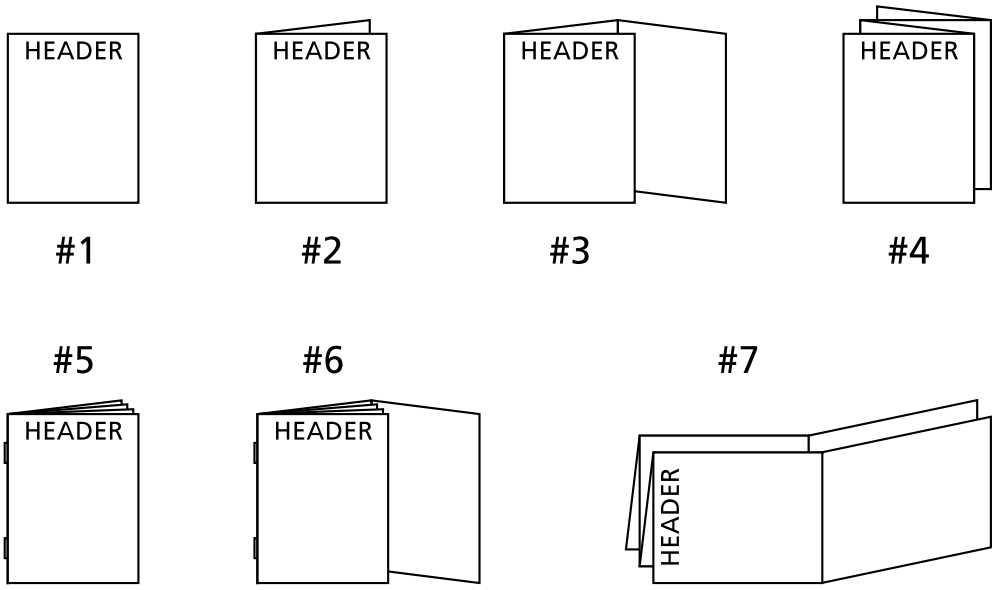
Revisions				SO 0046-2
Rev From	Rev To	ECO #	Date	Appr.
1189	0703	2030-03		

Notes

1. BD Cat. No. 261215
2. Blank (Sheet) Size : Length: 8.5" Width: 11"
   Number of Pages: 4 Number of Sheets: 1
   Page Size: Length 8.5" Width 5.5" Final Folded Size: 4.25" x 5.5"
3. Style (see illustrations below): #2



4. See Specification Control No. M775153 for Material Information
5. Ink Colors: Printed two sides [X] Yes [ ] No
   No. of Colors: 1 PMS# 2755 (blue)
6. Graphics are approved by Becton, Dickinson and Company. Supplier has the responsibility for using the most current approved revision level.

Label Design Date Proofer Date Checked By Date Part Number: M775153		BD Becton, Dickinson and Company 250 Schilling Circle Cockeysville, MD. 21030-0243 USA	
	Category and Description Package Insert Bio-Bag Type A	Sheet: 1 of 5 Scale: 1:1	A

BD Bio-Bag™ Environmental Chamber Type A

M775153
2003/07

INTENDED USE

Bio-Bag™ Type A is a transparent, individual, disposable environmental chamber that contains a gas generator consisting of one tablet of potassium borohydride and sodium bicarbonate and an ampule of hydrochloric acid, a catalyst cup containing palladium catalyst, and an indicator containing an ampule of resazurin. When the **Bio-Bag** containing all three components has been properly heat-sealed and the generator activated, an anaerobic environment will be created. An oxygen reduction indicator, resazurin, monitors the oxygen level.

Bio-Bag Type A is designed to provide an anaerobic environment suitable for the isolation of obligate or facultative anaerobic bacteria, while permitting visualization without disrupting the gaseous atmosphere. It is sized to hold either a standard 100 mm **BBL™** Petri dish, or anaerobic MIC microdilution tray.

SUMMARY AND EXPLANATION

Recognition of anaerobic organisms as causative agents of disease has become important to microbiologists and clinicians. New techniques in isolation, identification, and susceptibility testing have provided a better understanding of these fastidious organisms. Proper collection of specimens to prevent contamination by normal flora, to provide adequate material for testing, as well as appropriate transport of specimens to the laboratory, are critical in isolation and subsequent study of pathogens.[1-4]

By definition, anaerobic organisms require reduced levels or the absence of oxygen.[1] Some organisms can tolerate a short exposure to oxygen and are designated as aerotolerant.[1,3] The **Bio-Bag** Type A system, when directions are followed, provides a rapid reduction of atmospheric oxygen. Studies have shown levels of O_2 to be less than 1% at 1 h through 72 h.[5] Carbon dioxide is produced to enhance the growth of certain organisms.

Transparency of the **Bio-Bag** envelope allows macroscopic observation of each culture without disturbing the anaerobic atmosphere. Protection from exposure to oxygen is assured for the more fastidious organisms. As some anaerobic organisms exhibit colonies in 24 h, identification and antimicrobial susceptibility procedures can be initiated as soon as visible growth is observed.

Because of the individuality of this system, specimens can be set up as they arrive in the laboratory.

