



InTray™ Colorex™ Yeast

For In Vitro Diagnostic Use Only

INTENDED USE

The 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 OF USE

Candida species are involved in superficial oropharyngeal and urogenital infections, particularly for immuno-compromised 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.

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.

INOCULATION PROCEDURE

Allow the InTray™ to warm to room temperature. Lift the lower right corner of the flexible InTray™ label until the protective seal is completely visible. Remove the paper-foil seal by pulling the tab (Fig. 1). **Discard** the seal. **DO NOT REMOVE OR ALTER THE WHITE FILTER STRIP OVER THE VENT HOLE!**



Figure 1

Streak sample onto the agar surface (Fig. 2).

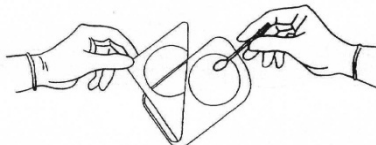


Figure 2

Reseal the InTray™ label to the plastic tray body. **Press all around the perimeter of the InTray™ to ensure a complete seal** (Fig. 3). Immediately label the InTray™ with patient or sample information and date. **DO NOT COVER THE VIEWING WINDOW.**

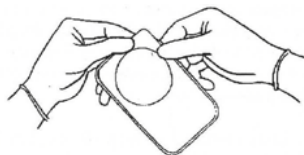


Figure 3

CULTURE AND RESULTS

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

INTERPRETATION

Organism	Colony Appearance
<i>C. albicans</i>	Green
<i>C. tropicalis</i>	Metallic blue
<i>C. krusei</i>	Pink, fuzzy
<i>C. glabrata</i>	White to mauve
Bacteria	Inhibited.

LIMITATIONS/PRECAUTIONS

For in vitro diagnostic 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.

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

REAGENTS

Colorex™ Yeast contains Agar, peptone nutrients, antimicrobial selective compounds and chromogenic additives.

QUALITY CONTROL

All Biomed products lots are performance verified with ATCC® microbe strains. Product performance is also verified periodically throughout the marked shelf life of each lot.

Organism	ATCC®	Colony Appearance
<i>C. albicans</i>	60193	Green
<i>C. tropicalis</i>	66029	Metallic blue
<i>C. krusei</i>	14243	Pink, fuzzy
<i>C. glabrata</i>	2001	White to mauve
<i>E. coli</i>	25922	Inhibited

SYMBOL KEY			
Symbol	Used For	Symbol	Used For
	Batch code		Temperature limitation
	Date of manufacture		Catalog number
	Use by YYYY-MM-DD or YYYY-MM		Caution, consult accompanying documents
	Manufacturer		Authorized representative in the European Community
	In vitro diagnostic medical device		in European community

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