Instructions For Use

ENGLISH

Sabouraud Dextrose Agar

Medium for cultivation and enumeration of yeasts and moulds from clinical and nonclinical specimens

INTENDED PURPOSE

Medium for the cultivation and enumeration of yeasts and moulds from clinical and non-clinical specimens. This medium is intended as an aid in the diagnosis, requiring further tests to complete the diagnostic results.

DESCRIPTION

Sabouraud Dextrose Agar (SDA) is a non-selective isolation medium used for the growth and maintenance of pathogenic and non-pathogenic fungi from clinical and nonclinical specimens. It is also used for recovery and total counting of yeasts and moulds in environmental monitoring.
This medium complies with EN ISO 11133 for microbiological examination of food, animal feed and water, where it is described as the main reference medium to carry out quantitative testing on culture media intended for fungi.
Its formula conforms to the recommendations of the harmonized method in the United States Pharmacopoeia (USP), European Pharmacopoeia (EP) and Japanese Pharmacopoeia (JP) for the microbiological examination of non-sterile products. The medium is also available as gamma-irradiated triple bagged plates, particularly suitable for use in restricted areas like isolators and clean rooms.

TYPICAL FORMULA*	(g/litre)
Pancreatic Digest of Casein	5.0
Peptic Digest of Animal Tissue	5.0
Dextrose	40.0
Agar	15.0
Final pH 5.6 ± 0.2 at 25°C	

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

METHOD PRINCIPLE

Pancreatic digest of casein and peptic digest of animal tissue provide amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. 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.
The medium can be supplemented with chloramphenicol to increase bacterial inhibition and recovery of dermatophytes.

PREPARATION

Dehydrated medium

Suspend 65 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil for 1 minute shaking frequently until completely dissolved. Sterilize in autoclave at 121°C for 15 minutes.

Medium in bottles

Melt the content of the bottle in a water bath at 100°C (losing the cap partially removed) until completely dissolved. Then screw the cap and check the homogeneity of the dissolved medium, if it is the case turning the bottle upside down. Cool at 45-50°C, mix well avoiding foam formation and aseptically distribute into Petri dishes.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as: Autoclave, water bath, sterile Petri plates, test tubes, inoculating loops, swabs, incubator, quality control organisms.

SPECIMENS

Clinical specimens should be sampled at the acute stage, before antimicrobial therapy (where possible) and examined as soon as possible after collection.
SDA is not suitable for direct inoculation of blood samples.
Good laboratory practices for collection, transport and storage of the clinical specimens should be applied. Refer to specific guidelines for more information about specimen collection and preparation.

TEST PROCEDURE

Ensure there is no visible moisture on the plates before use.

For use in medical microbiology

Streak the specimen as soon as possible after it is received in the laboratory to obtain isolated colonies. Prepared tubed slants primarily are intended for use with pure cultures for maintenance or other purposes. Incubation conditions may vary according to the type of specimen and the microorganisms being tested for.

For use in food, animal feed and water testing.

Refer to EN ISO 11133 for specific instructions.

For use in industrial microbiology

Control of non-sterile products

Refer to the procedure described in the harmonized chapters of the Pharmacopoeia.

Passive Air Monitoring

Take the lid off the settle plate and leave the medium exposed to the air for a period of time no longer than 4 hours (settling plates filled with 30 ml of medium may compensate for water loss during extended incubation periods). Plates can be placed according to the 1/1/1 scheme (for 1 h, about 1 above the floor, at least 1 m from the walls or any obstacle).

Surfaces and Personnel Hygiene Monitoring

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 a 90 mm plate by streaking the swab over the agar surface. Furthermore, the medium is suitable for personnel hygiene monitoring to detect microbial contamination of gloves or hands e.g. in a 5-finger-print.
Incubate the plates at 20-25°C for 5-7 days or at 30-35°C for 24-48 hours.

INTERPRETING RESULTS

Transfer of growth from slants to plated media may be required in order to obtain pure cultures of fungi. Examine for fungal colonies exhibiting typical microscopic and colonial morphology. Biochemical tests may be required for final identification.
The total combined yeasts/moulds count (TYMC) is considered to be equal to the number of CFU found per each plate.
When an acceptable criterion for microbiological quality is prescribed it is interpreted as follows:

- 10^1 CFU: maximum acceptable count = 20;
- 10^2 CFU: maximum acceptable count = 200;
- 10^3 CFU: maximum acceptable count = 2000, and so forth.

