References

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Symbol glossary: biomeddiagnostics.com/l/symbol-glossary

Document Revision History

Rev. F, August 2025
Updated manufactured by, logo and company address. Replaced R with TM, corrected the SAB FungID PNs to 11-593-001, 11-593-002, PDA-FungID was discontinued and removed from Limitations section.

Manufactured by:
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USA biomeddiagnostics.com

100-179 InTray SAB-FungID Rev. F (08/2025)

BIOMED™ DIAGNOSTICS
A DCN DX BRAND

InTray™ SAB-FungID™

Sabouraud's Dextrose Agar

REF 11-263-001 Σ 5

REF 11-263-002 Σ 20

Not available in all countries; please inquire.

A NONSELECTIVE CULTURE SYSTEM TO AID DETECTION OF Dermatophyte fungi

For *In Vitro* Diagnostic Use

IVD

Introduction

Intended Use

InTray™ SAB-FungID™ contains Sabouraud's dextrose agar, a non-selective medium used to aid in the detection of dermatophyte fungi from clinical specimens with mixed microbiota.

Description and Principle

InTray SAB-FungID is a dynamic system with built-in components and features that are designed for user compatibility and ease of dermatophyte fungi detection (i.e., 10x objective microscopy direct from the tray). The medium allows for the non-selective growth and observation of distinct colony morphology and color (i.e., pigments) of dermatophyte fungi.
Dermatophytes are fungi in the genera *Microsporum*, *Trichophyton* and *Epidermophyton*. They are capable of metabolizing keratin found in skin, hair and nails of living hosts. The fungi characteristically may invade the cutaneous tissue of the living host but rarely penetrate the subcutaneous tissue. Tinea and ringworm are two terms commonly used to describe dermatophytes.

Reagents and Appearance

Sabouraud's dextrose agar appears transparent with a light amber hue and contains peptic/casein digest, and dextrose with a final pH of 5.6 ± 0.2 at 25°C.

Precautions, Safety and Disposal

For *In Vitro* Diagnostic Use. For professional laboratory use only.
Read the Safety Data Sheets (SDSs) and follow the handling instructions. Wear appropriate protective eyewear, clothing and gloves.
Do not use if package is damaged.
Once the tray has been inoculated and resealed, re-open only in a biological safety cabinet. Because of the potential for containing infectious materials, prior to disposal, sterilize the tray by autoclaving at 121°C for 20 minutes.
Any serious incident that occurs in relation to this device shall be reported to the manufacturer and the competent authority, as required, of the country in which the user and/or the patient is established.

Storage

On receipt, store trays at 2–25°C in the dark. Avoid freezing or prolonged storage at temperatures greater than 40°C. Do not use trays if the medium shows signs of deterioration or contamination.

Shelf Life

InTray SAB-FungID has a shelf life of 12 months from the date of manufacture.

Procedure

Key Notes Regarding Specimen Collection

Specimen collection poses a major uncertainty in using this device.

NAILS - Often collecting viable material from infected nails is difficult because the living organisms are well under the nail itself. For best results, cut nails into small pieces.

HAIR - Samples should be grasped at the uninfected end and several (3–6) small pieces, about 2 cm long, should be cut from the infected portion for inoculation onto the medium.

SKIN - Scrapings should be taken with an inoculation tool that has been moistened with the medium or a sharp blade from the outer ridge of an active lesion. Vesicular fluid is unacceptable for dermatophyte culture. If the infected area is vesiculated, skin scrapings should be taken from the surface.

Prepare Sample:

Use aseptic technique during specimen collection and handling. Remove any soap residue from the sampling area. Clean the area with 70% alcohol and permit to air dry.

Collect Sample:

InTray SAB-FungID is designed for culturing hair, skin and nail samples (i.e., cuttings/ scrapings). All specimens should be handled according to CDC infectious materials isolation guidelines; cdc.gov/infectioncontrol/guidelines/isolation

Materials Provided

- InTray SAB-FungID test(s)

Materials Required but Not Provided

- Sterile inoculating tool (e.g., cotton swab/forceps/scalpel blade)
- Laboratory incubator capable of incubation at 25–30 °C

1. Prepare InTray

Allow tray(s) to warm to 18–25°C before use. before use. Immediately label the tray with patient/sample information and date. Pull back the lower right corner adjacent to the clear window of the tray label until the protective seal is completely visible Remove the seal by pulling the tab. Discard the seal.

DO NOT REMOVE OR ALTER THE WHITE FILTER STRIP OVER THE VENT HOLE!

2. Inoculate Sample

Inoculate the specimen on the center surface of the medium. A sterile inoculating loop that has been moistened by touching the surface of the medium may be used for inoculation of solids or scrapings

Re-seal all around the tray to ensure a complete seal by pressing the edges of the label against the plastic tray. DO NOT COVER THE VIEWING WINDOW. Complete re-seal prevents dehydration!

