remel

BactiDisk®

INTENDED USE

Remel BactiDisk[®] are stabilized cultures of bacteria or yeast recommended for use in laboratory quality control procedures.

SUMMARY AND EXPLANATION

PRINCIPLE

Gelatin is a solidifying agent which forms a solid disk to transport the culture. Skim milk, dextrose, and ascorbic acid are cryoprotective agents during the drying process. Charcoal neutralizes toxic substances that may develop during lyophilization. The microorganisms in BactiDisk® are derived from cultures of the American Type Culture Collection (ATCC®), under license, or from clinical and industrial culture collections.

REAGENTS (CLASSICAL FORMULA)*

Gelatin Ascorbic Acid
Skim Milk Charcoal (optional)
Dextrose Microorganism

PRECAUTIONS

This product is For the Quality Control of *In Vitro* Diagnostic Products and should be used by properly trained individuals. Precautions should be taken against the dangers of microbiological hazards by properly sterilizing specimens, containers, and media after use. Directions should be read and followed carefully.

Caution! BactiDisk[®] contains viable microorganisms that are potentially infectious. Organisms should be handled at the appropriate Biosafety Level according to CDC/NIH guidelines.⁴ Refer to the Material Safety Data Sheet for more detailed information.

STORAGE

Store product in its original container at 2-8°C until used. Allow product to equilibrate to room temperature before use. Do not incubate prior to use. Ensure the cap is replaced and tightened to prevent moisture and atmospheric exposure.

PRODUCT DETERIORATION

This product should not be used if (1) there is evidence of hydration, (2) the color of the disk has changed, (3) the expiration date has passed, or (4) there are other signs of deterioration.

MATERIALS REQUIRED BUT NOT SUPPLIED

(1) Loop sterilization device, (2) Inoculating loop, sterile forceps, (3) Incubators, alternative environmental systems, (4) Supplemental media

PROCEDURE

Each BactiDisk[®] is made from a gelatin formulation. For rehydration to occur, the disk must come in contact with both **warmth and moisture**. Rehydrate the disk according to either method outlined below using **nonselective** culture media.

- 1. Procedure A (Recommended for fastidious organisms)
 - Using sterile forceps, add the disk to 0.1 ml of Tryptic Soy Broth (TSB) (R064892).
 - Incubate at 35-37°C for 15 minutes or until the disk is dissolved. Do not exceed 1 hour.
 - c. Once the disk is dissolved, transfer a loopful of the TSB suspension to a suitable nonselective agar plate and streak for isolation. **Note:** To recover more colonies, transfer the entire contents of the suspension to the agar plate.
 - d. Incubate agar plate as described in the Table.

2. Procedure B

- a. Warm appropriate plated media to 35-37°C.
- b. Using sterile forceps, rub the disk across a suitable nonselective agar plate several times. The organisms will release onto the agar medium as the moisture from the agar surface dissolves the disk.
- c. Incubate agar plate as described in the Table.

Table: Suggested Subculturing for BactiDisk®

ORGANISM	MEDIUM	INCUBATION
Non-fastidious, gram-positive or gram-negative aerobes and facultative anaerobes	Blood Agar (TSA w/ 5% Sheep Blood)	Ambient, 24-72 h @ 35-37°C
CO ₂ dependent organisms (e.g., <i>Neisseria</i> spp., <i>Haemophilus</i> spp., <i>Gardnerella</i> spp.)	Chocolate Agar	5-10% CO ₂ , 24-72 h @ 35-37°C
Anaerobic organisms*	Nonselective Anaerobic (CDC) Blood Agar, Reducible Blood Agar, or Brucella Blood Agar w/ Hemin & Vitamin K	Ambient, up to 72 h @ 35-37°C (5-7 days may be required for <i>Porphyromonas gingivalis</i>)
Yeasts	Sabouraud Dextrose Agar or BHI w/ Sheep Blood Agar	Ambient, 48-72 h @ 25-30°C
Campylobacter spp.	Chocolate Agar	Microaerophilic, 48-72 h @ 35-37°C
Legionella spp.	Buffered CYE Agar	Ambient, 48-72 h @ 35-37°C
Bordetella spp.*	Bordet Gengou Agar	Ambient, 2-4 days @ 35-37°C

^{*}A moist chamber is required for prolonged incubation

^{*}Adjusted as required to meet performance standards.

NOTE: These instructions are for the initial inoculation of BactiDisk[®]. Quality control of diagnostic products should be performed as specified in the manufacturer's instructions for use (IFU) or other recommended guidelines.⁵⁻⁸

QUALITY CONTROL

All lot numbers of BactiDisk® have been tested using standard laboratory procedures and have been found to be acceptable. If aberrant results are observed, the product should not be used for quality control testing procedures.

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PACKAGING

Remel BactiDisk $^{\otimes}$ is packaged 10 Disks/Vial. Refer to Remel product catalog or visit <u>www.remel.com</u> for a complete list of available organisms.

Symbol Legend

REF	Catalog Number	
IVD	In Vitro Diagnostic Medical Device	
LAB	For Laboratory Use	
[]i	Consult Instructions for Use (IFU)	
A	Temperature Limitation (Storage Temp.)	
LOT	Batch Code (Lot Number)	
\subseteq	Use By (Expiration Date)	
₩	Biological Risk (Infectious Substance)	

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