Sabouraud Dextrose Agar + Neutralizing (Irradiated)

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

TYPICAL FORMULA*	(g/l)
Pancreatic Digest of Casein	5.0
Peptic Digest of Animal Tissue	5.0
Dextrose	40.0
Agar	15.0
Histidine	1.0
Lecithin	0.7
Polysorbate 80	5.0
Sodium Thiosulfate	0.5
Final pH 5.6 ± 0.2	

*Formula may be adjusted and/or supplemented as required to meet performance specifications

DESCRIPTION

Sabouraud Dextrose Agar + Neutralizing is a solid culture medium used for the determination of total aerobic viable count of yeasts and moulds in procedures for environmental monitoring and other applications.

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 derivates. Sodium thiosulfate neutralizes halogen compounds.

TECHNIQUE

Take a swab sample for irregular surfaces or use the sampling template 10x10 (ref. 96762) to sample a well defined area of the test surface. Inoculate an agar plate by streaking the swab over the agar surface. Gloves can be sampled (prior to removing or replacement) by touching all fingers and thumbs onto the agar surface.

Incubate inoculated plates aerobically at 30-35°C for 24-48 hours for determination of the total aerobic bacterial count, while for determination of the total aerobic bacterial count, plates are incubated at 20-25°C for 5-7 days. Individual incubation conditions can be chosen and should be validated at the application site.

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.

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.

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PRODUCT SPECIFICATIONS

NAME

Sabouraud Dextrose Agar + Neutralizing (irradiated)

STORAGE

10-25°C

pH OF THE MEDIUM

5.6 ± 0.2

USE

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

SHELFLIFE

6 months

QUALITY CONTROL

Appearance of Medium: Slightly opalescent, light amber

Expected Cultural Response

Inoculum: 50-100 CFU

Incubation: 30-35°C for 24 h (*C. albicans*) and 20-25°C for up to 3 days (all control strains)

Control strains		**Specification**
Candida albicans	WDCM 00054 (ATCC® 10231, NCPF 3179)	Good growth ($P_R \geq 0.7$)
Aspergillus brasiliensis	WDCM 00053 (ATCC® 16404, NCPF 2275)	
Saccharomyces cerevisiae	WDCM 00058 (ATCC® 9763, NCTC 10716)	

A productivity ratio (P_R) of 0.7 is equivalent to a recovery rate of 70%
Please refer to the actual batch related Certificate of Analysis (CoA)

PACKAGING

Ref. 10075S 90 mm Plate 20 (2 x 10) plates

TABLE OF SYMBOLS

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

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