

TMCK 001 – COMBO STERILITY KIT (USP/EP/JP/IP)

INTENDED USE

Sterility test media prepared in accordance with USP/EP/JP/IP. Each kit consists of 2 glass bottles (100ml) of Fluid Thioglycollate Medium (TMKH 001) and Soya Casein Digest Medium (TMKH 003). Recommended for all purpose.

PRODUCT SUMMARY AND EXPLANATION

Combo sterility kit is ready to use sterile media kit containing TMKH 001 and TMKH 003 for sterility Tests in accordance with USP/EP/JP/IP. These are used for validation of the compliance of pharmacopoeial raw materials, finished products and other articles. The Ready Prepared Media meet the requirements of Growth Promotion Test.

COMPOSITION

Ingredients	Gms / Ltr
FLUID THIOGLYCOLLATE MEDIUM (TMKH 001)	
Pancreatic digest of casein	15.000
Dextrose	5.500
Yeast extract	5.000
Sodium chloride	2.500
Agar	0.750
L-Cystine	0.500
Sodium thioglycollate	0.500
Resazurin sodium	0.001
SOYA CASEIN DIGEST MEDIUM (TMKH 003)	
Pancreatic digest of casein	17.000
Sodium chloride	5.000
Papaic digest of soybean (soyabean)	3.000
Dipotassium hydrogen phosphate	2.500
Glucose	2.500

PRINCIPLE

TMKH 001: Fluid Thioglycollate Medium is used for sterility testing of biological and for cultivation of aerobes, anaerobes and microaerophilic organisms. TMKH 003: Soybean Casein Digest Medium is recommended for sterility checking and for studying total aerobic microbial count in verification of microbiological testing procedures employed for sterility checking. This medium is a highly nutritious medium used for cultivation of a wide variety of organisms.

INSTRUCTION FOR USE

1. Remove the plastic cap.
2. Disinfect the part of the rubber stopper which is now exposed.
3. With the sterile or disposable needle and syringe.
4. Transfer the sample immediately into the culture bottle by puncturing the rubber stopper with the needle and injecting the sample.



5. Venting may be required for aerobic culture and not in case of anaerobic cultures.
6. Incubate TMKH 001 at 30-35°C for not more than 3 days and TMKH 003 at 30-35°C for 18-24 hours for bacteria and 5 days for fungus.

QUALITY CONTROL SPECIFICATIONS
Appearance

TMKH 001 : Light straw coloured solution with upper 10% or less medium pink on standing.

TMKH 003 : Light yellow coloured clear solution.

Quantity of Medium

: 100/200/500 ml of the medium in glass bottle

pH (at 25°C)

TMKH 001 : 7.1± 0.2

TMKH 003 : 7.3± 0.2

Sterility Check

: Passes release criteria

INTERPRETATION

Cultural characteristics observed after Incubation for aerobic and anaerobic bacteria. (*Incubate anaerobically).

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Incubation Temperature	Incubation Period
Fluid Thioglycollate Medium (TMKH 001)					
<i>Staphylococcus aureus</i>	6538	50-100	Luxuriant	30-35°C	= <3 days
<i>Escherichia coli</i>	8739	50-100	Luxuriant	30-35°C	= <3 days
<i>Bacillus subtilis</i>	6633	50-100	Luxuriant	30-35°C	= <3 days
<i>Pseudomonas aeruginosa</i>	27853	50-100	Luxuriant	30-35°C	= <3 days
* <i>Clostridium sporogenes</i>	19404	50-100	Luxuriant incubated anaerobically	30-35°C	= <3 days
* <i>Clostridium perfringens</i>	13124	50-100	Luxuriant incubated anaerobically	30-35°C	= <3 days
Soybean Casein Digest Medium (TMKH 003)					
<i>Streptococcus pneumoniae</i>	6305	50 -100	Luxuriant	30-35°C	18-24 hours
<i>Pseudomonas aeruginosa</i>	27853	50 -100	Luxuriant	30-35°C	18-24 hours
<i>Bacillus subtilis</i>	6633	50 -100	Luxuriant	30-35°C	18-24 hours
<i>Salmonella Typhimurium</i>	14028	50 -100	Luxuriant	30-35°C	18-24 hours
<i>Escherichia coli</i>	8739	50 -100	Luxuriant	30-35°C	18-24 hours
<i>Escherichia coli</i>	25922	50 -100	Luxuriant	30-35°C	18-24 hours
<i>Staphylococcus aureus</i>	25923	50 -100	Luxuriant	30-35°C	18-24 hours
<i>Candida albicans</i>	10231	50 -100	Luxuriant	30-35°C	5 Days

PACKAGING:

In pack size of 100 ml, 200ml and 500 ml glass bottles

STORAGE


On receipt, store bottles in the dark at 10 to 25° C. Avoid freezing and overheating. The medium may be used up to the expiration date and incubated for the recommended incubation times. Bottles from unopened packages can be used up to the expiration date. Opened bottles must be used immediately.

Product Deterioration: Do not use bottles if they show evidence of microbial contamination, discoloration, or any other signs of deterioration.

DISPOSAL

After use, prepared media, specimen/sample containers and other contaminated materials must be sterilized before discarding.

REFERENCES

1. Brewer, 1940, J. Am. Med. Assoc., 115:598.
2. The United States Pharmacopoeia, 2018, The United States Pharmacopoeial Convention, Rockville, MD.
3. British Pharmacopoeia, 2016, The Stationery office British Pharmacopoeia
4. European Pharmacopoeia, 2017, European Dept. for the quality of Medicines.
5. Williams H., (Ed.), 2005, Official Methods of Analysis of the Association of Official Analytical Chemists, 19th Ed., AOAC, Washington, D.C
6. Marshall, Gunnison and Luxen, 1940, Proc. Soc. Exp. Biol. Med., 43:672.
7. Nungester, Hood and Warren, 1943, Proc. Soc. Exp. Biol. Med., 52:287.
8. Portwood, 1944, J. Bact., 48:255.
9. MacFaddin J.F., 1985, Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria, Vol. 1, Williams and Wilkins, Baltimore.
10. Federal Register, 1992, Fed. Regist., 21:640.



Quantity



Lot / Batch Number



Temperature Unit



Manufacturer



Best Before



Certification of Good Manufacturing Practices



Catalogue No.



Authorized Representative



European Conformity



Consults Instructions for use :



QR Code



For In Vitro Diagnostic Use

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

***For Lab Use Only**
Revision: 15, Feb., 2022