CM 22643 – ALTERNATIVE THIOGLYCOLLATE MEDIUM (USP)

INTENDED USE
For sterility testing of biological products.

PRODUCT SUMMARY AND EXPLANATION
AlternativeThioglycollateMedium is formulated as described in N.I.H. Memorandum, U.S. Pharmacopoeia. This medium is recommended for sterility testing for detecting the presence of viable forms of microorganisms in or on pharmaceutical preparations. This medium is also used for sterility checking for devices having tubes with small lumina. Alternative thioglycollate Medium is generally used for products containing mercurial preservatives when the oxidation reduction indicator is not present or required. Lack of an indicator in the medium avoids possible toxicity to organisms. Alternative Thioglycollate Medium contains sodium thioglycollate that can neutralize the bacteriostatic effect of mercurial preservatives.

COMPOSITION

Ingredients	Gms / Ltr
Pancreatic digest of casein	15.000
Yeast extract	5.000
Dextrose monohydrate	5.500
Sodium chloride	2.500
L-Cystine	0.500
Sodium thioglycollate	0.500

PRINCIPLE
Absence of agar makes it suitable for testing viscous materials and devices having tubes with small lumina. Pancreatic digest of casein, yeast extract, dextrose monohydrate, L - cystine provides nitrogenous and carbonaceous compounds, vitamin B complex, trace elements and other essential growth nutrients. Sodium Thioglycollate and L-cystine lower the oxidation-reduction potential of the medium by removing oxygen radicals and thus preventing the accumulation of peroxides that can be toxic to some organisms. The sulfhydryl groups of these compounds also neutralize the antibacterial effect of mercurial preservatives with heavy metals. Dextrose is the fermentable carbohydrate energy source, and Sodium Chloride maintains the osmotic balance of the medium.

INSTRUCTION FOR USE
Labelthereadytousebottle. Inoculate the sample and Incubate at specified temperature and time.

QUALITY CONTROL SPECIFICATIONS

Appearance	: Yellow coloured clear solution
Sterility test	: Passes release criteria.
pH (at 25°C)	: 7.1±0.2

INTERPRETATION
Culturalcharacteristics observed after incubation.

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Incubation Temperature	Incubation Period
Neisseria meningitidis	13090	50 – 100	Luxuriant	35-37°C	24-72 Hours
Staphylococcus aureus	25923	50 – 100	Luxuriant	35-37°C	24-72 Hours
Streptococcus pyogenes	19615	50 – 100	Luxuriant	35-37°C	24-72 Hours
Bacteroides vulgatus	8482	50 - 100	Luxuriant	35-37°C	24-72 Hours
Clostridium sporogenes	11437	50 – 100	Luxuriant	35-37°C	24-72 Hours
Candida albicans	10231	50 – 100	Luxuriant	35-37°C	24-72 Hours
Bacillus subtilis	6633	50 – 100	Luxuriant	35-37°C	24-72 Hours
Bacteroides fragilis	25285	50 - 100	Luxuriant	35-37°C	24-72 Hours
Micrococcus luteus	10240	50 - 100	Luxuriant	35-37°C	24-72 Hours

PACKAGING:

Inpacksizeof100 ml X 25 bottles.

STORAGE

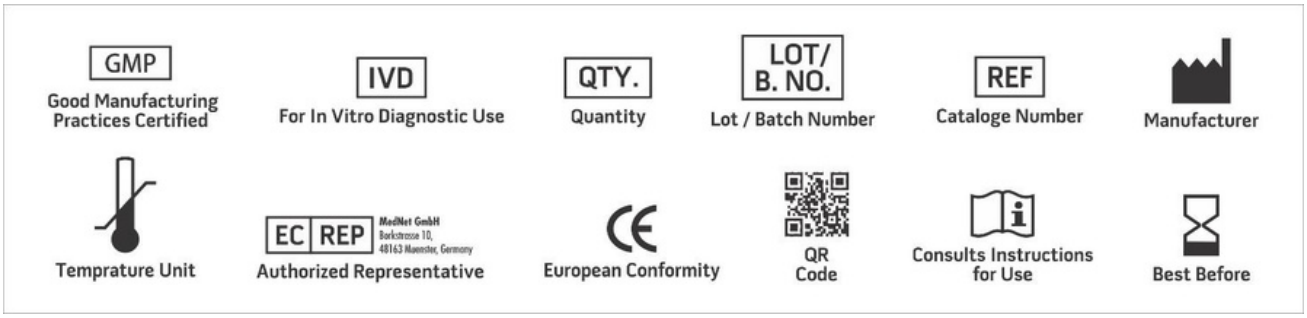
Onreceipt, store bottles in the dark at 10–25 °C. Avoid freezing and overheating. Do not open until ready to use. Minimize exposure to light. Bottled media stored as labeled until just prior to use may be inoculated up to the expiration date and incubated for the recommended incubation times. Allow the medium to warm to room temperature before inoculation

DISPOSAL

Afteruse,prepared plates, specimen/sample containers and other contaminated materials must be sterilized before discarding.

REFERENCES

1.N.I.H.Memorandum, 1955: Culture Media for Sterility Tests, 4th Revision. 2.The United States Pharmacopoeia 2011, US Pharmacopoeial Convention Inc.Rockville, M.D.



NOTE: Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

*For LabUse Only