

TMTH 011- SOYABEAN CASEIN DIGEST MEDIUM (USP/EP/BP/JP/IP)

INTENDED USE

Sterility test media prepared in accordance with harmonized method.

PRODUCT SUMMARY AND EXPLANATION

SOYABEAN CASEIN DIGEST MEDIUM (as per USP/EP/JP/BP) for cultivation of microorganism, sterility testing of molds and bacteria. This medium is used for the sensitivity testing of antimicrobial agents by the tube dilution method. It is also employed in diagnostic research in microbiology. This medium is used as a diluent and suspending medium for preparation of samples or test strains. It is also employed in sample preparation for testing of products, wherein incubation is carried out, only to serve sufficient resuscitation of the cell, while avoiding multiplication of the organism. This medium is recommended for sterility checking and for studying total aerobic microbial count in verification of microbiological testing procedures employed for sterility checking.

COMPOSITION

Ingredients	Gms / Ltr
Pancreatic digest of casein	17.000
Sodium chloride	5.000
Papaic digest of soyabean meal	3.000
Dextrose	2.500
Dipotassium hydrogen phosphate	2.500

PRINCIPLE

The combination of pancreatic digest of casein and papaic digest of soybean meal makes this medium nutritious by providing amino acids and long chain peptides for the growth of microorganisms. Natural sugars in soybean promote growth of fastidious organism. Dextrose is the fermentable source of carbon and dipotassium hydrogen phosphate serves as the buffer in the medium. Sodium chloride maintains the osmotic balance of the medium.

INSTRUCTION FOR USE

Inoculate the sample and Incubate at specified temperature and time.

QUALITY CONTROL SPECIFICATIONS

Appearance of prepared medium	:	Light yellow coloured clear solution
Quantity of Medium	:	9 ml and 10 ml of medium in tubes.
pH (at 25°C)	:	7.3 ± 0.2
Sterility Check	:	Passes release criteria

INTERPRETATION

Culture characteristics observed incubation period

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Incubation Temperature	Incubation Period
Growth promotion					
<i>Staphylococcus aureus</i>	6538	50-100	Luxuriant	30-35°C	18-24 Hours



<i>Staphylococcus aureus</i>	25923	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>Pseudomonas aeruginosa</i>	9027	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>Micrococcus luteus</i>	9341	50-100	Luxuriant	30-25°C	18-24 Hours
<i>Streptococcus pneumoniae</i>	6305	50-100	Luxuriant	30-35°C	18-24 Hours
<i>Candida albicans</i>	10231	50-100	Luxuriant	30-35°C	<=5 Days
<i>Candida albicans</i>	2091	50-100	Luxuriant	30-35°C	<=5 Days
# <i>Aspergillus brasiliensis</i>	16404	50-100	Luxuriant	30-35°C	<=5 Days
Sterility Testing (Growth promotion+ Validation					
<i>Staphylococcus aureus</i>	6538	50-100	Luxuriant	20-25°C	<=3 Days
<i>Staphylococcus aureus</i>	25923	50-100	Luxuriant	20-25°C	<=3 Days
<i>Escherichia coli</i>	8739	50-100	Luxuriant	20-25°C	<=3 Days
<i>Escherichia coli</i>	25922	50-100	Luxuriant	20-25°C	<=3 Days
<i>Pseudomonas aeruginosa</i>	9027	50-100	Luxuriant	20-25°C	<=3 Days
<i>Pseudomonas aeruginosa</i>	27853	50-100	Luxuriant	20-25°C	<=3 Days
<i>Bacillus subtilis</i>	6633	50-100	Luxuriant	20-25°C	<=3 Days
<i>Salmonella typhimurium</i>	14028	50-100	Luxuriant	20-25°C	<=3 Days
<i>Streptococcus pneumoniae</i>	6305	50-100	Luxuriant	20-25°C	<=3 Days
<i>Micrococcus luteus</i>	9341	50-100	Luxuriant	20-25°C	<=3 Days
<i>Candida albicans</i>	10231	50-100	Luxuriant	20-25°C	<=5 Days
<i>Candida albicans</i>	2091	50-100	Luxuriant	20-25°C	<=5 Days
# <i>Aspergillus brasiliensis</i>	16404	50-100	Luxuriant	20-25°C	<=5 Days

#Formerly Known as *Aspergillus niger*

PACKAGING:

Pack of 25 Ready-To-Use Liquid Medium tubes containing 9 ml and 10 ml in each tube.

Pack of 50 Ready-To-Use Liquid Medium tubes containing 9 ml and 10 ml in each tube.

STORAGE

On receipt, store tubes in the dark at 10-25 °C. Avoid freezing and overheating. Do not open until ready to use. Minimize exposure to light. Tubed 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

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques.

REFERENCES

1. The United States Pharmacopoeia, 2011, The United States Pharmacopoeial Convention. Rockville, MD.
2. British Pharmacopoeia, 2011, The Stationery office British Pharmacopoeia.



3. European Pharmacopoeia, 2011, European Dept. for the quality of Medicines.
4. Japanese Pharmacopoeia, 2008.
5. Indian Pharmacopoeia, 2007, Govt. of India, the controller of Publication, Delhi, India

QTY.
Quantity

**LOT/
B. NO.**
Lot / Batch Number


Temperature Unit


Manufacturer


Best Before

GMP
Certification of
Good Manufacturing Practices

REF
Catalogue No.

EC REP MediMer GmbH
Buckhorn 18,
48163 Münster, Germany
Authorized Representative

CE
European Conformity


Consults Instructions for use :


QR
Code

IVD
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: 25th March . 2022