtration control device.
  - for direct inoculation:
    The vacuum-filled atmosphere inside the bottle is maintained to guarantee the stability of the medium. As the outside of the bottle is not sterile, if the bottle top is **unscrewed**, surrounding air will be sucked in and may cause accidental contamination of the culture medium.
- Before unscrewing the bottle top in a controlled environment, the different parts of the bottle must be disinfected. The transparent cap must be removed, the top part of the stopper disinfected (see protocol described above) and the bottle vented using a sterile venting device.
- 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 box at 2-25°C until the expiry date.**
- **Do not freeze.**

SPECIMENS

Follow the recommendations of the pharmacopoeias to perform specimen preparation.

INSTRUCTIONS FOR USE

Sterility testing by membrane filtration:

According to the method described in the pharmacopoeias, the following technique must be applied:

1. Filter a small quantity of Rinsing Solution (Fluid A or Fluid D) through each membrane.
2. Divide the test product into two equal parts and filter through separate membranes. The quantity of filter will depend on the type of product and the quantity per container.
3. Rinse each membrane with 100 ml of Rinsing Solution. The number of rinses will depend on the product tested.
4. Pour 100 ml of Trypcase Soy broth onto one membrane and 100 ml of CLEAR - THIO onto the other.
5. Incubate for a minimum of 14 days:
   - Trypcase Soy broth at **20-25°C**.
   - CLEAR - THIO at **30-35°C**.

Direct inoculation:

Follow the methods described by the pharmacopoeias.
It is possible to use the ready-to-use medium in tubes (see the corresponding package insert).

READING AND INTERPRETATION

Refer to the indications of the pharmacopoeias.
After incubation, observe the bacterial growth, which is generally associated with turbidity of the broth.

QUALITY CONTROL

CLEAR - THIO has been 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).

LIMITATIONS OF THE METHOD

- Growth depends on the requirements of each individual microorganism. It is therefore possible that certain strains which have specific requirements (substrate, temperature, incubation conditions etc.) may not develop.
- Given the wide variety of specimens tested, it is the responsibility of the user to validate this broth for its specific intended use.

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

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

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
	Manufacturer
	Temperature limit
	Use by date
LOT	Batch code
	Consult Instructions for Use
	Date of manufacture

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
2015/08	12801**D**	Administrative	CONTENT OF THE KIT, QUALITY CONTROL, WASTE DISPOSAL, LITERATURE REFERENCES, INDEX OF SYMBOLS, REVISION HISTORY

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