Technical Data Sheet

Tryptic Soy Agar+ LTHThio contact- ICRplus

Ordering number: 1.46783.0020 / 1.46783.0200

Tryptic Soy Agar + LTHThio Contact- ICR+ is designed for the determination of the total aerobic and anaerobic microbial count on dry, sanitized surfaces and personnel in Isolators and Clean Rooms.

Ten lockable contact plates each with a diameter of 55 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 (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) and supplemented with neutralizers.Further plate designs are available with the identical media formulation:

- TSA LTHThio Contact-ICR (article number 146797): 55 mm contact plates, triple-bagged, gamma-irradiated; intended for microbial monitoring of dry, sanitized surfaces and personnel in Clean Rooms and isolators. The plate design allows aerobic incubation only.
- TSA + LTHThio Sedi.-ICR (article number 146786): 90 mm 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 incubation only.
- TSA + LTHThio Sedi. - ICR+ (article number 146787): 90 mm lockable settle plates, triple-bagged, gamma-irradiated; intended for viable air monitoring (passive and active) and personnel testing 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. Internal studies confirmed the neutralization efficiency of the neutralizers lecithin, polysorbate (Tween®) 80, histidine and sodium thiosulfate for disinfectants containing the following active agents:

- Alcohol (70 % ethanol or isopropyl alcohol)
- Aldehyde
- Dichloroisocyanurate
- Chlorine (e.g. Sodium hypochlorite)
- Glucoprotamine
- Hydrogen Peroxide
- Peracetic acid
- Phenols (low and high pH value)
- Low concentrated quaternary ammonium compounds

The neutralizing efficiency towards residues of disinfectants in use should be validated at the application site.

For neutralization of high concentrated quaternary ammonium compounds and/or polyhexamethylene biguanides the use of Neutralizer A Contact Plate is recommended (article number 146697).

Typical Composition

Casein Peptone	15 g/l
Soy Peptone	5 g/l
NaCl	5 g/l
Polysorbate (Tween®) 80	5 ml/l
Lecithin	0.7 g/l
Histidine	0.5 g/l
Sodium Thiosulfate	0.05 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 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 731 (corresponds to article 146783); 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 on sterility before using it and pay attention to aseptic handling 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. Similar recommendations are included in the PDA technical report No.13. 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. 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 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 +2 °C to +25 °C.

Condensation can be prevented by avoiding quick temperature shifts and mechanical stress.
Please store the plates at stable temperatures. The plates show minimum water condensation when stored at 15°C - 25°C.

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
Staphylococcus aureus With 50µl Cutasept F	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
Clostridium sporogenes	11437	10-100	44-48 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 10.0 (2019): 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 41 NF 36 (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 + LTHThio Contact - ICR+	1.46783.0020	20 x 55 mm plates
Tryptic Soy Agar + LTHThio Contact - ICR+	1.46783.0200	200 x 55 mm plates
Tryptic Soy Agar + LTHThio Contact - ICR	1.46797.0020	20 x 55 mm plates
Tryptic Soy Agar + LTHThio Contact - ICR	1.46797.0200	200 x 55 mm plates
Tryptic Soy Agar + LTHThio Sedi – ICR+	1.46787.0020	20 x 90 mm plates
Tryptic Soy Agar + LTHThio Sedi – ICR+	1.46787.0120	120 x 90 mm plates
Tryptic Soy Agar + LTHThio Sedi – ICR	1.46786.0020	20 x 90 mm plates
Tryptic Soy Agar + LTHThio Sedi – ICR	1.46786.0120	120 x 90 mm plates
Neutralizer A – Contact Ager – ICR+	1.46697.0020	20 x 55 mm plates
Neutralizer A – Contact Ager – ICR+	1.46697.0200	200 x 55 mm plates
Transport Bags, sterile	1.46509.0125	25 x 5 bags