

Sabouraud's Agar Plate (9cm)

Catalog : HBPM0235-14

Sabouraud's Agar Plate is used for the determination of the total count of settling microbe---yeasts and molds in clean room(zone).

Approximate Formula:

Ingredients	gm./liter
Mycological Peptone	10.0
Glucose	40.0
Agar	20.0
Final pH 5.6±0.2 at 25℃	

*Adjusted and/or supplemented as required to meet performance criteria.

Directions:

- 1.This product is triple wrapped and irradiated in the final packaging.
- 2.Take the plate to the sampling site, remove the corresponding outer packaging according to the GMP workshop or clean workshop level requirements, take off the last layer of packaging in the room to be sampled.
3. Mark the sampling site, time and personnel at the bottom of the plate before use.
4. Place according to the position specified in the reference inspection standard, open the lid, and expose according to the time specified in the standard.
5. Take the plate out of the test room and culture it according to the temperature and time specified in the reference test standard.
6. Observe the result.
7. During the experiment, 1-2 (or more) unused plates should be cultivated under the same conditions as blank control.

Principle and Interpretation:

Mycological provides nitrogenous compounds. Dextrose provides an energy source. High dextrose concentration and low pH favors fungal growth and inhibits contaminating bacteria from clinical specimens. For heavily contaminated samples, the plate must be supplemented with antibacterial agents for inhibiting bacterial growth. Agar is the solidifying agent.

Appearance:

Sabouraud's Agar is a kind of yellowish transparent gel.

Precautions:

1. Please check each plate before using it on sterility and pay attention to aseptic handling in order to avoid false positive results.
2. The medium should be disinfected after use.
3. The method of using this product is not mandatory, and users can adjust accordingly if they have specific reference materials.
4. During the method validation phase, the culture medium, incubation time, and incubation temperature should be evaluated to determine the optimal culture conditions for representative microorganisms in the environment.

Reference Value (reference range):

The blank control of this product should be sterile growth, otherwise this test is invalid.

Storage conditions and Shelf life:

Sabouraud's Agar Plate must be stored tightly capped in the original container at 2-25°C.

To prevent the lid being mist over, the recommended optimal storage temperature for long terms is 10-15°C

Expiration period: 6 months.

Quality control:

Cultural characteristics observed after incubation at 20-25°C for 48-72 hours.

Microorganism	Strains Number	Inoculum (CFU)	Growth	Recovery	Remarks
<i>Aspergillus Niger</i>	ATCC 16404	20-200	luxuriant	≥70%	White hypha
<i>Candida Albicans</i>	ATCC 10231	20-200	luxuriant	≥70%	Cream colonies

Reference:

1.GB/T 16294-2010 Test method for settling microbe in clean room (zone) of the pharmaceutical industry.

2.European Pharmacopoeia 8.0 (2014): 2.6.12. Microbial examination of non- sterile products (total viable aerobic count).

2.ISO 14698-1:2003: Cleanrooms and associated controlled environments – Biocontamination control - Part 1: General principles and methods.