Introduction

Intended Use

InTray[®] COLOREX[™] Yeast is designed for isolation and differentiation of major clinically significant *Candida* species. Suitable for direct streaking of samples from skin, sputum, urine or genitourethral swabs

Description and Principle

Candida species are involved in superficial oropharyngeal and urogenital infections, particularly for immunocompromised populations such as the elderly and HIV-positive patients "Early diagnosis is essential for early effective management of the patients." (WHO Guidelines on Standard Operating Procedures for Laboratory Diagnosis of HIV-Opportunistic Infections) Although C. albicans remains the major species involved, other types such as C. tropicalis, C. krusei or C. glabrata have increased proportionately as new antifungal agents have worked very effectively against C. albicans. This shows the importance of an accurate detection for a proper antifungal therapy choice.

Reagents and Appearance

COLOREX Yeast contains Agar, peptone nutrients, antimicrobial selective compounds and chromogenic additives, with a final pH of 6.1 \pm 0.2 at 25°C.

Precautions, Safety and Disposal For In Vitro Diagnostic Use

Read the Safety Data Sheets (SDSs) and follow the handling instructions. Wear appropriate protective eyewear, clothing and gloves.

Once the tray has been inoculated and resealed, re-open only in a biological safety cabinet. Because of the potential for containing infectious materials, the tray must be destroyed by autoclaving at 121°C for 20 minutes.

Storage

Upon receipt, store InTray COLOREX Yeast under refrigeration (2-8°C). Medium can be kept for one day at ambient temperature. Avoid freezing or prolonged storage at temperatures above 40°C. Do not open until ready to use. Do not use if the medium shows signs of deterioration or contamination.

Shelf Life

InTray COLOREX Yeast has a shelf life of 12 months from the date of manufacture.

Procedure

Key notes regarding specimen collection:

Specimen types include skin, sputum, urine, genitourethral swabs.



3 Inoculate Sample



Incubation

Incubate at 30-37°C for 48 hours under ambient atmosphere.

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 InTray COLOREX Yeast. The ability of the media to support growth and demonstrate expected biochemical reactions and morphology is verified by lot.

All InTray COLOREX Yeast lots are performance verified with ATCC[®] microbe strains. Product performance is also verified periodically throughout the marked shelf life of each lot.

Materials Provided

InTray COLOREX Yeast

2 Open Seals

Materials Required but Not Provided

- Sterile inoculating tool (loop/swab/forceps)
- Laboratory incubator capable of incubation at 30-37°C

Remove the paper-foil seal by pulling the tab.

Discard the seal.

Do not remove or alter the white filter strip over the vent hole!

Streak sample onto the agar surface.

Allow the InTray to warm to

Lift the lower right corner of the flexible

InTray label until the protective seal is

18-25°C

completely visible



Reseal InTray label to the plastic tray body.

Press all around the perimeter of the InTray to ensure a complete seal.

Immediately label the InTray with patient or sample information and date.

Do not cover the viewing window.

ATCC Control Strains

Organism	ATCC	Result
C. albicans	60193	Green
C. tropicalis	66029	Metallic blue
C. kreusei	14243	Pink, fuzzy
C. glabrata	2001	Mauve to brown

Scan for additional product information

Reading the Results

Evaluation

Organism:	Colony Appearance:
C. albicans	Green
C. tropicalis	Metallic blue
C. kreusei	Pink, fuzzy
C. glabrata	Mauve to brown

Other species Bacteria

Limitations

For In Vitro Diagnostics Use Only.

Specificity and sensitivity for C. albicans, C. tropicalis and C. krusei exceed 99% (Odds and Bernaerts 1994; J Clin Microbiol; 32). Definite identification requires additional testing.

White to mauve

Inhibited

InTray COLOREX Yeast 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 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.



Document Revision History Rev. D, September 2019

New format; added new catalog numbers, limitation about condensation, reference to online symbol glossary, document revision history; specified 18–25°C instead of room temperature; reorganized and retitled some sections.



Manufactured by: Biomed Diagnostics, Inc. 1388 Antelope Road White City, OR 97503 USA biomeddiagnostics.com

BIOMED

InTray[®] COLOREX[™] Yeast

REF	11-113-001	Σ 5
REF	11-113-002	Σ 20

Not available in all countries; please inquire. For In Vitro Diagnostic Use



© 2019 Biomed Diagnostics, Inc. All rights reserved. Trademarks: InTray[®], COLOREX[™] (Biomed Diagnostics, Inc.); ATCC[®] (American Type Culture Collection). Registered names, trademarks, etc. used in this document, even when not specifically marked as such, are not to be considered unprotected by law. 100-085 IFU InTray Colorex Yeast Rev. D (09/2019)