

Laboratory Procedure

BD Affirm™ VPIII Ambient Temperature Transport System

For collection and extended transport of vaginal specimens for use in the Affirm VPIII Microbial Identification Test.

I. INTENDED USE

Affirm™ VPIII Ambient Temperature Transport is a sterile ready-to-use system intended for the collection, transport and preservation of vaginal specimens for use only with the **Affirm VPIII** Microbial Identification Test. The **Affirm VPIII** Ambient Temperature Transport System (ATTS) should be used with those specimens where transport times are expected to exceed 1 h at ambient temperature (15 – 30°C) or 4 h at refrigerated temperatures (2 – 8°C).

II. SUMMARY

One of the routine procedures in the use of the **Affirm VPIII** Microbial Identification Test involves the collection and stable transportation of a vaginal specimen from the patient to the laboratory. This can be accomplished using the **Affirm VPIII** Ambient Temperature Transport System.

The **Affirm VPIII** Ambient Temperature Transport System is designed to stabilize the nucleic acid of *Candida* species, *Gardnerella vaginalis*, and *Trichomonas vaginalis* during specimen transport at ambient temperature (15 – 30°C) for up to 72 h. This system has also been qualified for transport use at 2 – 8°C. The Ambient Temperature Transport Reagent Dropper contents are dispensed into the Sample Collection Tube. The patient vaginal specimen is immediately collected and the polyester-tip swab containing the patient specimen is placed in the Sample Collection Tube containing the Ambient Temperature Transport Reagent. The swab shaft is broken at the scored point and the top portion of the swab is discarded. The Sample Collection Cap is placed over the exposed end of the swab and is firmly seated on the Sample Collection Tube. The capped Sample Collection Tube is sealed in the outer bag of the **Affirm VPIII** Ambient Temperature Transport System and transported to the laboratory within 72 h.

III. PRINCIPLES OF THE PROCEDURE

When a vaginal specimen is collected and processing is delayed past the recommended time frame, changes in the specimen may result in erroneous **Affirm VPIII** test results. The formulation of the ATTS Reagent and the design of the transport system allows preservation of the nucleic acids and inhibits growth of *Candida* sp., *Gardnerella vaginalis* and *Trichomonas vaginalis* from patient specimens for up to 72 h under ambient as well as refrigerated conditions.

IV. REAGENTS

Warnings and Precautions: For *in vitro* Diagnostic Use

Affirm VPIII Transport Reagent: Substance is toxic and highly flammable. Irritating to eyes, respiratory system and skin. Use in a well-ventilated place. Keep away from sources of ignition. No smoking. Wear protective clothing and gloves. Immediately remove any clothing soiled by the product. If inhaled, supply fresh air or oxygen; consult Material Safety Data Sheet (MSDS) and seek medical advice. After skin contact, immediately rinse with water. After eye contact, rinse immediately with plenty of water, consult MSDS and seek medical advice.

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 polyester-tip swab should not be used if the packaging is opened or damaged.

The Ambient Temperature Transport System should not be used if its foil pouch is open or the ATTS Reagent Dropper is damaged.

When specimen transport times exceed 72 h, a reduction in sensitivity may be observed.

Preparation and Storage of materials:

All materials are supplied ready for use. Store at ambient temperature (15 – 30°C).

Keep away from heat – contents are flammable (see “Precautions”).

V. MATERIALS PROVIDED

1. Instructions for Sample Collection, 1 package insert.
2. **Affirm VPIII** Ambient Temperature Transport System, 10 (446253) and 100 (446255).

Each plastic pouch in the **Affirm VPIII** Ambient Temperature Transport System contains what is required to collect one vaginal specimen for use only with the **Affirm VPIII** Microbial Identification Test. Each **Affirm VPIII** Ambient Temperature Transport System includes:

- Individually wrapped, pre-scored, sterile polyester-tip swab
- Sample Collection Tube
- Sample Collection Cap
- Ambient Temperature Transport Reagent Dropper (in foil pouch).

3. Patient Specimen Labels, 24 labels (446253) and 240 labels (446255)

VI. SPECIMEN COLLECTION

The **Affirm VPIII Ambient Temperature Transport System** was designed for use with those specimens where transport times are expected to exceed 1 h at ambient temperature or 4 h at refrigerated temperatures.

