Technical Data Sheet

Tryptic Soy Agar - ICR

Ordering number: 1.46001.0020 / 1.46001.0120

Tryptic Soy Agar - ICR in 90 mm settle plates is designed for the determination of the total aerobic microbial count in air via active or passive air monitoring as well as fingerprints of personnel in **Isolator**s and **C**lean **R**ooms.

Ten 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 (SoybeanCasein-Digest 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).

Further plate designs are available with the identical media formulation:

- TSA - ICR+ (article number 146685): 90 mm lockable settle plates, triple-bagged, gamma-irradiated; intended for microbial monitoring of air (passive and active) and personnel in Clean Rooms and Isolators. The plate design allows aerobic, microaerophilic and anaerobic incubation.

Mode of Action

Tryptic Soy Agar (TSA, Soybean Casein Digest Agar) is a complex medium for cultivation and isolation of a wide range of bacteria, yeasts and molds. The medium is supplemented with pyruvate to provide an efficient neutralization of hydrogen peroxide for use in Isolators.

Typical Composition

Casein Peptone	15 g/l
Soy Peptone	5 g/l
NaCl	5 g/l
Agar	15 g/l

The appearance of the medium is clear and yellowish. The pH value is in the range of 7.1-7.5. The medium can be adjusted and/or supplemented according to the performance criteria required.

Application and Interpretation

The plates are introduced into clean rooms 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 700 (corresponds to article 146001); digits 4-9: lot number; digits 10-14: batch specific individual number; digits 15-20: expiry date (YY/MM/DD).

Please check each agar plate on sterility before using it 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 Clean Room 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 aerobic bacterial count should be incubated at 30 to 35 °C for 48 to 72 hours, while 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. For anaerobic incubation we recommend to use the lockable version in „VENT"-position, which facilitates the gas exchange within the plate.

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 +2 °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 Recovery in %
Staphylococcus aureus	6538	10-100	20-24 h at 30-35 °C	50-200
Pseudomonas aeruginosa	9027	10-100	20-24 h at 30-35 °C	50-200
Bacillus subtilis	6633	10-100	20-24 h at 30-35 °C	50-200
Candida albicans	10231	10-100	44–48 h at 30-35 °C	50-200
Aspergillus brasiliensis	16404	10-100	44-48 h at 30-35 °C	50-200

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 9.0 (2016): 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: Clean Rooms 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 41 NF 33 (2018): <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
Tryptic Soy Agar - ICR	1.46001.0020	20 x 90 mm plates
Tryptic Soy Agar - ICR	1.46001.0120	120 x 90 mm plates
Tryptic Soy Agar - ICR+	1.46685.0020	20 x 90 mm plates
Tryptic Soy Agar - ICR+	1.46685.0120	120 x 90 mm plates
Transport Bags, sterile	1.46509.0125	25 x 5 bags

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