Incubation

Incubate inoculated trays in a dark humidified environment for up to 21 days at 25-30°C. Observe the trays daily through the clear viewing window.

Quality Control

This product has been tested and meets the CLSI (formerly NCCLS) Approved Standard for commercially prepared media (M22-A3). At the time of manufacture, quality control testing is performed on each lot of the InTray SAB-FungID. The ability of the media to support growth and demonstrate expected biochemical reactions and morphology is verified by lot. Refer to the CoA for lot-specific information.

Recommended Strains for QC Testing SAB-FungID

Test Strain	ATCC® Number	Expected Result
T. mentagrophytes	9533	Growth
T. rubrum	28188	Growth
C. albicans	60193	Growth
A. brasiliensis	16404	Growth

Reading the Results

Evaluation

Observe the medium for fungal colony growth, texture, morphology and pigmentation characteristic of dermatophytes and saprophytes. Without opening the InTray SAB-FungID, place the tray under a 10x objective microscope lens to view distinct fungal structures (i.e., hyphae, micro/macro-conidia). See the Quick Identification Chart below for reference (this is not a complete list of potential organisms; see the references listed below, as well as other standard mycology and microbiology references). Trays to be used with 10x objective ONLY!

Positives: If, within 1-21 days, the medium shows characteristic dermatophyte fungi colony growth, texture, morphology, pigmentation and microscopic structure, the InTray SAB-FungID is presumptive positive.

Negatives: Trays that show no colony growth after 21 days from the date of inoculation are presumptive negative.

Dermatophyte Identification

Microsporum canis Septate hyphae. Macroconidia: (10–25 x 35–110 µm) numerous, long, spindle-shaped, rough, thick walls are apparent at the knob-like ends. Microconidia: few in number, smooth and club-shaped.

Microsporum gypseum Septate hyphae. Macroconidia: (8–16 x 22–60 µm) large numbers, symmetrical, rough and relatively thin-walled with rounded ends, not pointed like *M. canis*. Microconidia: usually resent, club-shaped.

Trichophyton mentagrophytes Septate hyphae. Macroconidia: (4–8 x 20–50 µm) occasionally present, cigar-shaped, thin-walled, narrow attachments to septate hyphae, 1–6 cells, found in young cultures 5–10 days old. Microconidia: usually present in powdery cultures, very round, clustered on branched conidiophores; in fluffy cultures, smaller, fewer, teardrop shaped and easily confused with those of *T. rubrum*.

Trichophyton rubrum Septate hyphae. Macroconidia: (4–6 x 15–30 µm) abundant, rare or absent, however can be long, narrow, thin-walled, parallel sides, 2–8 cells, may form on the ends singly or in groups. Microconidia: (2–3 x 3–5 µm) lateral, teardrop shaped, form on macroconidia.

Saprophyte (Contaminants) Identification

Alternaria sp. Hyphae are septate and dark. Conidiophores are septate, variable in length and sometimes branched. Conidia are large (7–10 by 23–24 µm), brown, have both transverse and longitudinal stations, and found singly or in chains. They are usually round at the end nearest the conidiophore, producing a club-like shape.

Aspergillus sp. Microscopic morphology – Septate hyphae (2.5–8 µm in diameter); unbranched conidiophore arises from a specialized foot cell. The conidiophore is enlarged at the tip, forming a swollen vesicle completely or partially covered with flask-shaped phialides. The phialides produce chains of mostly round, sometimes rough conidia (2–5 µm in diameter).

Penicillium sp. Microscopic morphology – Septate hyphae (1.5–5 µm in diameter) with branched conidiophores that have secondary branches known at metulae. On the metulae, are flask-shaped phialides that bear unbranched chains of smooth or rough conidia (2.5–5 µm in diameter). The entire structure forms the characteristic “penicillus” or “brush” appearance.

Limitations

If a fungal infection is strongly suspected and the culture test result is negative, it may be appropriate to retest giving more care to specimen collection.

- Optimally, simultaneously inoculate samples on both InTray DM-FungID (Cat. Nos. 11-593-001, 11-593-002) and InTray SAB-FungID w /CC (Cat. Nos. 11-283-001, 11-283-002) (to inhibit contaminants).
- Transfer of fungal growth to slide examination: Stained slide preparations can be made as appropriate based on 10x objective examination of InTray SAB-FungID. Potato Dextrose Agar can be used to induce sporulation.
- Final culture identification is to be made by laboratory professionals only and may require further biochemical/culture testing.

InTray SAB FungID is an agar medium that is susceptible to condensation collection within the inner seal, especially when stored at low temperatures and/or having been exposed to extreme temperature fluctuations. If moisture is visible on the surface of the InTrays, dry them (with the seal removed and InTray label in a position allowing for air flow) under a BSL-2 cabinet just prior to inoculation. There should be no visible droplets of moisture on the surface of the agar when they are inoculated. The surface of the dried medium should be smooth and should not show signs (webbed ribbing pattern on the agar surface) of desiccation.