Tryptic Soy Agar + Neutralizing

General purpose medium for environmental and personnel monitoring with inactivation of disinfectants.

DESCRIPTION

Tryptic Soy Agar + Neutralizing is a general purpose medium used for the determination of total aerobic viable count in surfaces testing and air microbial control by dynamic sampling technique.

The composition of the base culture medium complies with the recommendations of the current United States, European and Japanese Pharmacopeia. In addition, neutralizing agents are included in the medium to inactivate residual disinfectants allowing detection of microorganisms surviving after treatment of surface and material with antiseptics.

These lockable, gamma-irradiated, triple-bagged plates are particularly suitable for use in restricted areas like isolators and clean rooms.

Features:

- 10 contact plates are packed in three transparent plastic bags;
- A label including a data matrix barcode identifies each plate;
- An irradiation dose of 9-20 kGy is used to sterilize the product in its final packaging, which includes the cardboard box;
- The locking lid allows for an easy locking of plates after sampling, adding security during transportation and incubation.

TYPICAL FORMULA	(g/l)
Pancreatic Digest of Casein	15.0
Pancreatic Digest of Soya Bean	5.0
Sodium Chloride	5.0
Agar	15.0
Histidine	1.0
Lecithin	0.7
Polysorbate 80	5.0
Sodium Thiosulfate	0.5

Final pH 7.3 ± 0.2 at 25°C

METHOD PRINCIPLE

Pancreatic digest of casein and pancreatic digest of soya bean provide amino acids, nitrogen, carbon, minerals, vitamins and other nutrients which support the growth of microorganism. Sodium chloride maintains the osmotic balance of the medium. Agar is the solidifying agent. Histidine inactivates aldehydes. Lecithin neutralizes quaternary ammonium compounds. Polysorbate 80 (Tween 80) is effective against phenolic compounds and mercurial derivates. Sodium thiosulfate neutralizes halogen compounds.

TEST PROCEDURE

Active Air Monitoring

Insert the plate without the lid in an air sampler and draw a volume or air from 100 to 1000 liters.

Surfaces and Personnel Hygiene Monitoring

Gently press the agar surface on the test surface for some seconds with a steady pressure. Do not move laterally the plate. Residues of the medium should be subsequently removed from the area tested.

After sampling return the lid and lock the plate. A click sound confirms lid is locked.

Incubation conditions may vary depending on the organisms under study. Total aerobic bacterial count can be obtained by incubating at 30-35°C for 48-72 hours. For detection of yeasts and moulds, plates can be incubated at 20-25°C for 5-7 days. Other conditions may be chosen but should be validated under the specific protocol used for environmental monitoring testing.

INTERPRETING RESULTS

Observe for the formation of colonies and record the number of CFU per plate. Colonies should be further isolated and identified with appropriate procedures.

APPEARANCE

Slightly opalescent, amber.

STORAGE

Store at 10-25°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

9 months.

QUALITY CONTROL

The plates are inoculated with the microbial strains indicated in the QC table.
Inoculum for productivity: ≤100 CFU.
Incubation conditions: 32.5 ± 2.5°C for 18-24 h (bacteria) and 48-72 h (fungi).

QC Table.

Microorganism		Specification
Staphylococcus aureus	ATCC® 6538	Good growth, 50-200% recovery
Staphylococcus aureus + 50 µl Aerodesin 2000	ATCC® 6538	Good growth, 50-200% recovery
Escherichia coli	ATCC® 8739	Good growth, 50-200% recovery
Pseudomonas aeruginosa	ATCC® 9027	Good growth, 50-200% recovery
Bacillus subtilis	ATCC® 6633	Good growth, 50-200% recovery
Candida albicans	ATCC® 10231	Good growth, 50-200% recovery
Aspergillus brasiliensis	ATCC® 16404	Good growth, 50-200% recovery

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is intended professional use only and must be used by properly trained operators.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to national and local regulations in force.

BIBLIOGRAPHY

1. USP 41 NF 36 (2018): <61> Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests; <1116> Microbiological Control and Monitoring of Aseptic Processing Environments.
2. EP 9.0 (2016): 2.6.12. Microbial examination of non-sterile products (total viable aerobic count).
3. JP 16th edition (2011): 4.05 Microbial Limit Test.
4. EU GMP Medicinal Products for Human and Veterinary use (2008): Annex1 Manufacture of Sterile Medicinal Products.
5. FDA Guidance for Industry (2004): Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice.
6. Swanson, K.J., F.F. Busta, E.H. Peterson, and M.G. Johnson (1992). Colony Count Methods, p. 75-95.

PRESENTATION	Format	Packaging	Ref.
Tryptic Soy Agar + Neutralizing	Lockable Contact Plate (triple-bagged, gamma-irradiated)	20 plates	15203S

TABLE OF SYMBOLS

LOT Batch code	Keep away from sunlight	Manufacturer	Use by	Fragile, handle with care
REF Catalogue number	Temperature limitation	Contains sufficient for <n> tests	Caution, consult Instruction For Use	Do not reuse

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