

Technical Data Sheet

Sabouraud Dextrose Contact Agar + Chloramphenicol - RT+

Ordering number: 1.46549.0020

Sabouraud Dextrose Contact Agar + Chloramphenicol - RT+ is designed for the determination of the total count of yeasts and molds on dry surfaces and personnel in controlled environments and for Room Temperature storage.

Ten contact plates each with a diameter of 55 mm are single-bagged in transparent, hydrogen peroxide impermeable sleeves (non-irradiated). The sleeves consist of polypropylene with a barrier of PE-EVOH- PE.

The formulation of the basic medium (Peptone Dextrose Agar) is prepared according to the recommendations of the current European, Japanese and United States Pharmacopoeia (EP, 2.6.12.; JP, 4.05 and USP, 61).

Sabouraud Dextrose Agar + Chloramphenicol is also available as:

- Sabouraud Dextrose Agar + Chloramphenicol - LI (article number 146003): 90 mm settle plates; single-bagged; non-irradiated; intended for determination of the total count of yeasts and molds. The plate design allows aerobic incubation only.

Mode of Action

Sabouraud Dextrose Agar (SDA) is a complex medium for cultivation and isolation of yeasts and molds.

The high concentration of Dextrose in addition with the low pH promotes the growth, the formation of spores (conidia and sporangia) as well as the formation of pigments of yeasts and molds. On the other side the growth of bacteria is inhibited. The addition of chloramphenicol will further inhibit the growth of the accompanying bacterial flora.

Typical Composition

Casein Peptone	5 g/l
Meat Peptone	5 g/l
Dextrose	40 g/l
Agar	18 g/l
Chloramphenicol	50 mg/l

The appearance of the medium is clear and yellowish. The pH value is in the range of 5.4-5.8. The medium can be adjusted and/or supplemented according to the performance criteria required.

Application and Interpretation

Each plate is provided with a label including a data matrix code for paperless plate identification. The code consists of a two-dimensional 20-digit serial number, which harbors the following information:

Digits 1-3: here code 862 (corresponds to article 146549); digits 4-9: lot number; digits 10-14: batch specific individual number; digits 15-20: expiration date (YY/MM/DD).

Please check each agar plate before using it on sterility and pay attention to aseptic handling in order to avoid false positive results.

According to ISO 14698 the plates are opened and the agar surface is pressed on the dry surface to be tested for some seconds with a steady pressure. Afterwards the plates are closed and transferred to an incubator. Residues of culture medium should be removed from the surface after sampling.

In addition, the plate model (plus or „+“) is supplied with a lockable lid. For safe transport after sampling without the risk of losing the lid as well as for aerobic incubation the plates should be locked in the "CLOSED"-position (turn the lid clockwise). For anaerobic or microaerophilic incubation in the "VENT"-position (turn the lid counter-clockwise) is mandatory, because this lid-position provides sufficient gas exchange with the atmosphere in the incubation chamber. Aerobic incubation while turning the lid in "VENT"-position is also possible, but may increase the desiccation of the agar plates during incubation.

Several recommendations are given by different guidelines for incubation: according to USP <1116> the plates used for environmental monitoring should be incubated between 20 and 35 °C for not less than 72 hours. According to the FDA Aseptic Guide the plates for determination of the total yeast and mold count should be incubated at 20 to 25 °C for 5 to 7 days. Individual incubation conditions can be chosen and should be validated at the application side.

Finally the number of CFU per plate is examined.

Grown colonies are recommended to be identified.

Storage and Shelf Life

The product can be used for sampling until the expiry date if stored upright, protected from light and properly sealed at +15 °C to +25 °C.

Condensation can be prevented by avoiding quick temperature shifts and mechanical stress.

The testing procedures as described on the CoA can be started up to the expiry date printed on the label.

Disposal

Please mind the respective regulations for the disposal of used culture medium (e.g. autoclave for 20 min at 121 °C, disinfect, incinerate etc.).

Quality Control

Control Strains	ATCC #	Inoculum CFU	Incubation	Expected Result
<i>Candida albicans</i>	10231	10-100	44-48 h at 20-25 °C	50-200 %
<i>Saccharomyces cerevisiae</i>	9763	10-100	70-74 h at 20-25 °C	50-200 %
<i>Aspergillus brasiliensis</i>	16404	10-100	70-74 h at 20-25 °C	50-200 %
<i>Escherichia coli</i>	8739	10,000-100,000	70-74 h at 20-25 °C	No growth

Please refer to the actual batch related Certificate of Analysis.

Literature

EU GMP Medicinal Products for Human and Veterinary use (2008): Annex1 Manufacture of Sterile Medicinal Products.

European Pharmacopoeia 8.0 (2014): 2.6.12. Microbial examination of non-sterile products (total viable aerobic count).

Guidance for Industry (2004): Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice.

ISO 14698-1:2003: Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods.

Japanese Pharmacopoeia 16th edition (2011): 4.05 Microbial Limit Test.

PDA Technical Report No. 13 (2014 Revised): Fundamentals of an Environmental Monitoring Program.

United States Pharmacopoeia 38 NF 33 (2015): <61> Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests; <1116> Microbiological Control and Monitoring of Aseptic Processing Environments.

Ordering Information

Product	Cat. No.	Pack size
Sabouraud Dextrose Contact Agar + Chloramphenicol - RT+	1.46549.0020	20 x 55 mm plates
Sabouraud Dextrose Agar + Chloramphenicol - LI	1.46003.0020	20 x 90 mm plates
Sabouraud Dextrose Agar + Chloramphenicol - LI	1.46003.0120	120 x 90 mm plates

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