



INSTRUCTIONS FOR USE – READY-TO-USE PLATED MEDIA

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For Laboratory Use Only

BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80, 90 mm LL •

BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80, 150 mm •

BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80, RODAC™ Locking Lid (LL) •

BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80 with Chloramphenicol, 90mm LL•

BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80 with Chloramphenicol, RODAC™ LL

INTENDED USE

BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80 is used for cultivation of fungi when monitoring the environmental and product hygiene in clean rooms of pharmaceutical production and fill rooms.

“**IC-XT Pack**” (Isolator Cleanroom-Extended Temperature) products are available in different plate formats; they are gamma-sterilized after the aseptic fill procedure to allow monitoring of the environmental and product hygiene and the efficiency of disinfection in clean rooms of pharmaceutical production and fill rooms, and in isolators. All IC-XT products are packaged in impermeable plastic films to allow an extended stability and storage at 2 to 25° C throughout the shelf life with exception of IC-XT products containing chloramphenicol for which storage is limited to 2 to 8° C throughout the shelf life. RODAC™ (Replicate Organism Detection and Counting) plates are particularly recommended for the use in the detection and enumeration of micro-organisms present on surfaces of sanitary importance.

PRINCIPLES AND EXPLANATION OF THE PROCEDURE

Sabouraud Glucose Agar is a general purpose medium devised by Sabouraud for the cultivation of dermatophytes.¹ The low pH of approximately 5.6 and the high glucose concentration, favorable for the growth of all fungi has made it a popular medium for the isolation of fungi from various sources. The medium is slightly inhibitory to contaminating bacteria due to the low pH. Sabouraud Glucose Agar is mentioned in the European Pharmacopeia and in the United States Pharmacopeia for the isolation of fungi and is used for the detection of fungi from foods.²⁻⁴

Sabouraud Glucose Agar is a peptone medium supplemented with glucose to support the growth of fungi. The peptones are sources of nitrogenous growth factors. Glucose provides an energy source for the growth of microorganisms. The high glucose concentration in Sabouraud Glucose Agar provides an advantage for the growth of the (osmotically stable) yeasts while most bacteria do not tolerate the high sugar concentration.

BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80 contains lecithin and polysorbate 80 to neutralize surface disinfectants.⁵⁻⁸ Lecithin is a neutralizer of quaternary ammonium compounds. Polysorbate 80 neutralizes phenols, hexachlorophene, formalin and, with lecithin, ethanol.⁹⁻¹¹

BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80 with Chloramphenicol contains chloramphenicol as selective agent. Chloramphenicol is a broad-spectrum antibiotic inhibitory to a wide range of gram-negative and gram-positive bacteria.^{15,16} Sodium pyruvate is added to absorb peroxides and radicals that develop during gamma-irradiation and during exposure to isolator air that contains residues of hydrogen peroxide.

The aseptic manufacturing processes of these media are controlled to ensure that the bioburden of the product is reduced to a minimum. Each piece of equipment used in the manufacturing has been qualified and validated. Using a proprietary filling process, Isolator Pack media are dispensed in a controlled environment, which has been verified as ISO class 5 and is monitored during production to assure that specifications are met. Once a medium is dispensed, the plates of all IC-XT products are packed and sealed in a dedicated, controlled environment (ISO class 7) into three impermeable plastics bags to reduce evaporation and oxidation of the medium to a minimum. This allows storage at room temperature for the whole shelf life period.

Because the entire triple-bagged product in its carton box is subjected to a sterilizing dose of gamma-irradiation, the contents inside the outer bag are sterile. This allows the inner bags to be aseptically removed and brought into an environmental-controlled area without introducing contaminants.

The microbiological status of these products has been validated according to ISO 11137.^{12,13} As a result from the validation tests, an irradiation dose of 9.6 kGy was determined to be the minimum irradiation dose necessary for achieving an SAL of 10^{-5} .¹⁴ The media are gamma-irradiated in the packaging material as delivered with 10 to 22 kGy to assure a reduction of the microbial load potentially present in the medium, on the dishes and on the packaging materials. Gamma-irradiation of the product is indicated by an orange to red color of the irradiation indicator stripe on the inner label. A yellow to mustard-colored indicator indicates insufficient irradiation.

The bags (with undamaged sealing seams) of the IC-XT products are impermeable to hydrogen peroxide. This applies to product packaged in one, two or three bags.

