Condalab

Reference: 0808 **Technical Data Sheet**

Product: **LC TSA + Penase Triple Wrapped. Irradiated**

Specification

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

Presentation

20 Plates/Irradiated
90 mm - Triple Wrapping
with: 21 ± 2 ml

Packaging Details
1 box with 2 BOPP bags (triple wrapping) with 10 plates/bag. Every pack exhibitis a irradiation indicator stacked on the side of the bag (8-14 KGy) with desiccant.
LATERAL LABELLING

Shelf Life
8 months

Storage
15-25 ºC

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 Tripticase 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.
Attention: Petri 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 smooth surfaces in the "clean zones" the contact plates are used as a plug or copy-pad which acts simultaneously as a sampler and culture medium to be incubated, without other intermediate operations. However, if the surfaces to be sampled are rough, it is preferable to delimit a surface (eg 5 x 5 cm) and thoroughly rub it with a moist, sterile swab that will be used immediately to inoculate the surface of the plate.
At the time of using the plates, the outer shell is removed, the plate is opened and the surface of the culture medium is inoculated with the swab. The plate is covered to avoid contamination, labeled appropriately with the data (place, date and time) of the sample. The inoculated plates are incubated at 30-35 º C for 24-72 h (bacteria) and 3-5 days for fungi (yeast & molds). Examined daily.

Attention: Petri 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.

Quality control

Physical/Chemical control

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

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 ºC. Read after 18-24 h to 72 h for bacteria and 3-5 days for fungi.

Microorganism	Growth
Escherichia coli ATCC® 8739, WDCM 00012	Good (≥70%)
Staphylococcus aureus ATCC® 6538, WDCM 00032	Good (≥70%)
Bacillus subtilis ATCC® 6633, WDCM 00003	Good (≥70%)
Candida albicans ATCC® 10231, WDCM 00054	Good (≥70%)
Aspergillus brasiliensis ATCC® 16404	Good (≥70%)
Ps. aeruginosa ATCC® 9027, WDCM 00026	Good (≥70%)
Penicillin Inactivation test	Correct - Penase content verified

Sterility Control

Incubation 48 hours at 30-35 ºC and 48 hours at 20-25 ºC: 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 Adminstrations) (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 aeuruginosa.
· 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, MªRª (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.