

Instructions for Use

Sabouraud Dextrose Agar

Pre-Poured Media

REF - PP0240

1. Intended Use

For *in vitro* diagnostic use. PP0240 Sabouraud Dextrose Agar is used for the isolation of yeasts and moulds from clinical, food, pharmaceutical and cosmetic samples and for environmental monitoring. It conforms to the formulation and performance requirements of the harmonised USP/EP/JP ^(1,2,3).

2. Composition*

<u>Ingredient</u>	<u>g/L</u>
Peptone	10.0
Glucose	40.0
Agar	15.0

*Adjusted/supplemented as needed to meet performance requirements

3. Summary and Explanation

PP0240 Sabouraud Dextrose Agar may be used for the isolation of pathogenic fungi from clinical, food, cosmetics, and pharmaceutical samples. It may also be used as a settle-plate to determine fungal contamination in clean-room atmospheres. The product is a modification of the medium originally described by Sabouraud⁽⁴⁾. The formulation conforms to European, United States and Japanese Pharmacopeia requirements. This medium complies with ISO11133:2014, where it is described as the main reference medium to carry out quantitative testing for fungi ⁽⁵⁾.

4. Principle

PP0240 contains peptone to supply nitrogen and other essential nutrients required for growth. Glucose (dextrose) is included as an energy and carbon source. At such a high concentration, glucose also produces inhibitory pressure against the growth of some bacterial species, which is reinforced by the low pH (5.6) ⁽⁶⁾. Yeasts develop as creamy-white colonies whereas fungi will grow in characteristic filamentous colonies of different colours.

5. Physical Characteristics

	Medium
Appearance and Colour	Straw firm gel
pH	5.6 ± 0.2

6. Materials Provided

PP0240 Sabouraud Dextrose Agar is supplied in packs of 10 x 90mm P090 Petri dishes (18-22ml fill) (product code: PP0240-P090); each plate is ink-jet printed with (abbreviated) product name, product code, lot number and expiry date.

7. Materials Needed but not Provided

Standard microbiological laboratory materials e.g., autoclave, sterile loops or swabs, collection containers, incubators, and quality control organisms.

8. Specimens

PP0240 Sabouraud Dextrose Agar is suitable for the testing of the following specimens:

- Clinical: scrapings or swabs from skin, hair, and nail samples
- Food Industry: Products for human consumption, animal feed and environmental samples
- Cosmetics
- Pharmaceuticals

Sampling and transport equipment must be used in accordance with the end user's suppliers' recommendations. Refer to appropriate standard method or local guidance on sample collection and subsequent processing.

9. Test Procedures and Interpretation of results

Allow media to come to room temperature.

Follow local, national, or international guidelines.

Based on sample type and information provided, check to see if the specimen needs to be pre-enriched or diluted prior to inoculation to the prepared medium.

Food and Environmental Samples:

Prepare a homogenised suspension using a ratio of 1:10 of sample to Maximum Recovery Diluent (E&O BM0760). Inoculate the medium with 0.1ml (or a maximum of 0.5ml) of the homogenised sample. Incubate as specified in the method being followed for testing.

Clinical Specimens:

Inoculate specimen directly (nail, skin scrapings, etc.) onto the agar surface using a sterile forceps or loop.

Incubate aerobically at 26-30°C for up to 28 days.

Cosmetic and Pharmaceutical Samples:

For solid or viscous samples, prepare a homogenised suspension using a ratio of 1:10 of sample to Letheen Broth Modified (E&O BM4284). With homogenised and liquid sample, media should be inoculated with 0.1ml (or a maximum of 0.5ml) of the sample.

Incubate plates aerobically at 20-25°C or 30-35°C, depending on test methodology, and examine the plates after 2 to 5 days for colonies for up to 10 days (typical colony appearance outlined in Quality Control table below). Perform further biochemical or mass spectroscopy testing to confirm identity of presumptive positive isolates. Refer to relevant local guidelines.