REAGENTS

Approximate Formulas* Per Liter Purified Water

All IC-XT products with **BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80**

Pancreatic Digest of Casein	5.0 g
Peptic Digest of Animal Tissue	5.0
Glucose	40.0
Lecithin	0.7
Polysorbate 80	5.0
Sodium Pyruvate	3.5
Agar	15.0

pH 5.6 ± 0.2

*Adjusted and/or supplemented as required to meet performance criteria.

In addition, **BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80 with Chloramphenicol** contains 0.4 g/L chloramphenicol as selective agent.

PRECAUTIONS

For laboratory use only.

The contents of the unopened and undamaged bags are sterile. Do not use packages if they show evidence of microbial contamination, discoloration, drying, cracking, open or damaged bags or other signs of deterioration. The inner bag of these products contains irradiation indicator dots or stripes (dark orange to red = irradiated; yellow to mustard-colored = not irradiated). Do not use the product if the irradiation indicators are yellow to mustard-colored!

Consult **GENERAL INSTRUCTIONS FOR USE** document for aseptic handling procedures, biohazards, and disposal of used product.

Packaging Information

IC-XT plates are packed in three plastic bags. The plastic bags used for packaging of these products consist of polyethylene/ polyethylene terephthalate (=PE/PET). The inner plastic bag contains a SORB-IT® silica gel desiccant bag. The triple-bagged stacks are packaged in white cartons.

The sealing seams of the bags are heat-sealed. The bags allow easy opening without the use of sharp objects such as scissors or knives. Bags can be peeled open at the ends of the stacks by tearing apart both plastic films of the bag. Apply aseptic techniques. Once the outer bag is opened, appropriate measures should be used to maintain the sterility of the inner bags and the contents.

STORAGE AND SHELF LIFE

On receipt, store **BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80** plates in the dark at 2 to 25°C, in their original bags until just prior to use. **BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80 with Chloramphenicol** are stored under the same conditions with the exception of the storage temperature of 2 to 8°C. Do not freeze or overheat! Avoid repeated and/or extreme variations in temperature during storage since this may cause the development of excessive moisture in the bags and plates.

The ideal storage temperature of **BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80** products is 15 to 22°C, with exception of the above-mentioned chloramphenicol containing products. Moisture appearing as a fine haze or as small droplets on the inner side of the lids, especially during or after refrigerated storage, is acceptable and is a sign for freshness of the media. Minimize exposure to light during the whole storage period.

The plates may be inoculated up to the expiration date and incubated for the recommended incubation times. The given shelf life and expiry applies to the product in unopened (completely sealed) bags.

USER QUALITY CONTROL

Inoculate representative samples of the medium with < 100 CFU (colony forming units) per plate of the strains listed in the Table. *Trichophyton mentagrophytes* is inoculated directly from a stock plate using a fresh fungal culture.

In addition to the fungal strains, test **BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80 with Chloramphenicol** for inhibition of *Staphylococcus aureus* and *Escherichia coli*. Inoculate each plate with 10³ to 5 x 10⁴ CFU.

See Table for incubation, expected growth and recovery respectively.

Species	Strains	Incubation	Expected Recovery (%)* / Expected growth** on Sabouraud Glucose Agar with LP ^a	Expected Recovery (%)* / Expected growth** on Sabouraud Glucose Agar with LP with Chloramphenicol ^b
<i>Candida albicans</i>	ATCC 10231	≤ 5d / 20-25°C ^{a,b} ≤ 24h / 30-35°C ^a	>70	>70
<i>Saccharomyces cerevisiae</i>	DSM 1333 (=ATCC 9763)	≤ 3d / 20-25°C ^a ≤ 5d / 20-25°C ^b	Good to excellent	>70
<i>Aspergillus brasiliensis</i>	ATCC 16404	≤ 5d / 20-25°C	>70	>70
<i>Aspergillus fumigatus</i>	ATCC 1028	≤ 5d / 20-25°C	Not tested	>70
<i>Escherichia coli</i>	ATCC 8739	18-48h/35-37°C ^a ≤ 5d / 20-25°C ^b	>70	Complete inhibition
<i>Staphylococcus aureus</i>	ATCC 6538	≤ 5d / 20-25°C	Not tested	Complete inhibition
<i>Trichophyton mentagrophytes</i>	ATCC 9533	≤ 3d / 20-25°C ^a ≤ 5d / 20-25°C ^b	Good to excellent	Good to excellent
Appearance of the uninoculated medium	Light amber, transparent to amber, transparent			Light amber to amber, transparent

* Recovery (%) = CFU_{Test medium} / CFU_{Reference medium} X 100

** Expected growth (growth intensity)

^a For incubation on **BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80**

^b For incubation on **BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80 with Chloramphenicol**

PROCEDURE

Materials Provided

See **PACKAGING/AVAILABILITY** for the available IC-XT products.

