Technical Data Sheet

Sabouraud Dextrose Agar + LTHTh selective - ICRplus

Ordering number: 1.46704.0020 / 0120

Sabouraud Dextrose Agar + LTHTh selective – ICR+ is designed for the determination of the total count of yeasts and molds in air via active or passive air monitoring as well as fingerprints of personnel in **I**solators and **C**lean **R**ooms.

Ten lockable settle plates each with a diameter of 90 mm are triple-bagged in transparent, hydrogen peroxide impermeable sleeves. The product is gamma-irradiated in the final packaging at a dose of 9-20 kGy. The sleeves consist of polypropylene with a barrier of PE-EVOH-PE.

The formulation of the basic medium (Sabouraud 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) and supplemented with neutralizers.

Further plate designs are available with the identical media formulation:

- SDA Contact + LTHTh - ICR+ selective (article number 146538): 55 mm lockable, pink colored contact plates, triple-bagged, gamma-irradiated; intended for microbial monitoring of dry, sanitized surfaces and personnel in cleanrooms and isolators. The plate design allows aerobic, microaerophilic and anaerobic incubation.
- SDA + LTHTh - ICR selective (article number 146016): 90 mm non-lockable, pink colored settle plates; triple-bagged; gamma-irradiated; intended for microbial monitoring of air (passive and active) and fingerprints of personnel in cleanrooms and isolators. The plate design allows aerobic, incubation.

Mode of Action

Sabouraud Dextrose Agar (SDA) is a complex medium for cultivation and isolation of yeasts and molds. The medium is supplemented with pyruvate to provide an efficient neutralization of hydrogen peroxide for use in isolators.

According to pharmacopoeia and ISO 18415, the neutralizers lecithin, polysorbate (Tween®) 80, histidine and sodium thiosulfate are suitable for neutralization of disinfectant residues containing the following active agents:

- Aldehydes
- Bis-biguanides
- Oxidizing compounds
- Parabens
- Phenolic compounds
- Quaternary ammonium compounds

The high concentration of dextrose in addition with the low pH value promotes the growth, the formation of spores (conidia and sporangia) as well as the formation of pigments of yeasts and molds. In addition, the medium contains irradiation resistant antibiotics to inhibit the accompanying bacterial flora.

Typical Composition

Ingredient	Amount per liter
Casein Peptone	5 g/l
Meat Peptone	5 g/l
Dextrose	40 g/l
Polysorbate (Tween®) 80	5 ml/l
Lecithin	0.7 g/l
Histidine	0.5 g/l
Sodium thiosulfate	0.3 g/l
Agar	18 g/l
Selective Supplements	

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

The plates are introduced into cleanrooms grade A or B by removing one bag in each material lock. For use in isolators the inner bag has a hole in the sealing to hang up the bag during decontamination. Do not leave plates which are unprotected (unwrapped) in an isolator during decontamination.

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 724 (corresponds to article 146704); 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 to avoid false positive results.

The plates may be used for passive or active air monitoring as described in USP chapter <1116> or ISO 14698. For active air sampling please follow the guidance of the air sampler. Typically, 1000 liter of air are sampled for quantification of CFU. The exposure time of opened settle plates should be validated with respect to the environmental conditions of the sampling area such as air flow rates, temperatures and relative humidity to preclude desiccation. Afterwards the plates are closed and transferred to an incubator. To protect the plates from secondary contamination during transport and incubation outside of the cleanroom zone, sterile transport bags (article number 146509) may be used.

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.

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

batch number of included plates).

Quality Control

Control Strains	**ATCC #**	**Inoculum CFU**	**Incubation**	**Expected Result Recovery in %**
Candida albicans + 100 µl Aerodesin 2000	10231	10-100	44-48 h at 20-25 °C	50-200
Aspergillus brasiliensis + 100 µl Aerodesin 2000	16404	10-100	70-74 h at 20-25 °C	50-200
Staphylococcus aureus + 100 µl Aerodesin 2000	6538	10,000-100,000	70-74 h at 20-25 °C	no growth
Escherichia coli + 100 µl Aerodesin 2000	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.

ISO 18415 (2017 [E]): Cosmetics – Microbiology – Detection of specified and non-specified microorganisms

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

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