

## Sabouraud Dextrose Agar + 0.1% Penase + Neutralizing (Irradiated)

Medium for detection of yeasts and moulds with inactivation of disinfectants.

### TYPICAL FORMULA\* (Per Litre of Purified Water)

Pancreatic Digest of Casein	5.0 g
Peptic Digest of Animal Tissue	5.0 g
Dextrose	40.0 g
Agar	15.0 g
Histidine	1.0 g
Lecithin	0.7 g
Polysorbate 80	5.0 ml
Sodium Thiosulfate	0.5 g
Penase*	1.0 ml
Final pH 5.6 ± 0.2	

\*Adjusted and/or supplemented as required to meet performance specifications

### DESCRIPTION

Sabouraud Dextrose Agar + 0.1% Penase + Neutralizing is a ready-to-use medium in contact plates used for the determination of total aerobic viable count of yeasts and moulds in procedures for environmental and personnel hygiene monitoring.

The composition of the base culture medium (SDA) complies with the recommendations of the harmonized USP/EP/JP method and EN ISO 11133. 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 gamma-irradiated, triple-bagged plates are particularly suitable for use in restricted areas like isolators and clean rooms.

### PRINCIPLE

Pancreatic digest of casein and peptic digest of animal tissue provide amino acids, nitrogen, carbon, minerals, vitamins and other nutrients which support the growth of microorganism. Dextrose is an energy source. Agar is the solidifying agent. The high concentration of dextrose and the acidic pH of the medium permit selectivity of fungi. Histidine inactivates aldehydes. Lecithin neutralizes quaternary ammonium compounds. Polysorbate 80 (Tween 80) is effective against phenolic compounds and mercurial derivatives. Sodium thiosulfate neutralizes halogen compounds. Penase is a preparation of penicillinase for inactivating residuals of penicillins.

- 1 Levy Unit (LU) is defined as the amount of penicillinase that inactivates 59.3 IU of Penicillin G per hour at pH 7.0 at 25°C.
- 1 International Unit (IU) is defined as the amount of enzyme needed to hydrolyze 1 µmole of Penicillin G (Penicillinase) per minute at pH 7.0 at 25°C.

### TECHNIQUE

**For active air monitoring**, insert the plate without the lid in an air sampler and draw a volume of air from 100 to 1000 liters.

**For surfaces and personnel hygiene monitoring**, such as for sampling of clothing and face masks, 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.

Incubate inoculated plates aerobically at 20-25°C for up to 5 days or at 30-35°C for 24-48 hours.

### INTERPRETATION OF RESULTS

Observe for the formation of fungal colonies exhibiting typical microscopic and colonial morphology. Record the number of CFU per plate. Colonies should be further isolated and identified with appropriate procedures.

### 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.

### WARNING AND PRECAUTIONS

**For professional use only.** Operators must be trained and have certain experience in the laboratory methods. Please read the instructions carefully before using this product. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this document.

Consult the Safety Data Sheet (SDS) for information regarding hazards and safe handling practices.

### DISPOSAL OF WASTE

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



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## REFERENCES

1. EN ISO 11133:2014+Amd1:2018+Amd2:2020. Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.
2. USP 41 NF 36 (2018): <61> Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests; <1116> Microbiological Control and Monitoring of Aseptic Processing Environments.
3. EP 9.0 (2016): 2.6.12. Microbial examination of non-sterile products (total viable aerobic count).
4. JP 16th edition (2011): 4.05 Microbial Limit Test.
5. EU GMP Medicinal Products for Human and Veterinary use (2008): Annex1 Manufacture of Sterile Medicinal Products.
6. FDA Guidance for Industry (2004): Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice.
7. Swanson, K.J., F.F. Busta, E.H. Peterson, and M.G. Johnson (1992). Colony Count Methods, p. 75-95.



## PRODUCT SPECIFICATIONS

### NAME

Sabouraud Dextrose Agar + 0.1% Penase + Neutralizing

### STORAGE

10-25°C

### pH OF THE MEDIUM

5.6 ± 0.2

### USE

Sabouraud Dextrose Agar + 0.1% Penase + Neutralizing is a medium used for cultivation of yeasts and moulds with inactivation of disinfectants

### SHELF LIFE

6 months

### QUALITY CONTROL

**Appearance of Medium:** Slightly opalescent, amber

#### Expected Cultural Response

Inoculum: 50-100 CFU

Incubation: 20-24 h/ 30-35°C (*C. albicans*, *S. aureus*, *E. coli*) and 44-74 h/ 20-25°C (*C. albicans*, *S. cerevisiae*, *A. brasiliensis*)

Control strains	Specification
<i>Candida albicans</i>	WDCM 00054 (ATCC® 10231, NCPF 3179)
<i>Aspergillus brasiliensis</i>	WDCM 00053 (ATCC® 16404, NCPF 2275)
<i>Saccharomyces cerevisiae</i>	WDCM 00058 (ATCC® 9763, NCTC 10716)
<i>Staphylococcus aureus</i>	WDCM 00193 (ATCC® 6538; NCTC 10788)
<i>Escherichia coli</i>	WDCM 00012 (ATCC® 8739; NCTC 12923)

A productivity ratio ( $P_R$ ) of 0.7 is equivalent to a recovery rate of 70%

#### Control of penicillinase activity with disc diffusion method

Inoculum:  $10^4$ - $10^5$  CFU

Incubation: 30-35°C for 24 h








Control strains	Specification
<i>Staphylococcus aureus</i>	ATCC® 6538 No inhibition by Penicillin G 10 IU and Ampicillin 10 µg
<i>Escherichia coli</i>	ATCC® 8739 No inhibition by Ampicillin 10 µg

Please refer to the actual batch related Certificate of Analysis (CoA)

### PACKAGING

Ref. 15333S      Contact Plate      20 plates packed by ten

### TABLE OF SYMBOLS

<b>LOT</b> Batch code	 Do not reuse	 Manufacturer	 Use by	 Fragile, handle with care
<b>REF</b> Catalogue number	 Temperature limitation	 Contains sufficient for <n> tests	 Consult instructions for use	



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