WARNING: Pathogenic microorganisms, including Hepatitis Viruses and Human Immunodeficiency Virus, may be present in clinical specimens. “Standard Precautions”¹⁻⁴ and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids.

VII. PROCEDURE

NOTE: READ ALL INSTRUCTIONS CAREFULLY BEFORE PROCEEDING.

Preparation of Transport System and Collection of Vaginal Sample –

Sample Collection is a critical step. Personnel collecting vaginal fluid specimens for transport with this system should be well trained on adequate sample collection *technique*. All samples for use with the **Affirm VPIII** Microbial Identification Test must be collected using the materials provided with this system.

1. Open the seal on outer plastic pouch of **Affirm VPIII** Ambient Temperature Transport System and remove all components [each plastic pouch contains enough material for the collection and transport of one vaginal specimen].
2. Tear open the foil pouch and remove the ATTS Reagent Dropper.
3. Break ampule in ATTS Reagent Dropper by firmly squeezing vial with finger and thumb.

CAUTION: Break ampule close to its center one time only. Do not manipulate dropper any further, as the plastic may puncture and injury may occur.

4. Dispense reagent from ATTS Reagent Dropper into Sample Collection Tube.
 5. Peel wrapper to expose patient swab. Remove swab. Discard wrapper.
 6. Collect patient specimen/take sample.
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- 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.
 - Using the sterile polyester-tip 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.
7. Immediately place the patient swab in the Sample Collection Tube containing the ATTS Reagent.
 8. Break swab shaft at pre-scored line just above the top of the tube. Discard remaining shaft into an infectious waste container.
 9. Place the Sample Collection Cap over the exposed end of the swab and firmly press the cap onto the Sample Collection Tube. The cap will ‘snap’ onto the tube when it is properly seated.
 10. Label the Sample Collection Tube with patient/lab identification information. Include date and time that sample was taken.

Transport and Storage of Vaginal Sample:

Send the capped Sample Collection Tube to the lab by sealing it in the emptied outer plastic pouch of the **Affirm VPIII** Ambient Temperature Transport System. Label plastic pouch with appropriate information.

VIII. LIMITATIONS OF THE PROCEDURE

The **Affirm VPIII** sample collection and specimen processing procedure has been designed for use with vaginal specimens that are only to be tested using the **Affirm VPIII** Microbial Identification Test. The use of this procedure with other specimen types has not been established.

The use of this product in a manner not specified above has not been established.

Separate swabs should be used for other tests, e.g. culture or microscopic slide samples. This kit is not intended for collecting culture specimens.

Swabs other than the ones provided with this system must not be used with the **Affirm VPIII** Ambient Temperature Transport System.

This system has been qualified for transport use at ambient conditions (15 – 30°C) and refrigerated conditions (2 – 8°C) for up to 72 h.

When specimen transport times exceed 72 h, a reduction in sensitivity may be observed.

Patient specimens must be collected immediately after the ATTS Reagent has been dispensed into the Sample Collection Tube. **DO NOT** pre-dispense the ATTS Reagent into the Specimen Transport Tube.

IX. EXPECTED VALUES AND PERFORMANCE CHARACTERISTICS

The **Affirm VPIII** Ambient Temperature Transport System has been designed to stabilize the nucleic acid of *Candida* species, *Gardnerella vaginalis*, and *Trichomonas vaginalis* during specimen transport at ambient temperature (15 – 30°C) for up to 72 h. This system has also been qualified for transport use at 2 – 8°C. Data is on file at Becton Dickinson Diagnostic Systems.

X. AVAILABILITY

446253 **Affirm VPIII** Ambient Temperature Transport System, 10 systems per carton.

446255 **Affirm VPIII** Ambient Temperature Transport System, 100 systems per carton.

XI. REFERENCES

1. National Committee for Clinical Laboratory Standards. 1997. Approved Guideline M29-A. Protection of laboratory workers from instrument biohazards and infectious disease transmitted by blood, body fluids and tissue. 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 Article 16(1) of Directive 89/391/EEC). Official Journal L262, 17/10/2000, p. 0021-0045.

5. Recommendations for preventing transmission of Human Immunodeficiency Virus and Hepatitis B Virus to patients during exposure-prone invasive procedures. MMWR 1991, Vol. 40. No. RR-8.

Approved By:

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Supervisor: _____ Date: _____

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