

Product: **Tryptone Soy Agar (TSA) Penase (Ph. Eur.) triple wrap, for microbiology****Specification**

General purpose medium for isolation and culture of microorganisms with penase.

**Presentation**

	<b>Packaging Details</b>	<b>Shelf Life</b>	<b>Storage</b>
30 Contact Plates/Ird. Contact Plates - Triple Wrapping with: 15 ± 2 ml	1 box with 3 x 10 plates BOPP plastic bags (triple wrapping) with stacks of 5 plates inside. Every pack exhibits a irradiation indicator stacked on the side of the bag (8-14 KGy). LATERAL LABELLING LOCKABLE PETRI LID	8 months	15-25 °C

**Composition**

Composition (g/l):	
Peptone from casein .....	15.0
Soya peptone.....	5.0
Sodium chloride.....	5.0
Agar.....	15.0
Penicillinase to inactivate: 10.000.000 UI PenG/L/min	

**Description /Technique**Description:

Soy Trypticase Agar with Penicillinase is used in the environmental monitoring of air and surfaces in areas where there may be contaminations or residues of penicillins or cephalosporins.

This widely used culture medium contains soya and casein peptones in proven proportions to support the growth of most microorganisms, including some very fastidious ones. It has been formulated according to the harmonized method of pharmacopoeias and ISO standards and is regularly used in routine diagnostic work for its reliability in the morphological aspects and reproducibility of the results. Penicillinase ensures the inactivation of penicillins or cephalosporins that may be present in the air or surfaces to be sampled, allowing the growth of organisms sensitive to these antibiotics.

Note: Contact plates are used for monitoring the microbiological contamination of surface and air inside cleanrooms, isolators, RABS, food industries and hospitals. The double/triple irradiated wrapping ensures that the package itself doesn't contaminate the environment as the first wrapper is removed just before entering the clean area.

Technique:

In the microbiological control of cleaning and disinfection of surfaces in the "clean zones" the contact plates are used as a plug or copy-pad that acts simultaneously as a sampler and culture medium to be incubated, without other intermediate operations. For this, the 65 mm diameter plates are filled so that the medium forms a suitable meniscus to produce a contact surface of approximately 25 cm<sup>2</sup>.

At the time of use the plates remove the outer shell, remove the cover of the plate and support the culture medium on the surface to be controlled, exerting a gentle pressure for about 10-15 seconds, to ensure good contact between the two surfaces. The plate is removed without rubbing and covered with its cover to avoid contamination. They are labeled appropriately with the sampling data (place, date and time) and are incubated. The inoculated plates are incubated at 30-35 ° C for 24-72 h (bacteria) and 3-5 days for fungi (yeast & molds). Examined daily.

When the effectiveness of a cleaning and / or disinfection process is verified, sampling with the contact plates should be done within two hours of the completion of the process, ensuring that the surfaces to be sampled are dry. Positive controls should always be included, sampling the area prior to disinfection or simultaneously monitoring unclean areas adjacent to the disinfected areas.

The frequency of cleaning / disinfection and subsequent sampling will be established by the responsible technician, depending on the results obtained and the proposed objectives.

The lid can be used **locking the plate** in two positions after taking the sample:

- **AIR:** lid closed, but leaving certain movement, for AEROBIC and ANAEROBIC incubations.
- **CLOSE:** lid completely closed. Better for transport, avoiding risk of contamination due to its possible opening during the transport.

**Attention:** Plates are used for monitoring the microbiological contamination of surface and air inside cleanrooms, isolators, RABS, food industries and hospitals. The double/triple irradiated wrapping ensures that the package itself doesn't contaminate the environment as the first wrapper is removed just before entering the clean area.

Wrapping resistant to hydrogen peroxide vapors penetration.

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**Quality control**
**Physical/Chemical control**

Color : Straw-coloured yellow      pH: 7.3 ± 0.2 at 25°C

**Microbiological control**

Control post addition of Penicillin - According to harmonized pharmacopoeial monographs and test methods

Analytical methodology according to ISO 11133:2014/A1:2018; A2:2020.

Aerobiosis. Incubation at 30-35 °C. Read after 18-24 h to 72 h for bacteria and 3-5 days for fungi.

**Microorganism**

*Escherichia coli* ATCC® 8739, WDCM 00012  
*Staphylococcus aureus* ATCC® 6538, WDCM 00032  
*Bacillus subtilis* ATCC® 6633, WDCM 00003  
*Candida albicans* ATCC® 10231, WDCM 00054  
*Aspergillus brasiliensis* ATCC® 16404, WDCM 00053  
*Ps. aeruginosa* ATCC® 9027, WDCM 00026  
*Penicillin Inactivation test*

**Growth**

Good (≥70%)  
 Good (≥70%)  
 Good (≥70%)  
 Good (≥70%)  
 Good (≥70%)  
 Good (≥70%)  
 Correct - Penase content verified

**Sterility control**

Incubation 48 h at 30-35 °C and 48 h at 20-25 °C: NO GROWTH.

Check at 7 days after incubation in same conditions.

**Bibliography**

- ATLAS, R.M. & L.C. PARKS (1993) Handbook of Microbiological Media. CRC Press, Inc. London.
- COLIPA (1997) Guidelines on Microbial Quality Management (MQM). Brussels.
- DOWNES, F.P. & K. ITO (2001) Compendium of Methods for the Microbiological Examination of Food, 4th ed, ASM, Washington D.C.
- EUROPEAN PHARMACOPOEIA 10.0 (2020) 10th ed. § 2.6.13. Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. EDQM. Council of Europe. Strasbourg.
- FDA (Food and Drug Administrations) (1998) Bacteriological Analytical Manual. 8th ed. Revision A. AOAC International. Gaithersburg, MD.
- HORWITZ, W. (2000) Official Methods of Analysis of AOAC INTERNATIONAL, 17th ed. Gaithersburg, MD. USA.
- ISO 9308-1 Standard (2000) Water Quality. Detection and enumeration of *E. coli* and coliform bacteria. Membrane filtration method.
- ISO 11731 Standard (2017) Water Quality. - Enumeration of *Legionella*.
- ISO 11133:2014/ Adm 1:2018. Microbiology of food, animal feed and water. Preparation, production, storage and performance testing of culture media.
- ISO 18415 Standard (2017) Cosmetics - Microbiology - Detection of specified and non-specified microorganisms.
- ISO 21149 Standard (2017) Cosmetics - Microbiology - Enumeration and detection of aerobic mesophilic bacteria.
- ISO 21150 Standard (2015) Cosmetics - Microbiology - Detection of *Escherichia coli*.
- ISO 22717 Standard (2015) Cosmetics - Microbiology - Detection of *Pseudomonas aeruginosa*.
- ISO 22718 Standard (2015) . Cosmetics - Microbiology - Detection of *Staphylococcus aureus*.
- ISO 22964 (2017) Microbiology of the food chain.- Horizontal method for the detection of *Cronobacter spp*
- PASCUAL ANDERSON, M<sup>a</sup>R<sup>a</sup> (1992) Microbiología Alimentaria. Díaz de Santos S.A., Madrid.
- USP 33 - NF 28 (2011) <62> Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. USP Corp. Inc. Rockville. MD. USA.