

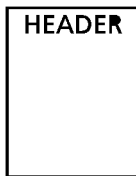
Revisions

SO 0191-5

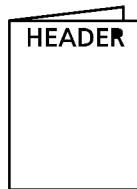
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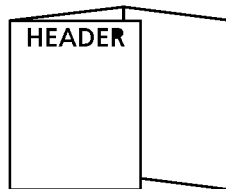
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- Style (see illustrations below): # 1



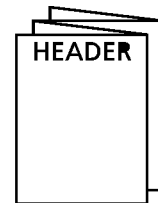
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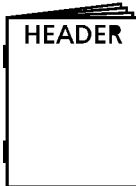
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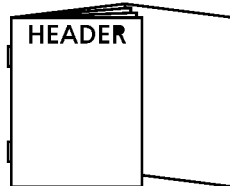
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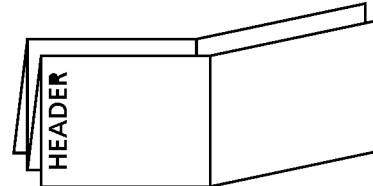
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Part Number: 8817741		Category and Description	Sheet: 1 of 3	A
		Package Insert, BBL Prepared Environmental Monitoring Plates	Scale: N/A	

BD BBL™ Prepared Isolator Pack Plates for Environmental Monitoring **Trypticase™ Soy Agar with Lecithin and Polysorbate 80, Isolator Pack**

8817741
2006/10

INTENDED USE

Trypticase Soy Agar (TSA) with Lecithin and Polysorbate 80 Isolator Pack plates are used for microbial load testing. The Isolator Pack plates are particularly useful for monitoring surfaces and air in Isolator Systems, clean rooms, and other environmentally-controlled areas when sterility of the medium is of importance.

SUMMARY AND EXPLANATION

RODAC environmental sampling plates are specially constructed so that an agar medium can be over-filled, producing a meniscus or dome-shaped surface that can be pressed onto a surface for sampling its microbial burden. These plates are used in a variety of programs to establish and monitor cleaning techniques and schedules.¹⁻⁵

After touching the surface to be sampled with the medium, the dish is covered and incubated at an appropriate temperature. The presence and number of microorganisms is determined by the appearance of colonies on the surface of the agar medium.⁶

The 100 x 15 mm and the 150 x 15 mm style plates can be used for active and passive air sampling. These plates are also designed for personnel monitoring of finger tips.

Collection of samples from the same area before and after cleaning and treatment with a disinfectant permits the evaluation of the efficacy of sanitary procedures.

The multi-wrap design has been validated to protect the medium from vapor hydrogen peroxide when used in an Isolator System.

PRINCIPLES OF THE PROCEDURE

Casein and soy peptones are sources of nutrients required for the replication of microorganisms. Sodium chloride maintains osmotic equilibrium. Lecithin and polysorbate 80, two commonly used neutralizers, are reported to inactivate residual disinfectants when the sample is being collected.⁶ Lecithin is incorporated to neutralize quaternary ammonium compounds and polysorbate 80 is used to neutralize substituted phenolic disinfectants.⁷⁻¹⁰

Because the entire multi-wrapped product is subjected to a sterilizing dose of gamma radiation, the contents inside the outer bag are sterile.¹¹ This allows the inner bags to be aseptically removed and brought into an environmentally-controlled area without introducing contamination.

The inner rolled sterile bag is included as a transport device.

Since the agar medium has been sterilized after packaging, the presence of microbial growth after sampling and incubation can be relied upon to represent the presence of environmental contaminants and not pre-existing microorganisms in the medium that may have been introduced during manufacture.

The **RODAC** and **RODAC SL** (secure lid) plates have a marked grid to facilitate counting organisms.

REAGENTS

Trypticase Soy Agar with Lecithin and Polysorbate 80

Approximate Formula* Per Liter Purified Water

Pancreatic Digest of Casein	15.0 g
Papaic Digest of Soybean Meal	5.0 g
Sodium Chloride	5.0 g
Lecithin	0.7 g
Polysorbate 80	5.0 g
Agar	15.0 g

*Adjusted and/or supplemented as required to meet performance criteria and, additionally, to compensate for radiation effects.

Warnings and Precautions: For Laboratory Use.

Observe aseptic techniques and established precautions against microbiological hazards throughout all procedures. After use, prepared plates and other contaminated materials should be sterilized by autoclaving.

Storage Instructions: On receipt, store plates in the dark with top side up (agar bed at bottom) at 2 – 8°C. Avoid freezing and overheating. Do not open until ready to use. Minimize exposure to light.

