

CM 22624 - SOYABEAN CASEIN DIGEST AGAR PLATE

INTENDED USE

For the sub culture of aerobic organisms in accordance with the harmonized method of USP/EP/BP/JP/IP.

PRODUCT SUMMARY AND EXPLANATION

Soyabean Casein Digest Agar, commonly known as Tryptone Soya Agar is used for the cultivation of various microorganisms and sterility testing of molds and bacteria. It is a multipurpose growth medium recommended for maintaining stock cultures, bioburden, plate counting, isolation of wide variety of microorganisms and sterility testing in pharmaceutical procedures because of its nutritional characteristics, absence of inhibitors and possibility of supplementation with several compounds. Tryptone Soya Agar conforms as per USP and European Pharmacopeia and is used in microbial limit test and antimicrobial preservative - effective test.

The media are gamma irradiated in the packaging material to assure a reduction of the microbial load potentially present in the medium, on the dishes, and on the packaging materials.

COMPOSITION

| Ingredients | Gms / Ltr |
|-----------------------------|-----------|
| Agar | 15.000 |
| Pancreatic digest of Casein | 15.000 |
| Papaic digest of Soybean | 5.000 |
| Sodium chloride | 5.000 |

PRINCIPLE

The combination of pancreatic digest of casein and papaic digest of soyabean makes this media nutritious by providing amino acids and long chain peptides for the growth of microorganisms. Sodium chloride maintains the osmotic balance.

INSTRUCTION FOR USE

Either streak, inoculate or surface spread the test inoculum aseptically on the plate. Alternatively, these plates can also be used as settle plates for environmental monitoring.

QUALITY CONTROL SPECIFICATIONS

| | | |
|--------------------|---|--------------------------------------|
| Appearance | : | Light yellow color medium |
| Quantity of Medium | : | 28 ± 2 ml of medium in 90 mm plates. |
| pH (at 25°C) | : | 7.3 ± 0.2 |
| Sterility Check | : | Passes release criteria |

INTERPRETATION

Cultural characteristics observed after incubation.

| Microorganism | ATCC | Inoculum (CFU/ml) | Growth | Recovery | Incubation Temperature | Incubation Period |
|---------------------------------|------|-------------------|-----------|----------|------------------------|-------------------|
| <i>Bacillus subtilis</i> | 6633 | 50-100 | Luxuriant | ≥ 70 % | 30-35°C | 24 Hours |
| <i>Streptococcus pneumoniae</i> | 6305 | 50-100 | Luxuriant | ≥ 70 % | 30-35°C | 24 Hours |



| | | | | | | |
|---|-------|--------|-----------|--------|----------|--------------|
| <i>Staphylococcus aureus</i> | 25923 | 50-100 | Luxuriant | >=70 % | 30-35 °C | 24 Hours |
| <i>Micrococcus luteus</i> | 9341 | 50-100 | Luxuriant | >=70 % | 30-35 °C | 24 Hours |
| <i>Staphylococcus aureus</i> | 6538 | 50-100 | Luxuriant | >=70 % | 30-35 °C | 24 Hours |
| <i>Escherichia coli</i> 25922 <i>Escherichia coli</i> | | 50-100 | Luxuriant | >=70 % | 30-35 °C | 24 Hours |
| 8739 <i>Pseudomonas aeruginosa</i> 27853 | | 50-100 | Luxuriant | >=70 % | 30-35 °C | 24 Hours |
| <i>Pseudomonas aeruginosa</i> | 9027 | 50-100 | Luxuriant | >=70 % | 30-35 °C | 24 Hours |
| <i>Salmonella typhimurium</i> | 14028 | 50-100 | Luxuriant | >=70 % | 30-35 °C | 24 Hours |
| <i>Candida albicans</i> 10231 <i>Candida albicans</i> 10231 | | 50-100 | Luxuriant | >=70 % | 30-35 °C | 24 Hours |
| <i>brasiliensis</i> 16404 * <i>Aspergillus brasiliensis</i> 16404 | | 50-100 | Luxuriant | >=70 % | 30-35 °C | 24 -72 Hours |
| <i>brasiliensis</i> 16404 | | 10-100 | Luxuriant | >=70 % | 20-25 °C | 24 -72 Hours |
| | | 10-100 | Luxuriant | >=70 % | 30-35 °C | 72-120 Hours |
| | | 10-100 | Luxuriant | >=70 % | 20-25 °C | 72-120 Hours |

*Formerly known as *Aspergillus niger*

PACKAGING:

Doubledlayered packing containing 5 No. of plates with one silica gel desiccant bag packed inside it.

STORAGE

On receipt,store the plates at 15–30 °C. Avoid freezing and overheating. Do not open until ready to use. Prepared plates stored in their original sleeve wrapping until just prior to use may be inoculated up to the expiration date and incubated for recommended incubation times. Allow the medium to warm to room temperature before inoculation.

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

DISPOSAL

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

REFERENCES

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6. Baron, E.J., L.R. Peterson, and S.M. Finegold. 1994. Bailey & Scott's diagnostic microbiology, 9th ed.Mosby-Year Book, Inc., St. Louis.
7. Chapin, K.C., and P.R. Murray. 1999. Media, p. 1687-1707. In P.R. Murray, E.J. Baron, M.A. Pfaller, F.C. Tenover, and R.H. Tenover (ed.), Manual of clinical microbiology, 7th ed. American Society for Microbiology, Washington, D.C
8. Clesceri, L.S., A.E. Greenberg, and A.D. Eaton (ed.). 1998. Standard methods for the examination of water and wastewater, 20th ed. American Public Health Association, Washington, D.C.
9. Downes, F.P. and K. Ito. (ed.). 2001. Compendium of methods for the microbiological examination of foods, 4th ed. American Public Health Association, Washington, D.C.
10. ISO 11137-1: 2006 + Amd 1:2013.Sterilization of health care products – Radiation - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
11. ISO 11137-2:2013. Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose.



QTY.
Quantity

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


Temperature Unit


Manufacturer


Best Before

GMP
Certification of
Good Manufacturing Practices

REF
Catalogue No.

EC REP MedNet GmbH
Balkstraße 10,
49153 Bielefeld, Germany
Authorized Representative

CE
European Conformity




Consults Instructions for use :

IVD
For In Vitro Diagnostic Use

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

***For LabUse Only**

