

# InTray™ COLOREX™ SCREEN

Chromogenic medium for selected pathogenic bacteria

**REF** Catalog# 10-7107      5 Test Box (2" well)

**REF** Catalog# 10-7101      20 Test Box (2" well)

For In Vitro Diagnostic Use Only



1-800-964-6466

White City, OR 97503

## INTENDED USE

InTray COLOREX Screen Test is a chromogenic medium used in the detection and presumptive identification of selected pathogenic species frequently detected in urinary tract, food sanitation, and veterinary applications, including gram-positive and gram-negative bacteria from clinical specimens.

## DESCRIPTION OF THE SYSTEM AND ITS PRINCIPLES

The medium used is designed to allow rapid and simple detection of specified bacteria by a unique color change when incubated for 24 hours. A presumptive positive results when the appropriate color colony is observed. Further biochemical tests may have to be performed in order to differentiate some species.

The bacteria species identifiable are as follows:

Bacteria Species	Color Change
<i>E. Coli</i>	rose
<i>Enterococcus sp.</i>	turquoise
<i>Klebsiella pneumoniae</i>	metallic blue
<i>Proteus mirabilis</i>	brown
<i>Staphylococcus aureus</i>	opaque cream
<i>S. saprophyticus</i>	opaque (pale) pink

## SPECIMEN COLLECTION AND HANDLING:

InTray COLOREX Screen Test may be used for oral, vaginal, urine, skin, ear, eye, urethral, nasal, throat or fecal specimens. It may also be used for work surface and sanitation quality control. (Aerobic bacteria only.)

## INOCULATION & ISOLATION PROCEDURES

**Step 1:** Bring the InTray to room temperature

**Step 2:** Inoculation Procedure. Pull back the lower right corner of the white label adjacent to the clear window of the InTray lid until the protective seal over the agar is completely visible. Remove the seal by pulling the tab and discard the seal. (Figure 1) Do not remove the white filter strip over the vent hole.

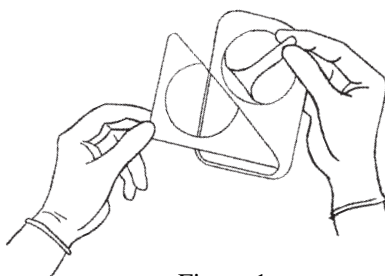


Figure 1

Using sterile technique obtain a sample with either a cotton swab or a microbiology loop. Place the sample on top of the agar. (Figure 2)

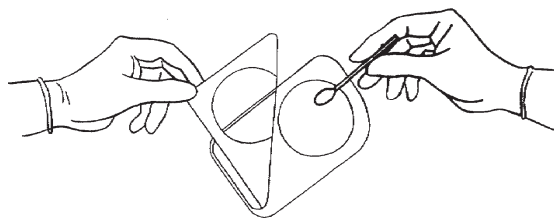


Figure 2

**Sanitation QC (optional).** Using sterile technique invert the InTray over the area to be tested and touch surface by lightly pressing down the agar portion of the tray. **Go to Step 4.**

**Step 3:** Isolation Technique. With a sterile microbiology loop, streak the media in the following pattern(s). This method allows individual colonies to grow separately enabling identification from a mixed species culture.

**Urine samples only - inoculate the agar using a calibrated loop (0.01 ml) by dipping the loop into the urine and (A) dragging the loop down the middle of the agar. Using a calibrated loop allows the technician to do a colony count.**

Using the sterile microbiology loop, (B) streak back and forth across the inoculated area. (Figure 3)

Colony count = (#colonies/10µ/mlx 100µl/ml)

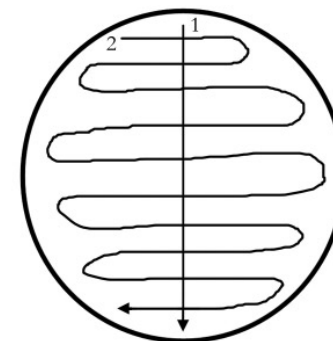


Figure 3

## All other samples

1. After inoculating the agar, streak through the inoculated area with a sterile loop.
2. Turn the InTray 80-90 degrees, streak through the first area with a sterile loop.
3. Turn the InTray another 80-90 degrees, streak through the second area with a sterile loop. (Figure 4)



Figure 4

**Step 4: Reseal the InTray** by pressing together the edges of the white label lid against the plastic tray. **Press all around the InTray to assure a complete seal** (Figure 5). **Label the InTray with the patient's name.**

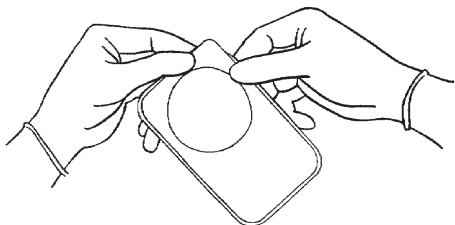


Figure 5

**Incubate the InTray for up to 72 hours at 37°C (98°F)** and observe the colony growth and specified color change through the clear anti-fog window. **DO NOT OPEN THE TRAY.**

#### LIMITATIONS OF THE PROCEDURE


This test gives presumptive positives only. Large samples may show confluent growth and interfere with observing specific colors.

#### QUALITY CONTROL

These products have been tested with either clinical isolates or ATCC strains of the indicated species. At the time of manufacture, quality control testing is performed on each lot of InTray medium. The ability of the medium to support growth and demonstrate expected biochemical reactions and morphology is verified. BioMed repeats these tests on retention samples through the duration of the shelf life.

Test Strain	Strain Number	Expected Results
<i>E. Coli</i>	ATCC 25922	Growth
<i>Enterococcus sp.</i>	Clinical isolate	Growth
<i>Klebsiella pneumoniae</i>	Clinical isolate	Growth
<i>Proteus mirabilis</i>	ATCC 43071	Growth
<i>Staphylococcus aureus</i>	Clinical isolate	Growth
<i>S. saprophyticus</i>	Clinical isolate	Growth

#### STORAGE

Upon receipt, store InTrays at 2°-8°C.  Avoid freezing or prolonged storage at temperatures greater than 30°C. This product has demonstrated a shelf life of 6 months at room temperature and 1 year under refrigeration from date of manufacture. Do not use InTray if the medium shows signs of deterioration or contamination.

#### REAGENTS











The InTray COLOREX medium contains agar, peptone and other extracts; chromogenic additives.

#### PRECAUTIONS

For in vitro diagnostic use only. Once the InTray has been inoculated and resealed, open only in a biological safety cabinet. Because of the infectious materials involved, the InTray must be destroyed by autoclave or equivalent means of disposal. (BioSafety Level 2)

#### REFERENCES

1. J. Merlino, S. Siarakas, G.J. Robertson, G.R. Funnell, T. Gottlieb, and R. Bradbury Evaluation of CHROMagar Orientation for differentiation and presumptive identification of gram-negative bacilli and Enterococcus species. J. Clin. Microbiol. 1996 34: 1788-1793
2. Z. Samra, M. Heifetz, J. Talmor, E. Bain and J. Bahar Evaluation of Use of a New Chromogenic Agar in Detection of Urinary Tract Pathogens. J. Clin. Microbiol. 1998 36: 990-994

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

The label on the InTray CS test includes a section where the patient information can be written. The information is: patient #, sample, source, name and date. It is up to the discretion of the practitioner to complete this section or not.

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