In procedures intended for environmental and personnel hygiene monitoring, observe daily for the formation of colonies.

STORAGE

The powder is very hygroscopic, store the powder at 10-30°C, in a dry environment, in its original container tightly closed. Store bottles and prepared plates 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

Dehydrated medium: 4 years.
Medium in bottles: 2 years.
Medium in tubes: 1 year
Ready-to-use plates: 6 months.

QUALITY CONTROL

Appearance of Dehydrated Medium: free-flowing, homogeneous, light-beige.

Appearance of Prepared Medium: slightly opalescent, light amber.

Expected Cultural Response:

Control strain		Inoculum	Incubation	Criteria
Saccharomyces cerevisiae	WDCM 00058; (ATCC® 9763; NCTC 10716)	50-100 CFU	3-5 days / 22.5 ± 2.5°C	Good Growth ($P_R \geq 0.7$)
Aspergillus brasiliensis	WDCM 00053; (ATCC® 16404)		72 ± 2 h / 22.5 ± 2.5°C	
Candida albicans	WDCM 00054; (ATCC® 10231)		46 ± 2 h / 22.5 ± 2.5°C	
Candida albicans	WDCM 00054; ATCC® 10231		24 - 48 h / 32.5 ± 2.5°C	

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).

PERFORMANCE CHARACTERISTICS

Performance testing of Sabouraud Dextrose Agar was carried out using the QC strains listed above. The results obtained met the established criteria.

LIMITATIONS

Invalid results can be caused by poor specimen quality, improper sample collection, improper transportation, improper laboratory processing, or a limitation of the testing technology. The operator should understand the principles of the procedures, including its performance limitations, in advance of operation to avoid potential mistakes.

The medium may support the growth of some bacteria. Incubation at 30-37°C, is suitable for yeasts, but dermatophytes may be inhibited above 30°C.

Some fungi (e.g., *Blastomyces dermatitidis*) may not be recovered on this medium due to the high carbohydrate content. For identification, organisms must be in pure culture.

SDA is intended as an aid in the diagnosis of infectious diseases, requiring further tests to complete the diagnostic results.

WARNING AND PRECAUTIONS

1) **For *in vitro* diagnostic use (IVD).**
2) **For laboratory professional use only.**
3) Operators must be trained and have certain experience. Please read the instructions carefully before using the product. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this document.
4) Consult the Safety Data Sheet (SDS) for information regarding hazards and safe handling practices.
5) Do not use if the product or packaging appears to be damaged.
6) Follow standard precautions. All patient specimens should be considered potentially infectious and handled accordingly.
7) Handle all specimens as if infectious using safe laboratory procedures. Dispose of hazardous or biologically contaminated materials according to the practices of your institution.
8) Avoid cross-contamination of samples by using disposable tips and changing them after each sample.
9) Do not mix reagents of different batches. Please use the product within the validity period.
10) Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are handled.
11) Results should be interpreted by a trained professional in conjunction with the patient's history and clinical signs and symptoms, and epidemiological risk factors.
12) Ensure laboratory equipment is calibrated and maintained in accordance with the laboratory's procedure.
13) When test results are transmitted from the laboratory to an informatics centre, attention has to be done to avoid erroneous data transfer.

DISPOSAL OF WASTE

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

BIBLIOGRAPHY

See the references at the end of this document.

TABLE OF SYMBOLS

See the table of symbols at the end of this document.

The product is available in the various configurations listed below. There may be additional product ref. numbers as well. For an updated listing of available products, visit **liofilchem.com**

Product	Format	Packaging	Ref.
Sabouraud Dextrose Agar (SDA)	Plate 90 mm	20 plates	10035
	Slant tube	10 x 7 ml	30093
	Bottle	6 x 100 ml	402280
		6 x 200 ml	412280
		6 x 500 ml	470040
		25 x 200 ml	452280
	Dehydrated media	500 g	610103
		100 g	620103
		5 kg	6101035

Revision History

Revision	Release Date	Change Summary
0	2024-01-29	Updated layout and content in compliance with IVDR 2017/746, version reset to revision 0

In case of malfunctions or defects, contact immediately Liofilchem (*) or the local representative.

In case of incident associated with the device, notify immediately Liofilchem (*) or its local representative and the National Competent Authority.

*Please login to https://www.liofilchemstore.it/login.php (user ID and password required) and click on Complaint.

This IFU document and the SDS are available from the online Support Center:

liofilchem.com/ifu-sds