10. Quality Control

Organism	Incubation	Result (Specificity)
<i>T. rubrum</i> (NCPF 419)	Yeasts: 25 ± 1°C aerobically for 48 hours	Growth: White fluffy colonies with dark red/brown underside
<i>C. albicans</i> (NCPF 3179)		Growth: White colonies
<i>S. cerevisiae</i> (NCPF 3178)	Fungi: 25 ± 1°C aerobically for 5-10 days	Growth: White colonies
<i>A. brasiliensis</i> (NCPF 2275)		Growth: White colonies Reverse side is pale yellow w hyphae

It is the responsibility of the user to perform Quality Control testing taking into consideration the intended use of the medium and in agreement with any local relevant guidelines (e.g., frequency, strains used, atmosphere, incubation temperature).

11. Performance

To fully verify PP0240 Sabouraud Dextrose Agar performance, samples were tested to assess colony morphology and recovery level (where an acceptable range is ≥70% and ≤120%) compared to a non-selective reference medium. Sample plates were inoculated with 30 to 150cfu for the yeasts and *A. brasiliensis*; with a direct point inoculation for *T. rubrum*. Plates were incubated aerobically at 25 ± 1°C for 2 - 10 days. All samples showed expected recovery and morphology of the required test organisms: *Candida albicans* (NCPF 3179), *Saccharomyces cerevisiae* (NCPF 3178) and *Aspergillus brasiliensis* (NCPF 2275). Typical growth and morphology were observed for *Trichophyton rubrum* (NCPF 419). Therefore, it can be concluded that PP0240 Sabouraud Dextrose Agar, meets performance criteria when used according to the instructions outlined above. Trend analysis data available upon request.

12. Limitations of the Media

- Due to natural variation, some fungal strains may grow poorly on this medium.
- For dermatophytes, the plates should be incubated at <30°C.
- This medium has a low level of selectivity. If high levels of background flora are likely to be present then use in conjunction with a secondary selective medium to suppress growth of non-target organisms.

13. Precautions and Warnings

This product is considered non-hazardous under CLP regulations. Wear such PPE as recommended by laboratory COSHH assessment. During and after use, always handle all materials in a manner conforming to Good Laboratory Practices and consider that material under test should be regarded as a potential biohazard if mishandled.

Refer to the E&O Poured Plate Material Safety Data Sheet.

14. Storage conditions and Shelf life

Store PP0240 in the original packaging between 2 and 8°C in the dark. Kept under these conditions it may be used up to date of expiry shown on product label.

Dispose of in accordance with local and national authority requirements. Do not use media if it is contaminated, discoloured, out of date, cracked or a precipitate is present. Additionally, do not use media if it has been stored inappropriately or the packaging has been damaged.

15. References

1. Council of Europe (2019) European Pharmacopoeia. 10th ed., Strasbourg: Council of Europe.
2. United States Pharmacopeial Convention (2019) The United States Pharmacopeia USP42, The National Formulary NF37. Rockville, MD: United States Pharmacopeial Convention.
3. The Ministry of Health, Labour and Welfare (2021) The Japanese Pharmacopoeia. 18th ed. Tokyo: Yakuji Nippo Limited.

4. Sabouraud, R. (1892) Contribution a l'étude de la trichophytie humaine. Etude clinique, microscopique et bacteriologique sur la pluralité des trichophytions de l'homme. Annual Dermatology Syphilis, 3, 1061-1087.
5. International Organization for Standardization (2014) 11133:2014 Microbiology of food, animal feed and water - Preparation, production, storage and performance testing of culture media. Geneva, ISO.
6. Ali, S., Fradi, A. and Al-araji, A. (2017) Effect of some physical factors on growth of five fungal species. Eur. J. Acad. Res., 2, 1069-1078.

Version History*

001 11/09/23 - New Document Created

*Note: minor typographical, grammatical, and formatting changes are not included in the revision history.



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TABLE OF APPLICABLE SYMBOLS

IFU/PP0240 REV. 001

REF o REF Catalogue number	LOT Batch code	IVD In vitro Diagnostic Medical Device	Manufacturer	Use by
Temperature limitation	Contents sufficient for <n> tests	Consult Instructions for Use	Keep away from direct light	Store in a dry place