PRINCIPLES OF THE PROCEDURE

An anaerobic atmosphere is achieved in each sealed **Bio-Bag** Type A system. A self-contained generator consists of an ampule of a weak hydrochloric acid solution and a gas-generating tablet. When the ampule is crushed, the acid reacts with the tablet resulting in the formation of a mixture of gases including hydrogen and carbon dioxide. Hydrogen, in the presence of the palladium catalyst, quickly reacts with the atmospheric oxygen in the bag to form water. Removal of oxygen is indicated by the change in color, red to colorless, of the resazurin indicator included with the system.

REAGENTS

Each **Bio-Bag** Type A system consists of:

1 Gas Impermeable Environment Chamber

1 Gas Generator (containing one tablet of potassium borohydride and sodium bicarbonate and a 0.5 mL ampule of 1.8N hydrochloric acid)

1 Catalyst Container

1 Anaerobic Indicator (containing a 0.5 mL ampule of 0.001% resazurin)

Warnings and Precautions:

For *in vitro* Diagnostic Use.

Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. "Standard Precautions"[6-9] and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids.

WARNING: Hydrogen is generated. This gas is flammable and may be explosive. Avoid exposure to sparks or flame.

Do not use generator if it appears damaged or previously activated.

Do not allow generator to come in contact with water prior to use. Store in tightly closed bag with desiccant to assure integrity of the generator tablet.

Do not activate generator until **Bio-Bag** has been properly sealed.

Repeat procedure if indicator change is not observed 2 h after generation process.

Storage: Store at room temperature 15 – 30ºC. Store in tightly closed bag with desiccant to assure integrity of the generator tablet.

PROCEDURE

Materials Provided: Bio-Bag Environmental Chamber Type A (See "Availability")

Materials Required But Not Provided: Heat sealer, media of choice in 100 mm Petri dish and incubator.

For Petri Dish

1. Place inoculated Petri dish into **Bio-Bag**.
2. Place one Anaerobic Indicator, one Anaerobic Generator and one Catalyst Container into the **Bio-Bag** positioned on each side of the dish.

   Important: Insert so the arrows shown on the labels of the Anaerobic Indicator and Anaerobic Generator are pointing up toward the open end of the bag. Position catalyst cup so that grid is not in contact with the bag.

   NOTE: Plastic sleeve on Anaerobic Generator must be positioned directly over glass ampule.
3. Expel excess air from **Bio-Bag**, then insert open end of **Bio-bag** into a heat sealer and seal closed. Seal above notches in the bag.
4. Hold sealed **Bio-Bag** in upright position (heat-sealed end up).

For MIC Microtiter Plate

1. Place Anaerobic Indicator and Catalyst into bottom of the bag parallel to open end. Slide inoculated MIC Microtiter Plate into the **Bio-Bag** so that the long end of the tray is parallel to the open end of the **Bio-Bag**.
2. Place Anaerobic Generator beside the MIC Microtiter Plate so that the arrows on the labels of the Anaerobic Indicator and Anaerobic Generator are pointing in the same direction. Position catalyst cup so that grid is not in contact with the bag.

   NOTE: Plastic sleeve on Anaerobic Generator must be positioned directly over glass ampule.
3. Expel excess air from **Bio-Bag**, then insert open end of the **Bio-Bag** into a heat sealer and seal closed. Seal above notches in the bag.
4. Hold the sealed **Bio-Bag** so that the arrows on the labels of the Anaerobic Indicator and Anaerobic Generators are pointing in an upright position.

5. (a) First, crush Indicator ampule. To do so, pinch Indicator at label position, using thumb and forefinger. Allow solution from crushed ampule to saturate pledget inside the Indicator, permitting color to develop in approimately 30 sec.

   (b) Next, crush Generator ampule. To do so, pinch Generator at label position, using thumb and forefinger. Then, tap middle of Generator tube with forefinger allowing tablet (inside Generator) to drop into the generating solution.
6. Continue holding **Bio-Bag** in upright position until all gas is evolved. Allow approximately 60 sec. NOTE: If several bags are being set up at the same time, separate **Bio-Bags** to prevent accumulation of heat from the catalyst.
7. Place sealed **Bio-Bag** in incubator at desired temperature.
8. Check for gradual dissipation of color in Indicator's polyester pledget to confirm anaerobiosis.
9. It is recommended that the Indicator be rechecked at the end of 2 h. In case indicator color has not fully dissipated in 2 h, the proper atmosphere has not been generated.

Quality Control

A stock culture of *Bacteroides fragilis* subsp. *fragilis*, or other anaerobic organism, should be tested in the **Bio-Bag** Type A system periodically to assure adequate conditions for recovery and characteristic morphology.

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent NCCLS guidance and CLIA regulations for appropriate Quality Control practices.

