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SURFACE SAMPLE COLLECTION MEDIUM

BacterContactTM Sabouraud Dextrose Agar + 0.1% Penase + Neutralizing

Ready-to-use medium on 60mm plates for detection of yeasts and moulds with inactivation of disinfectants.

Code: 4109025

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1. INTENDED USE

BacterContactTM Sabouraud Dextrose Agar + 0.1% Penase + Neutralizing for the determination of total aerobic viable count of yeasts and moulds in procedures for environmental and personnel hygiene monitoring.

The packaging with semi-permeable Cellophane film helps balance the humidity of the environment during storage.

2. PRINCIPLES

Pancreatic digest of casein and peptic digest of animal tissue provide amino acids, nitrogen, carbon, minerals, vitamins and other nutrients which support the growth of microorganism. Dextrose is an energy source. Agar is the solidifying agent. The high concentration of dextrose and the acidic pH of the medium permit selectivity of fungi. Histidine inactivates aldehydes. Lecithin neutralizes quaternary ammonium compounds. Polysorbate 80 (Tween 80) is effective against phenolic compounds and mercurial derivates. Sodium thiosulfate neutralizes halogen compounds. Penase is a preparation of penicillinase for inactivating residuals of penicillins.

- 1 Levy Unit (LU) is defined as the amount of penicillinase that inactivates 59.3 IU of Penicillin G per hour at pH 7.0 at 25°C.
- 1 International Unit (IU) is defined as the amount of enzyme needed to hydrolyze 1 μmole of Penicillin G (Penicillinase) per minute at pH 7.0 at 25°C.

3. TYPICAL COMPOSITION

For 1 liter of medium (refrance)

Dextrose	40,0 g
Pancreatic digest of animal tissues	5,0 g
Pancreatic digest of casein	5,0 g
Agar	15,0 g
Histidine	1,0 g
Lecithin	0,7 g
Polysorbate 80	5,0 g
Sodium Thiosulfate	0,5 g
Penase	1,0 mL

pH of the ready-to-use medium at 25 °C: $5,6 \pm 0,2$

4. PREPARATION

The environmental plates are ready-to-use, no preparation required.

5. INSTRUCTIONS FOR USE

Preparation:

 Prepare a test diagram for the areas that are to be tested and label plates with the corresponding location identification. Ensure that the label cannot be readily wiped off or removed. RODAC plates are prepared so that the agar surface is convex for

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sampling flat surfaces. Prior to sampling, the plates should be warmed to room temperature in the plastic sleeve for approximately 15 - 20 minutes with agar up and the lid down. Remove the quantity of plates from the sleeve that are required for testing. The location/ site identification should be written on the base (agar portion, not the lid) of the plate.

Sampling:

- While wearing gloves, remove the lid from the plate with one hand. With the other hand, hold the base (agar portion of the plate) with thumb and middle finger. Use the index finger to gently press the plate on the test surface. Make sure the entire agar surface touches the test surface. Do not move the plate laterally while sampling as it will spread contaminants making enumeration difficult. Place the lid back on the plate and tape closed. Be sure to clean the test area after sampling to remove any residual growth media remaining on the surface.
- For total yeast and mold count (Microbial Limit Test), plates should be incubated for
 5 to 7 days at 20 25°C (EP/USP) prior to colony counting.

6. RESULTS

Observe daily for the formation of colonies.

7. QUALITY CONTROL

BacterLab ensures the quality of each product batch by testing with ATCC reference strains.

Reference strains	Incubation conditions	Expected results
Candida albicans ATCC 10231	Incubate for 72h at 20 – 25°C	
Aspergillus brasiliensis ATCC 16404	mediate 101 7211 at 20 – 23 C	Good growth ($P_R \ge$
Staphylococcus aureus ATCC 25923	Incubate for 24h at 30 – 35°C	0,7)
Escherichia coli ATCC 25922	incubate 101 2411 at 30 – 33 C	

8. STORAGE AND TRANSPORT CONDITIONS

- Storage: $2 8^{\circ}$ C.
- Transportation: Ambient temperature.

9. PACKAGING

Packaging: 10 plates/ box or as per customer request.

10. SHELF LIFE

- Expiration Date: 06 months from the manufacturing date.

11. BIBLIOGRAPHY

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- USP 41 NF 36 (2018): <61> Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests; <1116> Microbiological Control and Monitoring of Aseptic Processing Environments.



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- JP 16th edition (2011): 4.05 Microbial Limit Test.
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- FDA Guidance for Industry (2004): Sterile Drug Products Produced by Aseptic Processing Current Good Manufacturing Practice.
- Swanson, K.J., F.F. Busta, E.H. Peterson, and M.G. Johnson (1992). Colony Count Methods, p. 75-95.
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