

Technical Data Sheet

Tryptic Soy Agar – LI acc. EP / USP

Ordering number: 1.46004.0020 / 1.46004.0120

Tryptic Soy Agar - LI 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 controlled environments.

Ten settle plates each with a diameter of 90 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 (Soybean-Casein 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).

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.

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 TSA settle plates are utilized for microbial monitoring of air (passive and active) and personnel testing in controlled environments.

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 791 (corresponds to article 146004); 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.

The plates may be used in controlled environments (cleanroom areas beside grade A and B) 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 samples 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 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 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.

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 Recovery in %
<i>Staphylococcus aureus</i>	6538	10-100	20-24 h at 30-35 °C	70-200 %
<i>Escherichia coli</i>	8739	10-100	20-24 h at 30-35 °C	70-200 %
<i>Pseudomonas aeruginosa</i>	9027	10-100	20-24 h at 30-35 °C	70-200 %
<i>Bacillus subtilis</i>	6633	10-100	20-24 h at 30-35 °C	70-200 %
<i>Candida albicans</i>	10231	10-100	20-24 h at 30-35 °C	70-200 %
			44-48 h at 20-25 °C	50-200 %
<i>Aspergillus brasiliensis</i>	16404	10-100	44-48 h at 30-35 °C	70-200 %
			70-74 h at 20-25 °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 Directorate for the Quality of Medicines and Healthcare. (2014): The European Pharmacopoeia. 8th Ed. Chapter 2.6.12 Microbiological examination of non-sterile products: Microbial enumeration tests and Chapter 2.6.13 Microbiological examination of non-sterile products: Test for specified products. Strasbourg, France.

Japanese Ministry of Health, Labour and Welfare. (2011): The Japanese Pharmacopoeia. 16th Ed. Chapter 4.05 Microbial Limit Test I. Microbiological examination of non-sterile products: Total viable aerobic count and II. Microbiological examination of non-sterile products: Test for specified products. Japanese Ministry of Health, Labour and Welfare. Tokyo, Japan.

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

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

United States Pharmacopeial Convention. (2014): The United States Pharmacopeia 38/National Formulation 33, Supp. 2. Chapter <61> Microbiological examination of non-sterile products: Microbial enumeration tests and Chapter <62> Microbiological examination of non-sterile products: Test for specified products. Rockville, Md., USA.

Ordering Information

Product	Cat. No.	Pack size
Tryptic Soy Agar - LI	1.46004.0020	20 x 90 mm plates
Tryptic Soy Agar - LI	1.46004.0120	120 x 90 mm plates
ReadyPlate™ TSA ISO, FDA-BAM, EP+USP	1.46431.0020	20 pcs
ReadyPlate™ TSA ISO, FDA-BAM, EP+USP	1.46431.0100	100 pcs

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