

Tryptic Soy Agar + Lactamator 1000 IU (Irradiated)

General purpose medium for environmental monitoring with inactivation of β -lactam antibiotics.

TYPICAL FORMULA	(g/l)
Casein Peptone	15.0
Soy Peptone	5.0
Sodium Chloride	5.0
Agar	15.0
Lactamator	1000 IU
Final pH 7.3 \pm 0.2	

DESCRIPTION

Tryptic Soy Agar + Lactamator 1000 IU (Irradiated) is a general purpose medium used for environmental monitoring with inactivation of β -lactam antibiotics (penicillins, cephalosporins and carbapenems).

These triple-wrapped irradiated plates are particularly suitable for use in restricted areas like isolators and clean rooms.

PRINCIPLE

Casein peptone and soy peptone provide amino acids, nitrogen, carbon, minerals, vitamins and other nutrients which support the growth of microorganism. Sodium chloride maintains the osmotic balance of the medium. Agar is the solidifying agent. Lactamator is a mixture of Penicillinase and Cephalosporinase, designed for the inactivation of a wide range of beta-lactam antibiotics.

- 1 International Unit (IU) is defined as the amount of enzyme needed to hydrolyze 1 μ mole of Penicillin G (Penicillinase) or 1 μ mole of Cephalosporin C (Cephalosporinase) per minute at pH 7.0 at 25°C.

TECHNIQUE

Use settle plate sampling method. Alternatively, if sample is being cultured from a swab, inoculate the plates by streaking directly the swab on the medium surface.

For detection of bacteria incubate the plates at 30-35°C for 18-72 hours.

For detection of yeasts and moulds incubate at 20-25°C for 2-7 days.

INTERPRETATION OF RESULTS

Observe daily for the formation of colonies.

STORAGE AND TRANSPORT CONDITIONS

2-8°C away from light, until the expiry date on the label. However, our stability studies have shown that the transport at 18-25°C for 4 days, or at 35-39°C for 48 hours, does not alter in any way the performance of the product. Eliminate if signs of deterioration or contamination are evident.

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product must be used by properly trained operators only.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to the national and local regulations in force.

REFERENCES

1. USP 41 – NF 33 (2018) <61> Microbiological examination of non-sterile products: Microbial enumeration tests; <62> Microbiological examination of non-sterile products: Test for specified microorganisms; Harmonised Methods. <1116> Microbiological control and monitoring of aseptic processing environments. The United States Pharmacopeial Convention, Rockville, MD. USA.
2. European Pharmacopeia 9.0 (2016) 16th ed. Chapter 2.6.12 - Microbiological examination of non-sterile products: Microbial enumeration tests; Chapter 2.6.13 - Microbiological examination of non-sterile products: Test for specified microorganisms. . Council of Europe Strasbourg, France.
3. Swanson, K.J., F.F. Busta, E.H. Peterson, and M.G. Johnson (1992). Colony Count Methods, p. 75-95.



PRODUCT SPECIFICATIONS

NAME

Tryptic Soy Agar + Lactamator 1000 IU + Neutralizing (Irradiated)

PRESENTATION

Ready-to-use plates (90 mm) containing 22 ± 1 ml of medium

STORAGE

2-8°C

PACKAGING

Ref.	Content	Packaging
10103S	20 plates	<ul style="list-style-type: none"> • 10 triple-wrapped plates • 2 x 10 plates in cardboard box

pH OF THE MEDIUM

7.3 ± 0.2

USE

Tryptic Soy Agar + Lactamator 1000 IU + Neutralizing (Irradiated) is a general purpose medium used for environmental monitoring with inactivation of β -lactam antibiotics (penicillins, cephalosporins and carbapenems). Particularly suitable for use in restricted areas

TECHNIQUE

Refer to technical sheet of the product

APPEARANCE OF THE MEDIUM

Clear to slightly opalescent, amber

SHELF LIFE

6 months

QUALITY CONTROL

- Control of general characteristics, label and print
- Sterility control
7 days at $22.5 \pm 2.5^\circ\text{C}$, in aerobiosis
7 days at $32.5 \pm 2.5^\circ\text{C}$, in aerobiosis
- Microbiological control
Inoculum for productivity: 50-100 CFU
Inoculum for evaluation of lactamator activity: 10^4 - 10^6 CFU
Incubation Conditions: 24-48 h at $32.5 \pm 2.5^\circ\text{C}$ for bacteria; 24-72 h at $22.5 \pm 2.5^\circ\text{C}$ for fungi

Microorganism

Growth

<i>Staphylococcus aureus</i>	ATCC® 6538	Good
<i>Escherichia coli</i>	ATCC® 8739	Good
<i>Pseudomonas aeruginosa</i>	ATCC® 9027	Good
<i>Bacillus subtilis</i>	ATCC® 6633	Good
<i>Clostridium sporogenes</i> *	ATCC® 11437	Good
<i>Candida albicans</i>	ATCC® 10231	Good
<i>Aspergillus brasiliensis</i>	ATCC® 16404	Good

*anaerobiosis










Control of penicillinase and cephalosporinase activities with disc diffusion method

Microorganism

Specification

<i>Staphylococcus aureus</i>	ATCC® 6538	No inhibition by Penicillin G 10 IU, Ampicillin 10 μg , Cefotaxime 30 μg , Cefepime 30 μg and Meropenem 10 μg
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TABLE OF SYMBOLS

 Batch code	 Do not reuse	 Manufacturer	 Use by	 Fragile, handle with care
 Catalogue number	 Temperature limitation	 Contains sufficient for <n> tests	 Caution, consult instructions for use	



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