Prepared plates stored in their original wrapping at 2 – 8°C should be warmed to room temperature prior to use.

The product is validated from the time of manufacture to be stable at room temperature (25°C) for 192 h (8 days). Plates may be inoculated up to their expiration date and incubated for the recommended incubation times. Discard the unused portion of all packaging.

Product Deterioration: The contents of unopened or undamaged packages are sterile. At the time the integrity of the outer and/or inner bags or seals is compromised, the product should no longer be considered sterile. Do not use packages if they show evidence of damage, microbial contamination, drying or other signs of deterioration.

SPECIMEN COLLECTION AND HANDLING

This product is not for use directly with clinical specimens.

PROCEDURE

Material Provided: **Trypticase Soy Agar with Lecithin and Polysorbate 80 Isolator Pack** in **RODAC**, **RODAC SL**, 100 mm x 15 mm style and 150 mm x 15 mm style plates.

Materials Required But Not Provided: Ancillary culture media, reagents, quality control organisms and laboratory equipment as required.

Test Procedure: The bags may be opened by either peeling apart the two films, or by cutting with sterile scissors. To peel open, grasp and hold the edge of the clear plastic and pull corner of the white opaque outer layer away from the plastic. Open the outer bag using aseptic technique. Once the outer bag is opened, appropriate measures should be used to maintain the sterility of the inner bags and their contents.

Surface sampling (RODAC and RODAC SL plates):

Selected surfaces are sampled by firmly pressing the agar medium against the test area. Hold the plate with thumb and second finger and use index finger to press plate bottom firmly against surface. Pressure should be the same for every sample. Do not move plate laterally; this spreads contaminants over the agar surface making resolution of colonies difficult. Slightly curved surfaces may be sampled with a rolling motion.

Areas (walls, floors, etc.) to be assayed 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.
- Incubate exposed plates at 35 – 37°C for 48 h, and 25°C for 7 days or as required.

User Quality Control:

1. Examine plates for signs of deterioration as described under "Product Deterioration."
2. Check performance by inoculating a representative sample of plates with pure cultures of stable control organisms that give known, desired reactions. The following test strains are recommended:

Test Strain	Expected Results
<i>Pseudomonas aeruginosa</i> ATCC™ 9027	Growth
<i>Staphylococcus aureus</i> ATCC 6538	Growth

RESULTS

After incubation, count the colonies.

Counting of plates containing a profusion of growth can lead to considerable error. A basic decision to be made is whether distinct colony margins can be observed.

Count all visible colonies. Spreading colonies should be counted as one but care should be taken to observe other distinct colonies intermingled in the growth around the plate periphery or along a hair line. These should also be counted as one colony, as should bi-colored colonies and halo-type spreaders. It is generally agreed that 200 colonies is the approximate maximum that can be counted on **RODAC** and **RODAC SL** plates.

Colony counts may be recorded by:

1. Simply keeping individual counts.
2. Number of viable particles per square foot (agar area is 3.97 square inches).
3. Means and standard deviations.

Subculture colonies of interest so that positive identification can be made by means of biochemical testing and/or microscopic examination of organism smears.

LIMITATIONS OF THE PROCEDURE

This prepared plated medium is intended for the enumeration of microorganisms from the air and from surfaces of sanitary importance. For identifi-

cation, the organisms must be in pure culture. Biochemical tests may be performed for complete identification. Appropriate texts should be consulted for further information.¹²⁻¹⁴

AVAILABILITY

Cat. No.	Description
299896	BBL™ Trypticase™ Soy Agar with Lecithin and Polysorbate 80 Isolator Pack, Pkg. of 10 RODAC™ plates
292335	BBL™ Trypticase™ Soy Agar with Lecithin and Polysorbate 80 Isolator Pack, Ctn. of 100 RODAC™ plates
222252	BBL™ Trypticase™ Soy Agar with Lecithin and Polysorbate 80 Isolator Pack, Pkg. of 10 RODAC™ SL (secure lid) plates
222253	BBL™ Trypticase™ Soy Agar with Lecithin and Polysorbate 80 Isolator Pack, Ctn. of 100 RODAC™ SL (secure lid) plates
292648	BBL™ Trypticase™ Soy Agar with Lecithin and Polysorbate 80 Isolator Pack, Pkg. of 10 100 mm x 15 mm style plates
292649	BBL™ Trypticase™ Soy Agar with Lecithin and Polysorbate 80 Isolator Pack, Ctn. of 100 100 mm x 15 mm style plates
292650	BBL™ Trypticase™ Soy Agar with Lecithin and Polysorbate 80 Isolator Pack, Pkg. of 5 150 mm x 15 mm style plates

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