BIOMÉRIEUX

REF 42620

049683 - 01 - 2018-11

EN

Sabouraud Dextrose Chloramphenicol agar (SDCA-F)

For microbiological control only

INTENDED USE

Enumeration of yeasts and molds in non-sterile pharmaceutical products.

This medium enables the enumeration of yeasts and molds in non-sterile pharmaceutical products.

It is recommended by the European Pharmacopoeia (C agar medium).

EXPLANATION AND PRINCIPLE

The high concentration of dextrose optimizes fungal growth. The acidic pH and the inclusion of 50 mg/L of chloramphenicol improve the selectivity of the medium by inhibiting most species of bacteria.

COMPOSITION OF THE MEDIUM

Theoretical formula

This medium has been adjusted and/or supplemented according to the performance criteria required:

Casein and meat peptone (bovine and porcine)	10 g
Dextrose	40 g
Chloramphenicol	0.05 g
Agar	15 g
Purified water	1 L
pH 5.6	

WARNINGS AND PRECAUTIONS

- **For microbiological control only.**
- **For professional use only.**
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest; do not inhale).
- All samples and inoculated media should be considered infectious and handled appropriately. Aseptic technique and usual precautions for handling the microbial group studied should be observed throughout this procedure; refer to the Laboratory Biosafety Manual – WHO – Geneva – Latest edition, or the current regulations in the country of use.
- The media should not be used as manufacturing material or components.
- Do not use reagents after the expiry date.
- Do not use reagents if the packaging is damaged.
- Do not use reagents which show signs of contamination.
- Before use, make sure the tamper-proof systems are intact (capsule, seal, stopper).
- The medium must be used according to the procedure indicated in this package insert. Any change or modification in the procedure may affect the results.

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED

Reagents:

- Peptoned Buffer Solution pH 7.0 (Ref. 42609).

Materials:

- General microbiology laboratory equipment.
- Sterile Petri dishes.
- Bacteriology incubator.
- Water baths.

STORAGE CONDITIONS

- Store the bottles at +15°C/+25°C in their box until the expiry date.
- After the media have been dispensed into Petri dishes, they can be stored for 1 week at +2°C/+8°C.

- Sabouraud Dextrose Chloramphenicol agar in bottles can only be regenerated twice.

SPECIMENS

Follow the recommendations of the European Pharmacopoeia for the preparation of samples.

For pour-plate inoculation, test samples should be 1 mL of a 1/10 dilution of the sample in buffered peptone solution.

PROCEDURE

1. Loosen the cap on the bottle.
2. Place the bottle of agar in a water bath equipped with a security system set to approximately +50°C, increase the temperature to +95°C and leave the agar to melt (approximately 45 minutes).
3. Screw the cap back on (wear protective gloves against high temperature) and then mix.
4. Leave the bottles between 1 and 5 minutes at room temperature on the lab bench before transferring them to a thermostatically controlled water bath set at a maximum of +45°C. Maintain the products at this temperature until use, without exceeding 30 minutes.
5. Inoculate according to the method described in the European Pharmacopoeia:[3]
   a. Dispense 1 mL of diluted sample into a sterile Petri dish.
   b. Pour 15-20 mL of Sabouraud Dextrose Chloramphenicol agar maintained at a maximum of +45°C and mix carefully.
   c. Leave to cool on a flat horizontal surface until completely solid.
   d. Incubate at +20°C/+25°C for up to 5 days.

   Tests should be performed in duplicate for the successive dilutions chosen.

RESULTS AND INTERPRETATION

- After incubation, observe the fungal growth.
- Select plates with a dilution containing the highest number of colonies, but less than one hundred.
- Count the colonies on the plates.
- For interpretation of results and enumeration, follow the recommendations of the European Pharmacopoeia.

QUALITY CONTROL

This product has been designed and developed to meet the most stringent quality requirements.

The results of the strains tested in the batch by batch quality control are given on the quality control certificate available on the technical library that can be accessed via our corporate website (www.biomerieux.com).

LIMITATIONS OF THE METHOD

- The medium inhibits most bacterial strains. However, certain *Pseudomonas* strains may grow.
- Growth of certain molds such as *Rhizomucor pusillus* requires 7 days of incubation at +18°C/+25°C.
- Given the wide variety of samples studied, it is the responsibility of the user to validate this medium for its specific intended use.

WASTE DISPOSAL

Unused reagents may be considered as non-hazardous waste and disposed of accordingly.

Dispose of used reagents as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products.

It is the responsibility of each laboratory to handle waste and effluents produced, according to their nature and degree of hazardousness, and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

LITERATURE REFERENCES

1. SABOURAUD R. - Les Teignes - Masson, Paris 1910.
2. Lorian (ed.) - 1980 - Antibiotics in laboratory medecine - Williams & Wilkins, Baltimore.
3. European Pharmacopoeia Ph. Eur. *.

* This document is in compliance with current version of Pharmacopoeias.

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
	Manufacturer

Symbol	Meaning
	Temperature limit
	Use by date
LOT	Batch code
	Consult Instructions for Use
	Date of manufacture

LIMITED WARRANTY

bioMérieux warrants the performance of the product for its stated intended use provided that all procedures for usage, storage and handling, shelf life (when applicable), and precautions are strictly followed as detailed in the instructions for use (IFU).

Except as expressly set forth above, bioMérieux hereby disclaims all warranties, including any implied warranties of merchantability and fitness for a particular purpose or use, and disclaims all liability, whether direct, indirect or consequential, for any use of the reagent, software, instrument and disposables (the "System") other than as set forth in the IFU.

PACKAGING

Ready-to-use media

REF	Units/Pack	Short name
42620	6 x 200 mL bottles	SDCA-F

1 package insert downloadable from www.biomerieux.com/techlib

REVISION HISTORY

Change type categories

N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user

Note: *Minor typographical, grammar, and formatting changes are not included in the revision history.*

Release Date	Part Number	Change Type	Change Summary
2018-11	049683-01	Administrative	Formatting and wording changes. Updated sections: Intended Use / Reagents and Materials Required but not Provided / Warnings and Precautions / Storage Conditions / Procedure / Results and Interpretation / Quality Control / Waste Disposal / Index of Symbols / Limited Warranty / Revision History

bioMérieux SA
376 Chemin de l'Orme
69280 Marcy-l'Etoile - France

673 620 399 RCS LYON
Tel. 33 (0)4 78 87 20 00
Fax 33 (0)4 78 87 20 90
www.biomerieux.com