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By Natalie	D EYE BY 9 Morio at 1:53 pm, Jul 19, 2017	Category and Description	Sheet: 1 of 5
rt Number: 88	335631JAA	Package Insert, BD BBL™ TSA w/Lecithin & Tween RODAC Plates	

RODAC Plates

③ BD BBL™ Prepared RODAC™ Plates

BBL™ Trypticase™ Soy Agar with Lecithin and Polysorbate 80

8835631JAA(02) 2017-06

INTENDED USE

Prepared **BD RODAC™** (Replicate Organism Detection and Counting) plates are recommended for the detection and enumeration of microorganisms present on surfaces of sanitary importance.

SUMMARY AND EXPLANATION

BD RODAC plates are specially constructed so that an agar medium can be overfilled, producing a meniscus or dome-shaped surface that can be pressed onto a surface for sampling its microbial content. **BD RODAC** plates are used in a variety of programs to establish and monitor cleaning techniques and schedules.¹⁻⁶

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 detected by the appearance of colonies on the surface of the agar medium.⁵⁻⁷ 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.

PRINCIPLES OF THE PROCEDURE

Peptones are sources of nutrients required for the replication of microorganisms. Lecithin and polysorbate 80, two commonly used neutralizers, are reported to inactivate residual disinfectants when the sample is being collected. ^{5,7} Lecithin is incorporated to neutralize quaternary ammonium compounds and polysorbate 80 is used to neutralize substituted phenolic disinfectants. ^{5,7-10}

The prefilled **BD BBL™ RODAC** plate is specially modified to lock the agar bed in place during transit and use. The 65 x 15 mm style dish has a special 10 mm grid to facilitate counting colonies.

REAGENTS

Formula:

BD BBL™ 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	
Polysorbate 80	5.0 g
Agar	
*Adjusted and/or supplemented as required to meet performance of	criteria

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

Warnings and Precautions:

For Laboratory Use

Storage Instructions: On receipt, store plates in the dark with top side up (agar bed at the bottom) at 2 to 8 °C. Freezing and overheating must be avoided. Do not open until ready to use. Prepared plates stored in their original sleeve wrapping at 2 to 8 °C until just prior to use may be inoculated up to the expiration date and incubated for recommended incubation times. Allow the medium to warm to room temperature before inoculation.

Product Deterioration: Do not use plates if they show evidence of microbial contamination, discoloration, drying, cracking or other signs of deterioration.

SPECIMEN COLLECTION AND HANDLING

These products are not for use directly with clinical specimens. After use, prepared plates and other contaminated materials should be sterilized by autoclaving.

PROCEDURE

Material Provided: Depending upon which product is ordered, one of the prepared **BD RODAC** plates listed in "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: Observe aseptic techniques and established precautions against microbiological hazards throughout all procedures.

- Use a xylene-base felt-tip marker, wax pencil or label to consecutively number the plates that are to be used.
- 2. Note on the report form the location of the site to be tested. Remove the lid and hold it to avoid accidental contamination. Apply the plate's agar surface directly to the surface being tested and exert moderate vertical pressure. Replace the cover and repeat with additional plates as required for the sampling program. Note: Caution should be exercised to avoid rubbing on the site; otherwise, the agar bed may be broken and the usefulness of the plate affected.
- After samples have been collected, incubate all plates for 48 to 72 h at 35 °C.
- 4. When incubation has been completed, count the colonies. An automatic colony counter is recommended, or the grid on the bottom of the BD RODAC plate will serve as a useful guide for estimation.

User Quality Control:

- Examine plates for signs of deterioration as described under "Product Deterioration."
- 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
Pseudomonas aeruginosa ATCC® 9027	Growth, yellow to gold colonies
Staphylococcus aureus ATCC 6538	Growth, yellow to gold colonies

RESULTS

Because interpretations are relative, each laboratory should establish its own values for what constitutes a clean area. The Committee on Microbial Contamination of Surfaces of the Laboratory Section of the APHA believes that the guidelines presented below for general-use media represent realistic microbial objectives for patient room floors immediately after cleaning.¹¹

Colonies per BD RODAC Plate

Good	<u>Fair</u>	Poor
0-25	26–50	50 and over

These figures represent attainable results immediately after cleaning and do not take into account the progressive accumulation of contamination which may occur between that time and the next cleansing. Counts below five colonies per **BD RODAC** plate are achievable in such critical areas as operating rooms, but there is no evidence that these levels must be maintained in order to prevent infections or that any particular level of contamination in such areas is directly correlated with an increased risk of infection.¹²

Other guidelines for judging **BD RODAC** counts have been published.^{3,4}

	Colonies per BD RODAC Plate		
Critical Areas	Good	Fair	Poor
Floors O.R., O.B., Isolation (terminal clean-up) Nursery	0–5	6–15	16 and up
Table Tops Patient rooms	0–5	6–15	16 and up
Floors	0–25	26–50	51 and up
Table tops Bathrooms	0–5	6–15	16 and up
Floors	0–25	26–50	51 and up
Sinks & Tubs	0–15	16–25	26 and up
Toilet Seat	0–5	6–15	16 and up
All other floors	0–25	26–50	51 and up
All other horizontal non-porous surfaces	0–5	6–15	16 and up

