Sabouraud Dextrose Agar Plate

**Intended Use**

Recommended for the subculture of *Candida albicans* in accordance with the harmonized method of USP/EP/BP/JP.

**Composition**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Gms / Litre</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dextrose (Glucose)</td>
<td>40.000</td>
</tr>
<tr>
<td>Mixture of Peptone and Tryptone (1:1)##</td>
<td>10.000</td>
</tr>
<tr>
<td>Agar</td>
<td>15.000</td>
</tr>
<tr>
<td>pH after sterilization (at 25°C)</td>
<td>5.6±0.2</td>
</tr>
</tbody>
</table>

Mixture of Peptone digest of animal tissue and Pancreatic digest of casein (1:1)#

**Formula adjusted, standardized to suit performance parameters**

**Directions**

Either streak, inoculate or surface spread the test inoculum (50-100 CFU) aseptically on the plate.

**Principle And Interpretation**

Fungi were among the first microorganisms recognized because some of the fruiting structures, such as the mushrooms, are large enough to be seen without a microscope. Fungi can be grouped simply on the basis of morphology as either yeasts or moulds (9). Fungal diseases that occur on the skin, hair and mucous membrane are called superficial mycoses, and the organism that cause them, the dermatophytes (10). Where fungi are to be isolated, it is good practice to use a medium that favors their growth but is not optimal for the growth of bacteria.

Sabouraud Dextrose Agar is Carliers modification (3) of the formulation described by Sabouraud (11) for the cultivation of fungi (yeasts, moulds), and aciduric microorganisms. Sabouraud Dextrose Agar is recommended for microbiological examination of non-sterile products in accordance with the harmonized method of USP/EP/BP/JP (12,2,4,7). This medium is also employed in microbial limit tests in pharmaceutical testing, food, cosmetics, and clinical specimens (1).

Peptone and Tryptone provides carbonaceous, nitrogenous compounds, long chain amino acids, vitamins and other essential growth nutrients. Dextrose (Glucose) provides an energy source. High dextrose concentration and low pH favors fungal growth and inhibits contaminating bacteria from clinical specimens (8).

Some pathogenic fungi may produce infective spores, which are easily dispersed in air, so examination should be carried out in safety cabinet. For heavily contaminated samples, the plate must be supplemented with inhibitory agents for inhibiting bacterial growth. Growth of white colonies may be indicative of presence of *Candida albicans*. The total combined yeast and molds count is considered to be equal to the number of colony forming unit found using this medium, if bacterial colonies are detected they are counted as part of total yeast and mold count. In case the bacterial colonies exceeds the acceptance criterion, then antibiotics can be supplemented in this medium.

**Type of specimen**

Pharmaceutical samples

**Specimen Collection and Handling**

For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per pharmaceutical guidelines (2,4,7,12). After use, contaminated materials must be sterilized by autoclaving before discarding.

**Warning and Precaution**

Read the label before opening the pack. Wear protective gloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.
**Limitations**
1. For heavily contaminated samples, the media must be supplemented with inhibitory agents for inhibiting bacterial growth with lower pH.
2. Some pathogenic fungi may produce infective spores which are easily dispersed in air, so examination should be carried out in safety cabinet.
3. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium.
4. Environmental Monitoring Test: Exposure of media plates for 4 h as a settle plate or in air sampler or even under laminar air flow may lead reduction in some available moisture on the surface. This may cause development of tiny cracks in the agar or slight shrinkage. This however, does not impact the performance of the media.
5. Each lot of the medium has been tested for the organisms specified on the COA. It is recommended to users to validate the medium for any specific microorganism other than mentioned in the COA based on the user’s unique requirement.

**Performance and Evaluation**

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

**Quality Control**

**Appearance**
Sterile Sabouraud Dextrose Agar in 90 mm disposable plates.

**Colour of medium**
Light amber coloured medium.

**Quantity of medium**
25 ml of medium in 90 mm disposable plates.

**pH**
5.40-5.80

**Sterility Test**
Passes release criteria.

**Growth Promotion Test**
Growth Promotion was carried out in accordance with the harmonized method of ICH (USP/EP/BP/JP), after an incubation at 30-35 °C for 24-48 hours. Recovery rate is considered as 100% for bacteria growth on Soybean Casein Digest Agar and fungus growth on Sabouraud Dextrose Agar.

