

SABOURAUD DEXTROSE AGAR

IVD in Class A, EU Reg. 2017/746
For in vitro diagnostic use **IVD**

Medium for the cultivation and enumeration of yeasts and moulds from different materials.

DESCRIPTION

Sabouraud Dextrose Agar (SDA) is a non selective isolation medium used for the growth and maintenance of pathogenic and non-pathogenic fungi from clinical and nonclinical specimens. It is also used for recovery and total counting of yeasts and moulds in environmental monitoring.

This medium complies with EN ISO 11133 for microbiological examination of food, animal feed and water, where it is described as the main reference medium to carry out quantitative testing on culture media intended for fungi. Its formula conforms to the recommendations of the harmonized method in the United States Pharmacopoeia (USP), European Pharmacopoeia (EP) and Japanese Pharmacopoeia (JP) for the microbiological examination of non sterile products.

PRINCIPLE

Pancreatic digest of casein and peptic digest of animal tissue provide amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. 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.

| COMPOSITION | g/L |
|--------------------------------|------|
| Pancreatic Digest of Casein | 5.0 |
| Peptic Digest of Animal Tissue | 5.0 |
| Dextrose | 40.0 |
| Agar | 15.0 |

Final pH 5,6 ± 0,2 at 25°C

WARNING AND PRECAUTIONS

For in vitro diagnostic use.

Observe the precautions normally taken when handling laboratory reagents.

Dehydrated medium: HIGHLY HYGROSCOPIC. During the handling, wear dust protection mask. Avoid the eye contact. Do not use beyond the expiration date or if the product shows signs of deterioration, an altered color or has compacted.

Prepared Medium: The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous.

Safety Data Sheet is available on request for professional users.

All waste must be disposed of according to local directives.

STORAGE AND STABILITY

| | |
|--------------------|---------|
| Dehydrated medium: | 10-30°C |
| Prepared medium: | 10-25°C |

SABOURAUD DEXTROSE AGAR is stable until the expiration date indicated on the label under the recommended storage conditions.

PREPARATION

Dehydrated medium: Suspend 65 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Dispense into appropriate containers. Sterilize in autoclave at 121°C for 15 minutes.

Prepared medium (bottles): Melt the content of the bottle in a water bath at 100°C until completely dissolved. Then check the homogeneity of the dissolved medium, if it is the case turning the bottle upside down. Cool at 45-50°C, mix well avoiding foam formation and aseptically distribute into Petri dishes.

PROCEDURE

Streak the specimen as soon as possible after it is received in the laboratory. Streak the specimen onto the medium with a sterile inoculating loop to obtain isolated colonies.

For isolation of fungi from potentially contaminated specimens, a selective medium should be inoculated along with the nonselective medium.

Incubate the plates at 25-30 °C in an aerobic atmosphere in an inverted position (agar side up) with increased humidity. All cultures should be examined at least weekly for fungal growth and should be held 4-6 weeks before being reported as negative.

RESULTS

After sufficient incubation, the plates should show isolated colonies in streaked areas and confluent growth in areas of heavy inoculation. Examine plates for fungal colonies exhibiting typical color and morphology. Additional procedures should be performed to confirm findings.

QUALITY CONTROL

Dehydrated medium: free-flowing, homogeneous, light beige.

Prepared medium: slightly opalescent, light amber.

Incubation conditions: 32.5 ± 2.5°C for 24-48 h (C. albicans) and at 22.5 ± 2.5°C for up to 5 days (all listed organisms), under aerobic atmosphere.

| MICROORGANISM | GROWTH |
|--------------------------------------|----------------|
| Saccharomyces cerevisiae ATCC® 9763 | Luxuriant/Good |
| Candida albicans ATCC® 10231 | Luxuriant/Good |
| Aspergillus brasiliensis ATCC® 16404 | Luxuriant/Good |

REFERENCES

- UNI EN ISO 11133:2020.
- European Pharmacopoeia 6.5 (2009) 2.6.13. Microbiological examination of non-sterile products: Test for specified microorganisms.
- United States Pharmacopoeia 32 NF 27 (2009) Microbiological examination of non-sterile products: Test for specified microorganisms.
- Japanese Pharmacopoeia 4.05 (2008) Microbiological examination of non-sterile products: Test for specified microorganisms.
- Sabouraud, R. (1892) Ann. Dermatol. Syphilol. 3:1061.

PRESENTATION

| | Packaging | REF. |
|---|---------------|-------|
| Dehydrated medium: SABOURAUD DEXTROSE AGAR | 100 g (1.5 L) | 11145 |
| | 500 g (7.7 L) | 10145 |
| | 5 Kg (77.0 L) | 13145 |

| Prepared medium: SABOURAUD DEXTROSE AGAR | 20 x 10 mL Tubes | 5095/20 |
|---|------------------------------------|------------|
| | 6 x 100 mL Bottles | 63326 |
| | 6 x 200 mL Bottles | 63226 |
| | 20 pcs (60 mm ready-to-use plates) | 1754224/20 |
| | 20 pcs (90 mm ready-to-use plates) | 2604109/20 |
| | 20 Contact plates | 31010 |

| | | |
|---|-------------------|-------|
| SABOURAUD DEXTROSE AGAR + NEUTRALIZING | | |
| | 20 Contact plates | 31012 |

| | | |
|--|-------------------|-------|
| SABOURAUD DEXTROSE AGAR + NEUTRALIZING (IRRADIATED) | | |
| | 20 Contact plates | 31014 |

SYMBOLS

| | | | |
|--|--|--|-------------------|
| | Read the instructions | | Biological hazard |
| | CE Mark (product complies with the requirements of Regulation (EU) 746/2017) | | |
| | Temperature limitation | | Use by |
| | For in vitro diagnostic use | | Manufacturer |