

Revisions


Rev from	Rev to	ECO #
B	C	2720-04

Notes:

- BD Cat. Number 446250
- Blank (Sheet) Size : Length: 11" Width: 8.5"
 Number of Pages: 2 Number of Sheets: 1
 Page Size: Length 11" Width 8.5" Final Folded Size: 5.5" x 4.25"
- Style (see illustrations below): # 1



- See Specification Control Number 670091JAA for Material Information
- Ink Colors: Printed two sides Yes No
 No. of Colors: 1 PMS# Black
- Graphics are approved by Becton, Dickinson and Company. Supplier has the responsibility for using the most current approved revision level

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Proofer	Date			
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Part Number: 670091JAA		Category and Description Package Insert, Affirm Sample Collection Set	Sheet: 1 of 3 Scale: N/A	A

BD Affirm™ VPIII Sample Collection Set For use with the Affirm™ Microbial Identification Test

670091JAA(C)
2004/03

INTENDED USE

The Affirm™ VPIII Sample Collection Set is used for collecting vaginal fluid specimens for use with the Affirm VPIII Microbial Identification Test.

REAGENTS

Affirm VPIII Sample Collection Sets (24), each containing:

- 1 Individually wrapped, pre-scored sterile swab
- 1 Sample Collection Tube
- 1 Sample Collection Tube Cap
- 1 Resealable Sample Transport Bag
- 1 Instruction sheet

Warnings and Precautions

For *in vitro* Diagnostic Use.

Read all instructions carefully before use.

Specimens collected with the Affirm VPIII Sample Collection Set should *only* be used for testing with the Affirm VPIII Microbial Identification Test.

Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. Standard Precautions¹⁻⁴ and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids.

Proper handling and disposal methods should be established. Wipe up any spillage of patient specimens immediately and disinfect with an appropriate disinfectant. Treat the cleaning materials as biohazardous waste.

The swab should not be used if its packaging is open or damaged.

Storage

The Affirm VPIII Sample Collection Sets should be stored at 15-30°C.

LIMITATIONS OF THE PROCEDURE

The Affirm VPIII Sample Collection Set has been designed for use with vaginal specimens. The use of this collection kit with other types of specimens has not been established.

Specimens held longer than 1 h at 15-30°C, or 4 h at 2-8°C may cause false results.

Affirm VPIII swabs should not be used for other tests or for culture or microscopic slide samples. This kit is not intended for collecting culture specimens.

AVAILABILITY

Cat. No.	Description
446250	Affirm™ Sample Collection Set, 24 sets
446252	Affirm™ VPIII Microbial Identification Test, 24 tests
250100	BD MicroProbe™ Processor, 120 V
211918	BD MicroProbe™ Processor, 220/240 V
446251	Affirm™ VPIII Sample Collection Swabs, 100
446255	Affirm™ VPIII Ambient Temperature Transport System (72 h transport system), 100 systems

REFERENCES

1. National Committee for Clinical Laboratory Standards. 2001. Approved Guideline M29-A2. Protection of laboratory workers from occupationally acquired infections, 2nd ed. NCCLS, Wayne, Pa.
2. Garner, J.S. 1996. Hospital Infection Control Practices Advisory Committee, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Guideline for isolation precautions in hospitals. *Infect. Control Hospital Epidemiol.* 17:53-80.
3. U.S. Department of Health and Human Services. 1999. Biosafety in microbiological and biomedical laboratories, HHS Publication (CDC), 4th ed. U.S. Government Printing Office, Washington, D.C.
4. Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC). *Official Journal L262*, 17/10/2000, p. 0021-0045.

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PROCEDURE

Materials Provided: 24 each: Individually wrapped, pre-scored sterile swabs, Sample Collection Tubes, Sample Collection Tube Caps, Resealable Sample Transport Bags.

Materials Required But Not Provided (see "Availability"): Affirm VPIII Microbial Identification Test, BD MicroProbe Processor with Lysis Block, thermometer.

NOTE: READ ALL INSTRUCTIONS CAREFULLY BEFORE PROCEEDING.

Sample collection is a critical step. Personnel collecting vaginal fluid specimens should be well trained to ensure adequate sample collection. All samples must be collected using the materials (swabs and tubes) provided in the set.

Vaginal Sample Collection

1. Label the **Sample Collection Tube (SCT)** with the patient identification information. Include the time the sample was collected.
2. Place the patient in position for a pelvic examination. Insert an UNLUBRICATED speculum (WITHOUT JELLY OR WATER) into the vagina to permit visualization of the posterior vaginal fornix.
3. Using the sterile swab, obtain a sample from the posterior vaginal fornix. Twist or roll the swab against the vaginal wall two or three times, ensuring the entire circumference of the swab has touched the vaginal wall. Swab the lateral vaginal wall while removing the swab. (see Figure 1)
4. Immediately place the swab in the Sample Collection Tube (SCT).
5. With the swab touching the **BOTTOM** of the collection tube, grasp the pre-scored handle of the swab just above the top of the tube and bend until the swab breaks (Figure 2). When the swab is fully inserted into the collection tube, the score mark on the swab is approximately 1 cm above the top of the collection tube. Discard the broken handle into an infectious waste container.
6. Place the cap over the exposed end of the swab and firmly press the cap onto the tube. The cap will "snap" onto the tube when it is properly seated.
7. Place the capped **Sample Collection Tube (SCT)** into the plastic **Sample Transport Bag** for transport for testing with the **Affirm VPIII Microbial Identification Test**.

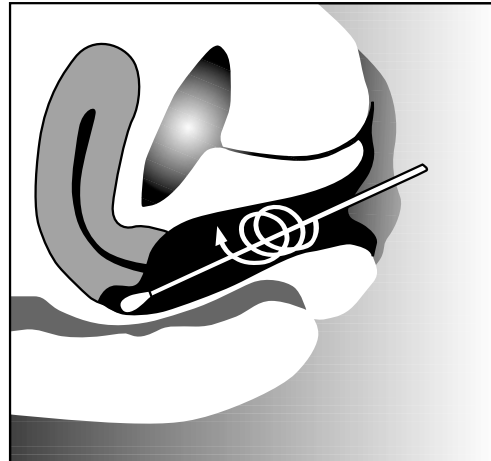


Figure 1

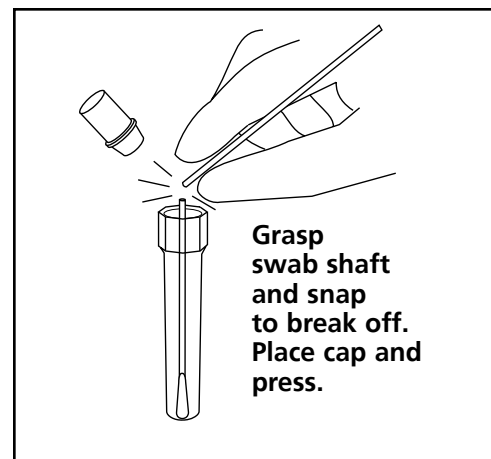


Figure 2

Transport and Storage of Vaginal Sample

Transport the vaginal sample to the processing area as soon as possible following collection. The elapsed time between placing the swab into the **Sample Collection Tube** and proceeding with sample preparation should be no longer than one (1) h for samples stored at 15-30°C, or no longer than four (4) h for samples stored at 2-8°C.

If it is not possible to proceed with sample preparation within this time frame, the **Affirm VPIII Ambient Temperature Transport System** (see "Availability") may be used.

When using the **Affirm VPIII Sample Collection Set**, specimens held longer than 1 h at room temperature or 4 h at 2-8°C prior to preparation may cause false results.