**Growth Promoting Properties**
Growth of microorganism comparable to that previously obtained with previously tested and approved lot of medium occurs at the specified temperature for not more than the shortest period of time specified inoculating <= 100 cfu (at 30-35°C for <=24 hours).

**Indicative properties**
Colonies are comparable in appearance and indication reaction to those previously obtained with previously tested and approved lot of medium occurs for the specified temperature for a period of time within the range specified inoculating <=100cfu (at 30-35°C for 24-48 hours).

**Cultural Response**

<table>
<thead>
<tr>
<th>Organism</th>
<th>Inoculum (CFU)</th>
<th>Growth</th>
<th>Observed Lot value (CFU)</th>
<th>Recovery</th>
<th>Incubation temperature</th>
<th>Incubation period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>50 -100</td>
<td>Luxuriant (white colonies)</td>
<td>35 -100</td>
<td>&gt;=70 %</td>
<td>30 -35 °C</td>
<td>24 -48 hrs</td>
</tr>
<tr>
<td><em>Candida albicans ATCC 10231 (00054</em>)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Growth Promotion + Indicative</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Growth Promotion + Total yeast and mould count</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Aspergillus brasiliensis ATCC 16404 (00053</em>)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please refer disclaimer Overleaf.
### Additional Microbiological Testing

<table>
<thead>
<tr>
<th>Organism</th>
<th>Growth</th>
<th>Temperature</th>
<th>pH</th>
<th>Time</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Candida albicans</em> ATCC 2091 (00055*)</td>
<td>luxuriant</td>
<td>35 - 100</td>
<td>&gt;=70%</td>
<td>30 - 35 °C</td>
<td>24 - 48 hrs</td>
</tr>
<tr>
<td><em>Saccharomyces cerevisiae</em> ATCC 9763 (00058*)</td>
<td>luxuriant</td>
<td>35 - 100</td>
<td>&gt;=70%</td>
<td>30 - 35 °C</td>
<td>24 - 48 hrs</td>
</tr>
<tr>
<td><em>Escherichia coli</em> ATCC 25922 (00013*)</td>
<td>good (inhibited on media with low pH)</td>
<td>35 - 100</td>
<td>&gt;=70%</td>
<td>30 - 35 °C</td>
<td>24 - 48 hrs</td>
</tr>
<tr>
<td><em>Escherichia coli</em> ATCC 8739 50 - 100 (00012*)</td>
<td>good (inhibited on media with low pH)</td>
<td>35 - 100</td>
<td>&gt;=70%</td>
<td>30 - 35 °C</td>
<td>24 - 48 hrs</td>
</tr>
<tr>
<td><em>Escherichia coli</em> NCTC 9002 50 - 100</td>
<td>good (inhibited on media with low pH)</td>
<td>35 - 100</td>
<td>&gt;=70%</td>
<td>30 - 35 °C</td>
<td>24 - 48 hrs</td>
</tr>
<tr>
<td><em>Trichophyton rubrum</em> ATCC 28191</td>
<td>good</td>
<td>20 - 25 °C</td>
<td>&lt;=5 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Lactobacillus casei</em> ATCC 334</td>
<td>luxuriant</td>
<td>35 - 100</td>
<td>&gt;=70%</td>
<td>30 - 35 °C</td>
<td>24 - 48 hrs</td>
</tr>
</tbody>
</table>

Key: (#) - Formerly known as Aspergillus niger, (*) - corresponding WDCM numbers

### Storage and Shelf Life

On receipt store between 20-30°C Use before expiry date on the label. Product performance is best if used within stated expiry period.

### Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with sample must be decontaminated and disposed of in accordance with current laboratory techniques (5,6).

### Reference


Revision : 02 / 2020

### Disclaimer

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia™ publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia™ Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal or therapeutic use but for laboratory, diagnostic, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.