LIMITATIONS OF THE PROCEDURE

Accurate enumeration of the environmentally stressed enteric bacteria from air and surface samples is often hampered when selective media are employed. 13 Isolation and identification of a specific organism or group of organisms may be accomplished by replicating or subculturing from a **BD RODAC** plate containing the broad-spectrum medium to a selective or differential medium. 5

The guidelines provided are based on results obtained using a general-use medium; i.e., Standard Methods Agar with Lecithin and Polysorbate $80.^{3,11}$

These prepared plated media are intended for the enumeration of microorganisms on surfaces of sanitary importance. For identification, the organisms must be in pure culture. Morphological, biochemical and/ or serological tests may be performed for complete identification. Consult appropriate texts for detailed information and recommended procedures. 14-16

AVAILABILITY

Cat. No. Description

221288 **BD BBL™ Trypticase™** Soy Agar with Lecithin and Polysorbate 80, Pkg. of 20 **BD RODAC™** plates.

221287 **BD BBL™ Trypticase™** Soy Agar with Lecithin and Polysorbate 80, Ctn. of 10 x 10 **BD RODAC™** plates.

REFERENCES

- Hall, L. B., and M. J. Hartnett. 1964. Measurement of the bacterial contamination on surfaces in hospitals. Public Health Rep. 79:1021-1024.
- 2. Vesley, D., and G. S. Michaelson. 1964. Application of a surface sampling technique to the evaluation of bacteriological effectiveness of certain hospital housekeeping procedures. Health Lab. Sci. 1:107-113.
- 3. Pryor, A. K., and C. R. McDuff. 1969. A practical microbial surveillance system. Exec. Housekeeper, March.
- 4. Dell, L. A. 1979. Aspects of microbiological monitoring for nonsterile and sterile manufacturing environments. Pharm. Technol. 3:47-51.
- Hickey, P.J., C.E. Beckelheimer, and T. Parrow. 1992. Microbiological tests for equipment, containers, water, and air, p. 397-412. *In R.T.* Marshall (ed.), Standard methods for the examination of dairy products, 16th ed. American Public Health Association, Washington, D.C.
- Sveum, W.H., L.J. Moberg, R.A. Rude, and J.F. Frank. 1992. Microbiological monitoring of the food processing environment, p. 51-74. *In C.* Vanderzant, and D.F. Splittstoesser (ed.), Compendium of methods for the microbiological examination of foods, 3rd ed. American Public Health Association, Washington, D.C.
- McGowan, J.E., Jr. 1985. Role of the microbiology laboratory in prevention and control of nosocomial infections, p. 110-122. *In* E.H. Lennette, A. Balows, W.J. Hausler, Jr., and H.J. Shadomy (ed.), Manual of clinical microbiology, 4th ed. American Society for Microbiology, Washington, D.C.
- 8. Quisno, R., I. W. Gibby, and M. J. Foter. 1946. A neutralizing medium for evaluating the germicidal potency of the quaternary ammonium salts. Am. J. Pharm. *118*:320.
- Erlandson, A. L., Jr., and C. A. Lawrence. 1953. Inactivating medium for hexachlorophene (G-11) types of compounds and some substituted phenolic disinfectants. Science 118:274-276.
- Brummer, B. 1976. Influence of possible disinfectant transfer on Staphylococcus aureus plate counts after agar contact sampling. Appl. Environ. Microbiol. 32:80-84.
- Committee on Microbial Contamination of Surfaces of the Laboratory Section, American Public Health Association. 1970. Health Lab. Sci. 7:256-264.
- Fincher, E.L. 1965. Surface sampling applications, methods and recommendations, p. 189-199. Proceedings of an Institute on the Control of Infections in Hospitals. University of Michigan, Ann Arbor.
- Petersen, N. J., K. L. Brigham, J. H. Marshall, L. A. Venice, W. W. Bond, and M. S. Favero. 1970. Use of fecal coliform bacteria in evaluating microbial contamination in pediatric wards. Health Lab. Sci. 7:91-96.
- 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.
- Murray, P.R., E.J. Baron, M.A. Pfaller, F.C. Tenover, and R.H. Yolken (ed.). 1995. Manual of clinical microbiology, 6th ed. American Society for Microbiology, Washington, D.C.
- Forbes, B.A., D.F. Sahm, and A.S. Weissfeld. 1998. Bailey & Scott's diagnostic microbiology, 10th ed. Mosby, Inc., St. Louis.

Technical Information: In the United States contact BD Technical Service and Support at 1.800.638.8663 or www.bd.com.



SURFACE CONTAMINATION

e samples obta	ined by:	Date:				
Specimen Number	Location of Tested Surface	Time of Sampling	A - B*	Colony Count Per Plate	Accepted level	Comments
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
	= Before cleaning					1
	incubator:			_		

Date: ______ Date: _____



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