

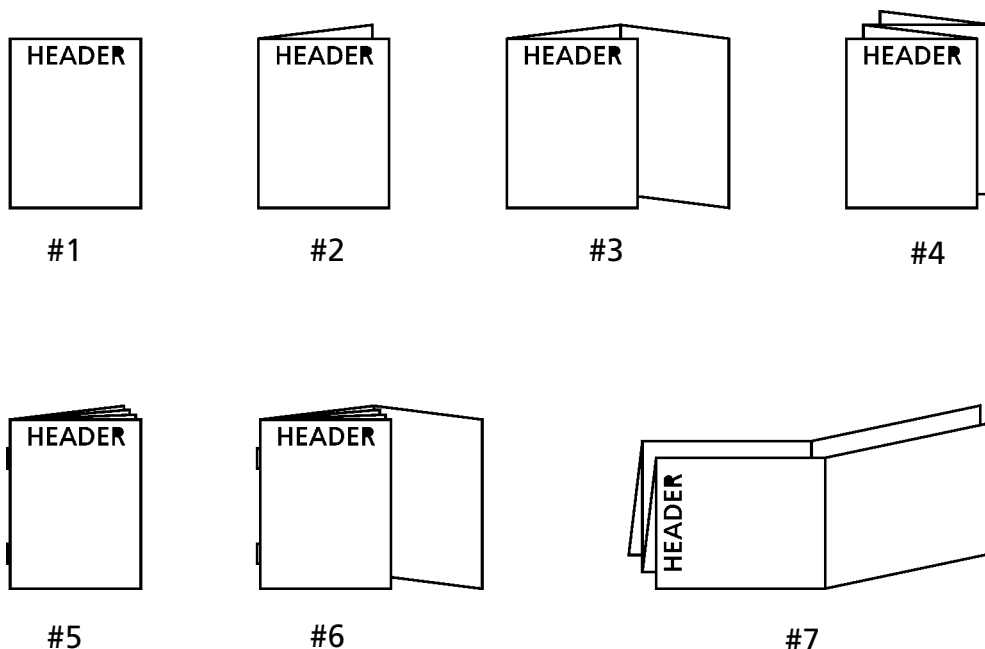
Revisions

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Part Number: 8809391JAA		Category and Description Package Insert, Trypticase Soy Agar w Penicillinase	Sheet: 1 of 2	A
			Scale: N/A	

BD BBL™ Prepared Sterile Pack Plates

Trypticase™ Soy Agar with Penicillinase, Sterile Pack

8809391JAA
2010/09

INTENDED USE

Trypticase™ Soy Agar with Penicillinase is a general purpose medium which supports the growth of a variety of bacteria and fungi. The Sterile Pack plates are useful for microbial load testing of environmentally-controlled areas, clean rooms, pharmaceuticals, and other instances when sterility of the medium is of importance.

SUMMARY AND EXPLANATION

The nutritional composition of the **Trypticase** Soy Agar base has made it a popular medium for many years. The medium is used for a multitude of purposes, including maintenance of stock cultures, aerobic microbial counts, and isolation of microorganisms from a variety of specimen types.¹⁻³ It is included in the compendia of methods for the examination of water, wastewater and foods.^{4,5}

PRINCIPLES OF THE PROCEDURE

The combination of casein and soy peptones in **Trypticase** Soy Agar renders the medium highly nutritious by supplying organic nitrogen, particularly amino acids and longer-chained peptides. The sodium chloride maintains the osmotic equilibrium. Penicillinase inactivates antibiotics such as penicillins and cephalosporins. Because the entire double-bagged product is subjected to a sterilizing dose of gamma radiation, the contents inside the outer bag are sterile.⁶ This allows the inner bag to be aseptically removed without introducing contaminants.

A third 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 true recovery and not pre-existing medium contamination.

REAGENTS

Formula:

Trypticase™ Soy Agar with Penicillinase

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
Agar	15.0 g
Penicillinase	50.0 mL

* Adjusted and/or supplemented as required to meet performance criteria and 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 to 8°C. Do not freeze or overheat. Do not open until ready to use. Minimize exposure to light. Prepared plates stored in their original wrapping at 2 to 8°C should be warmed to room temperature prior to use. Packages may be stored at room temperature (not exceeding 30°C) for up to 120 hours. Plates may be inoculated up to their expiration date and incubated for recommended incubation times. Discard the unused portion of all packages.

Product Deterioration: The contents of unopened or undamaged packages are sterile. Do not use packages if they show evidence of damage, microbial contamination, drying, or other signs of deterioration.

SPECIMEN COLLECTION AND HANDLING

Samples suitable for culture may be obtained using various techniques. Samples should be transported in the appropriate manner.

PROCEDURE

Material Provided: Depending upon which product is ordered, one of the prepared plate types listed under "Availability" is provided.

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

Test Procedure: The bags may be opened by 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 the corner of the opaque white layer away from the plastic. If sterility of the inner bag and medium is of importance for your procedure, 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 bag and its contents.

For general use, plate the sample as soon as possible with the intent for colony isolation. If the sample is being cultured directly from a swab, roll the swab over a small area of the surface at the edge; then streak from this inoculated area.

The agar surface should be smooth and moist, but without excessive moisture that could cause confluent growth. Incubate at temperatures and atmospheres suitable for isolation of specific organisms.^{1,2,4,5,7}

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>Staphylococcus aureus</i> ATCC™ 6538	Moderate to heavy growth. Colonies medium to large, opaque, circular, entire with cream-yellow to gold pigment.
<i>Bacillus subtilis</i> ATCC 6633	Moderate to heavy growth. Colonies medium to large, opaque, irregular, greyish white to tan.

EXPECTED RESULTS

After incubation, it is desirable to have isolated colonies of organisms from the original sample.

Subculture colonies of interest so that positive identification can be made by means of biochemical testing and/or microscopic examination of organism smears.^{1,2,7}

LIMITATIONS OF THE PROCEDURE

This is a primary isolation medium; therefore, isolated organisms should be identified by serological and/or biochemical tests. Appropriate texts should be consulted for further information.^{1,2,7}

At the time the integrity of the outer and/or inner bag or seal is compromised the product should no longer be considered sterile.

AVAILABILITY

Cat. No.	Description
221839	Trypticase™ Soy Agar with Penicillinase, Sterile Pack, Pkg. of 10 100 x15 mm style Plates.
221837	Trypticase™ Soy Agar with Penicillinase, Sterile Pack, Pkg. of 5 150 x15 mm style Plates.

REFERENCES

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3. MacFaddin, J.F. 1985. Media for isolation-cultivation-identification-maintenance of medical bacteria, vol. 1, Williams & Wilkins, Baltimore.
4. Greenberg, A.E., L.S. Clesceri, and A.D. Eaton (ed.). 1992. Standard methods for the examination of water and wastewater, 18th ed. American Public Health Association, Washington, D.C.
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6. Association for the Advancement of Medical Instrumentation. 1984. Process control guidelines for gamma radiation sterilization of medical devices. Association for the Advancement of Medical Instrumentation, Arlington, Va.
7. Holt, J.G., N.R. Krieg, P.H.A. Sneath, J.T. Staley, and S.T. Williams (ed.). 1994. Bergey's Manual of determinative bacteriology, 9th ed. Williams & Wilkins, Baltimore.

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