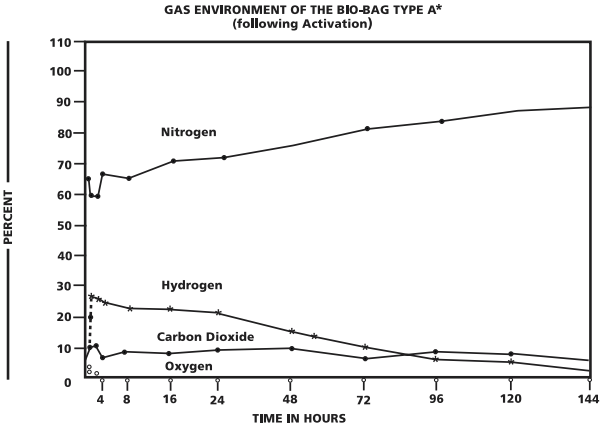
LIMITATIONS OF THE PROCEDURE

Exposure to oxygen prior to insertion into the **Bio-Bag** Type A may be harmful to some fastidious anaerobic pathogens.

Tablets in the generator may deteriorate if exposed to moisture. Care must be taken to store unused generators in closed storage bag with desiccants supplied.

RESULTS AND PERFORMANCE CHARACTERISTICS

Studies have shown **Bio-Bag** Type A to provide a suitable environment for the isolation of facultative and obligate anaerobic bacteria.[5]



Results:

Average percentage of 8 samples

*Studies performed at Marion Laboratories, Kansas City, Mo.

Plate Isolation of Anaerobes Following Incubation In Bio-Bag Environmental Chamber Type A*

BACTERIA	SOURCE	RATE OF GROWTH	
		24 h	48 h
B. biacutus	Tracheostomy	1+	4+
B. fragilis subsp. *distasonis*	Abscess	1+	4+
B. fragilis subsp. *fragilis*	Peritoneal Cavity	4+	4+
B. fragilis subsp. *fragilis*	Right Temple	4+	4+
B. fragilis subsp. *fragilis*	Appendix	4+	4+
B. fragilis subsp. *fragilis*	Abdominal Abscess	4+	4+
B. fragilis subsp. *fragilis*	Appendix	3+	4+
B. fragilis subsp. *fragilis*	Wound	4+	3+
B. fragilis subsp. *ovatus*	Blood	4+	4+
B. fragilis subsp. *vulgatus*	Wound	3+	4+
B. fragilis subsp. *vulgatus*	Wound	2+	3+
B. fragilis subsp. *vulgatus*	Midline incision	4+	4+
B. melaninogenicus subsp. *asaccharolyticus*	Tracheostomy	4+	4+
B. melaninogenicus subsp. *asaccharolyticus*	Bronchial Aspirate	2+	2+
B. melaninogenicus subsp. *asaccharolyticus*	Tracheostomy	2+	2+
B. melaninogenicus subsp. *intermedius*	Wound	1+	2+
B. oralis	Wound	1+	4+
C. cadaveris	Appendix	4+	4+
C. innocuum	Drain (Colostomy)	2+	4+
C. perfringens	Wound	4+	4+
C. perfringens	Abdominal Drain	4+	4+
C. perfringens	Peritoneal Cavity	4+	4+
C. perfringens	Peritoneal Cavity	4+	4+
C. perfringens	Blood	4+	4+
C. perfringens	Bowel resection	4+	4+
C. septicum	Wound	1+	4+
C. sphenoides	Pilonidal Cyst	4+	4+
C. sphenoides	_ _ _	2+	4+
C. sordelli	Appendix	2+	3+
C. sporogenes	Peritonitis	1+	3+
C. tetani	Peri-Rectal Abscess	4+	4+
E. lentum	Pus	0	3+
F. mortiferum	Dental Abscess	1+	3+
F. mortiferum	Peritoneal Cavity	3+	3+
F. necrophorum	Cervix	2+	4+
F. nucleatum	Mouth Abscess	2+	2+
P. acnes	Blood	2+	2+
P. asaccharolyticus	Wound	2+	3+
P. asaccharolyticus	Drainage (Abdomen)	3+	3+
P. asaccharolyticus	Abscess	2+	3+
P. asaccharolyticus	Wound	2+	2+
P. magnus	Leg	2+	3+
P. magnus	Wound	2+	3+
P. anaerobius	Cervix	2+	2+
P. anaerobius	Bowel Fistula	3+	3+
P. anaerobius	Leg	1+	2+
P. anaerobius	Wound	1+	3+
P. anaerobius	Pus	1+	4+
P. anaerobius	Blood	4+	4+
P. anaerobius	Peritoneal Cavity	0	2+
V. parvula	_ _ _	1+	4+

Key: 1+ = Scant Growth
2+ = Good Growth - Discrete Colonies
3+ = Heavy Growth - Discrete Colonies
4+ = Heavy Confluent Growth w/Few Discrete Colonies

* Study performed by Wilson J. Fahlberg, Ph. D., Baylor College of Medicine, Houston, TX, Methodist Hospital and Memorial Hospital System, Houston, TX.

AVAILABILITY

Cat. No.	Description
261215	**Bio-Bag**™ Environmental Chamber Type A, 25 sets per carton.
261214	**Bio-Bag**™ Environmental Chamber Type A, 100 sets per carton.

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Becton,Dickinson and Company
7 Loveton Circle
Sparks, Maryland 21152 U.S.A.
800-638-8663