

### Specification

Medium with neutralisers for the enumeration and cultivation of fungi, according to harmonized pharmacopoeial monographs and test methods, in surfaces.

### Presentation

30 Contact Plates/lrd  
Contact Plates - Triple Wrapping  
with: 15 ± 2 ml

#### Packaging Details

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

#### Shelf Life

8 months

#### Storage

15-25 °C

### Composition

Composition (g/l):

D(+)-Glucose.....	40.0
Peptone from casein .....	5.0
Meat Peptone.....	5.0
Lecithine.....	0.7
Polysorbate 80.....	5.0
Histidin.....	1.0
Sodium thiosulphate 5H <sub>2</sub> O.....	0.5
Agar.....	15.0

## Description /Technique

### Description

Sabouraud Dextrose Agar is a modification of the classical Sabouraud medium for the cultivation of fungi. This formula helps to maintain the morphology of fungi, providing a reliable medium for both cultivation and differentiation.

Its selectivity is due to a low pH and a high glucose concentration, which together with incubation at a relatively lower temperature (25 -30°C) favours the growth of fungi while discouraging that of bacteria.

The mixture of peptones employed has been selected to provide the fungi with all their nitrogen requirements.

The addition of the neutralizing agents TLHTh (Tween 80 - Lecithin - Histidine - Sodium Thiosulphate) may inactivate a variety of disinfectants.

\* The combination of lecithin, polysorbate 80 and histidine neutralizes aldehydes and phenolic compounds.

\* The combination of lecithin and polysorbate 80 neutralizes the quaternary ammonium compounds.

\* The polysorbate 80 neutralizes hexachlorophene and mercurial derivatives.

\* Sodium thiosulphate neutralizes halogen compounds.

\* Lecithin neutralizes chlorhexidine.

\* Histidine neutralizes formaldehyde.

### Technique

Contact plates are used in the microbiological control of disinfection and cleaning of surfaces. It acts simultaneously as a sampler and incubation culture medium without the need for any other intermediate steps.

The plates come in a form appropriate for this function and can be used with different culture media depending on the type of microbe that needs to be controlled. On average the plates provide a contact surface of approximately 25 cm<sup>2</sup>.

To use, remove the cover and gently press the culture medium on the surface to be controlled, ensuring contact between the two surfaces. The Contact plate is removed and covered with the lid to prevent air contamination. It is advisable that the lid is secured with adhesive tape and the bottom labelled with the sampling data (place, date and time).

If the sample surfaces are rough, the contact plates will not make good contact, even when the pressure is increased. In these cases it is advisable to delineate an sample surface area of 25 cm squared and rub this area vigorously with a wet sterile swab and then rub the swab over the Contact plate.

If verifying the effectiveness of a cleaning or disinfection process, contact plates should be used within two hours after the end of the process, ensuring that the sample surface is dry. It is advisable to always include positive controls, sampling the area before disinfection or dirty areas beside the disinfected area.

The technician will determine the frequency of sampling and disinfection according to performance criteria. Apply the agar directly onto surface to be monitored ensuring that the pressure is distributed over the whole plate for 10 seconds. Clean the surface where the sample was collected in order to remove any traces of agar.

The inoculated plates are incubated at 32-35 ° C for 24-48 hours and examined daily. For fungi, the incubation is carried out at 22-25 ° C for 5 days and examined daily.

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: 5.6 ± 0.2 at 25°C

### Microbiological control

Growth Promotion Test 50-100 CFU according to harmonized Pharmacopoeia monographs (EP) and test methods & ISO 11133:2014/A1:2018

Spiral Spreading: Practical range 50 - 100 CFU (productivity).

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

Aerobiosis. Incubation at 20-25°C. Reading ≤5 days.

### Microorganism

*Aspergillus brasiliensis* ATCC® 16404, WDCM 00053

*Candida albicans* ATCC® 10231, WDCM 00054

### Growth

Good (≥70%)

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.

## Bibliography

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