

Specification

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

Presentation

| | Packaging Details | Shelf Life | Storage |
|---|--|------------|----------|
| 30 Contact Plates/lrd. 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.

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 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 cm².

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.

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 30-35-37 °C. Read after 18-24 h to 72 h for bacteria and 3-5 days for fungi.

Microorganism
Growth

| | |
|---|-------------|
| <i>Escherichia coli</i> ATCC® 8739, WDCM 00012 | Good (≥70%) |
| <i>Staphylococcus aureus</i> ATCC® 6538, WDCM 00032 | Good (≥70%) |
| <i>Bacillus subtilis</i> ATCC® 6633, WDCM 00003 | Good (≥70%) |
| <i>Candida albicans</i> ATCC® 10231, WDCM 00054 | Good (≥70%) |
| <i>Ps. aeruginosa</i> ATCC® 9027, WDCM 00026 | Good (≥70%) |
| <i>Salmonella typhimurium</i> ATCC® 14028, WDCM 00031 | Good (≥70%) |
| <i>Aspergillus brasiliensis</i> ATCC® 16404, WDCM 00053 | Good (≥70%) |
| <i>L. monocytogenes</i> ATCC® 13932, WDCM 00021 | Good (≥70%) |
| <i>Bacillus cereus</i> ATCC® 11778, WDCM 00001 | Good (≥70%) |
| <i>Enterococcus faecalis</i> ATCC® 29212, WDCM 00087 | Good (≥70%) |
| <i>Clostridium perfringens</i> ATCC® 13124, WDCM 00007 | Good (≥70%) |
| <i>Clostridium sporogenes</i> ATCC® 19404, WDCM 00008 | Good (≥70%) |
| <i>Stph. aureus</i> ATCC® 25923, WDCM 00034 | Good (≥70%) |
| <i>Escherichia coli</i> ATCC® 11775, WDCM 00090 | Good (≥70%) |

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.

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