Materials Not Provided

Ancillary culture media, reagents and laboratory equipment as required.

Test Procedure

IC-XT products are used in a variety of procedures. Follow the appropriate references for sampling, inoculation, and incubation.²⁻⁴

Locking Lid (LL) plates feature a locking system specifically designed to ensure higher security and convenience throughout handling while reducing the risk of accidental contamination. The LL mechanism allows for an easy locking of plates after sampling and for a safer transport from a controlled environment to the laboratory. The locked position of the plate ensures a secure fit between the lid and the base thereby minimizing unintentional opening of plates while allowing for appropriate aeration during incubation.

The RODAC™ Locking Lid (LL) plated media are used in the replicate organism detection and counting procedure to monitor the hygiene status of surfaces or in certain types of air samplers.

For surface testing, introduce the plates into the room or area to be tested or monitored. RODAC™ LL plates are provided in the unlocked position. Remove lid from the plate. Apply the plate's surface directly to the surface being tested and exert moderate pressure. Do not rub the agar surface or move laterally on the test surface! Return the lid and lock the plate by simply twisting the base and the lid of the plate into the locked position. Plates can be easily unlocked by untwisting. Areas (walls, floors etc.) to be tested may be divided into sections or grids and samples taken from specific points within the grid.

Grid method:

1. Subdivide surface (floor or wall) into 36 equal squares per 100 square feet of area by striking five equidistant dividing lines from each of two adjacent sides.
2. These dividing lines intersect at twenty-five points.
3. Number these intersections consecutively in a serpentine configuration.
4. Use red numerals for odd numbers, black numerals for even numbers.
5. Omit number 13 which falls in the center of the total area.
6. Sample odd points at one sampling period, even points at the next sampling period.
7. For areas greater than 100 square feet, extend grid to include entire area.
8. For areas smaller than 25 square feet, divide the areas into twenty-five equal squares (sixteen intersections). Sample eight even-numbered or odd-numbered intersections at each sampling period.
9. For areas between 25 and 100 square feet, divide into 36 equal squares as in #1.
10. Mark plates with intersection numbers.

Products supplied in 90 mm LL dishes are used in general microbiological procedures.

Products supplied in 150 mm dishes are generally used in air sedimentation procedures.

Incubate inoculated plates for up to 7 days at 20 to 27° C or as required.

Results

Examine plates for fungal colonies exhibiting typical color and morphology. Biochemical tests and microscopic and serological procedures must be performed for identification of the isolates.

LIMITATIONS OF THE PROCEDURE

Since **BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80** is only weakly selective, bacteria may grow on the media, especially after a prolonged incubation.

If bacterial contamination of the specimens, materials, or areas under investigation is suspected, media with a higher selectivity such as **BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80 with Chloramphenicol**, Sabouraud Agar with Chloramphenicol, Sabouraud Agar with Gentamicin and Chloramphenicol or Sabouraud Agar + Penicillin + Streptomycin should be used.

Extended sedimentation exposure followed by incubation in dry air may lead to cracking, splitting or other desiccation of the agar gel, especially in dry environments. Media shrinkage may also occur during extended incubation in incubators with air circulation. Provide sufficient moisture during incubation since media shrinkage may affect the fertility of the medium.

Use of this medium with clinical specimens has not been validated.

REFERENCES

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PACKAGING/AVAILABILITY

Product Name	Cat. No.	Number of plates per package
BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80, 90mm LL	257662	100
BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80, 150 mm	257629	30
BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80, RODAC™ Locking Lid (LL)	257630	100
BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80 with Chloramphenicol, 90mm LL	257619	100
BD BBL™ IC-XT Pack Sabouraud Glucose Agar with Lecithin and Polysorbate 80 with Chloramphenicol, RODAC™ LL	257628	100

FURTHER INFORMATION

For further information please contact your local BD representative.



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