Instructions For Use

ENGLISH

Sabouraud CAF Agar

Medium for cultivation and enumeration of yeasts and moulds.

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 CAF Agar is a selective medium for the isolation of pathogenic and non-pathogenic fungi microorganisms (molds and yeasts) from clinical and nonclinical specimens.
This medium conforms to Sabouraud Dextrose Agar (recommended by EN ISO 11133 for the microbiological examination of food, animal feed and water) but with the addition of chloramphenicol.

TYPICAL FORMULA*	(g/litre)
Pancreatic Digest of Casein	5.0
Peptic Digest of Animal Tissue	5.0
Dextrose	40.0
Chloramphenicol	0.5
Agar	15.0
Final pH 5.6 ± 0.2 at 25°C	

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

METHOD PRINCIPLE

Enzymatic digest of casein and enzymatic 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 glucose and the acidic pH of the medium permit selectivity of fungi.
The addition of chloramphenicol will further inhibit the growth of the accompanying bacterial flora of heavily contaminated material, due to its wide spectrum.

PREPARATION

Dehydrated medium

Suspend 65.5 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 118°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.
Sabouraud CAF Agar 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 excessive moisture on the plate before use.
Inoculate the medium with specimen. Incubate at 20-25°C or 30-35°C in an inverted position (agar-side up), and cap loosened for tubes. The cultures are generally examined after 48-72 hours of incubation for the detection of yeasts.

For more details, consult appropriate guidance.

Note: Incubation time and temperature vary according to the type of specimen and the microorganisms being tested for. The user is responsible for choosing the appropriate parameters for the intended use, in accordance with current standards.

INTERPRETING RESULTS

After incubation, observe the microbial growth. Examine for fungal colonies exhibiting typical microscopic and colonial morphology. Biochemical tests may be required for final identification.

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, amber.

Expected Cultural Response:

Control strain		Inoculum	Incubation	Criteria	Specification
Candida albicans	ATCC® 10231	50-100 CFU	46 ± 2 h / 22.5 ± 2.5°C	($P_R \geq 0.5$)	Good Growth
Candida albicans	ATCC® 10231		22 ± 2 h / 32.5 ± 2.5°C		Good Growth
Aspergillus brasiliensis	ATCC® 16404		72 ± 2 h / 22.5 ± 2.5°C		Good Growth
Saccharomyces cerevisiae	ATCC® 9763				Good Growth
Trychophyton mentagrophytes	ATCC® 9533		up to 7 days / 30 ± 2 °C		Good Growth
Escherichia coli	ATCC® 8739	10^4-10^6 CFU	72 ± 2 h / 32.5 ± 2.5°C	-	Inhibited

A productivity ratio (P_R) of 0.5 is equivalent to a recovery rate of 50%.

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

PERFORMANCE CHARACTERISTICS

Performance testing of Sabouraud CAF 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.
Growth depends on the requirements of each individual microorganism. It is therefore possible that certain strains which have specific requirements (substrate, temperature, incubation conditions, etc.) may not develop.

Given the wide variety of samples studied, it is the responsibility of the user to validate this medium for its specific intended use.

Sabouraud CAF Agar 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.

See ordering info 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 CAF Agar	Plate 90 mm	20 plates	11035
	Slant Tube	10 x 9 ml	31023
	Bottle	6 x 100 ml	402370
		6 x 200 ml	412370
	Dehydrated media	500 g	610203
		100 g	620203
		5 kg	6102035

Revision History

Revision	Release Date	Change Summary
0	2024-02-01	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