

**Vaginal Trichomonas, Gardnerella,  
Candida DNA Probe**  
7763/LAB7763

**CLINICAL SIGNIFICANCE/PURPOSE**

The Affirm™ VPIII Microbial Identification Test is a DNA probe test. It is intended for use in the detection and identification of *Candida* species, *Gardnerella vaginalis* and *Trichomonas vaginalis* nucleic acid in vaginal fluid specimens from patients with symptoms of vaginitis/vaginosis.

BD Affirm VPIII Microbial ID Test			
Organism	Sensitivity %	Specificity %	Accuracy %
<i>Candida sp.</i>	82.3	98.4	95.2
<i>G. vaginalis</i>	95.2	100	95.3
<i>T. vaginalis</i>	92.8	99.9	98.9
Overall	90.1	99.4	96.5

**SAMPLE INFORMATION**

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

Acceptable specimen: Vaginal specimen in BD Affirm VPIII Ambient Temperature Transport System. See collection instructions under "Procedure".

Transport:

- Ambient temperature (15-30 °C) for up to 72 hours
- Refrigerated temperature (2-8 °C) for up to 72 hours

Unacceptable:

- No swab in BD Affirm VPIII Ambient Temperature Transport System
- Swab not from BD Affirm collection kit
- Frozen
- Sources from other than vaginal site
- BD Affirm Transport Reagent not added to swab (swab is dry)
  - Before rejection compress swab against the side of the transport tube.
- Specimen exceeding 72 hours after collection
- Self-collected vaginal specimens. See Limitations.

**SUPPLIES/MATERIALS**

Affirm VPIII Ambient Temperature Transport System (100 systems/box), Cardinal # 446255  
Each plastic pouch includes;

- Individually-wrapped, pre-scored sterile swab
- Sample collection tube
- Sample collection cap

Store at ambient temperature (15-30°C)

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**SAFETY PRECAUTIONS**

Affirm VPill transport reagent: toxic and highly flammable. Irritating to eyes, respiratory system, and skin. Use in well-ventilated place. Keep away from sources of ignition. Wear protective clothing and gloves. After skin contact, immediately rinse with water. After eye contact, immediately rinse with plenty of water, consult MSDS sheet, and seek medical advice.

**PROCEDURE**

**Order:** 7763/LAB 7763 Vaginal Trichomonas, Gardnerella, Candida DNA Probe

**Test performed:** Allina Health Central Laboratory, 7 days/week, all shifts

- Turnaround time: Stat – 90 min
- Routine orders will be performed as workflow permits, but must be completed within the 8 hr. shift.

**Specimen**

**collection:** The following instructions are provided on the kit packages and in package insert.

1. Open the foil pouch and remove the ATTS (Ambient Temperature Transport System) Reagent Dropper
2. Break ampule in ATTS Reagent Dropper by firmly squeezing the dropper close to its center with finger and thumb, **ONE TIME ONLY**.
3. Dispense entire ATTS Reagent into Sample Collection Tube by continuing to squeeze the dropper.  
Note: The patient specimen must be collected immediately after the ATTS reagent has been dispensed. **Do NOT pre-dispense the ATTS reagent into the Specimen Transport Tube.**
4. Peel wrapper to expose patient swab. Remove swab, discard wrapper.
5. Collect patient specimen
  - Place the patient in position for a pelvic examination. Insert speculum into the vagina to permit visualization of the posterior vaginal fornix.
  - Using the sterile swab, obtain a sample from the posterior vaginal fornix. Twist or roll the swab against the vaginal walls 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.
6. Immediately place the patient swab in the Sample Collection Tube containing the ATTS Reagent.
7. 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. Discard the remaining shaft into an infectious waste container.
8. 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.
9. Label the Sample Collection Tube with patient identification information. Include date and time that the sample was collected.
10. Transport to Allina Health Laboratory, refrigerated or at ambient temperature.

## METHOD LIMITATIONS

- The Affirm VPIII Microbial Identification Test is for use with vaginal specimens from patients with symptoms of vaginitis/vaginosis. Performance with other specimens or other patient populations has not been established.
- Patient specimen must be collected immediately after the ATTS reagent has been dispensed into the Sample Collection tube.
- The assay is intended to be used with the Affirm VPIII Ambient Temperature Transport System Set. Other methods of collection have not been evaluated.
- Specimen collection is a critical step. Personnel collecting the vaginal specimen should be well-trained to minimize the possibility of inadequate specimens.
- Blood and water-based lubricants do NOT interfere with the test.
- Detection is dependent on the quantity of organisms present in the specimen. This is influenced by patient factors, stage of infection, organism strain, and adequate specimen collection.
- A negative test result does not exclude the possibility of vaginitis/vaginosis.
- The presence of *G. vaginalis*, although suggestive, is not diagnostic for bacterial vaginosis. As in many clinical situations, diagnosis should not be based on the results of a single laboratory test. Results should be interpreted in conjunction with other clinical and laboratory data.
- Mixed infections may occur. Therefore, a test indicating the presence of *Candida* species, *G. vaginalis*, and/or *T. vaginalis*, does not rule out the presence of other organisms, including *Mobiluncus mulieris*, *Mycoplasma hominis*, and/or *Prevotella bivia*.
- The presence or absence of *Candida* species, *G. vaginalis*, or *T. vaginalis* cannot be used as a test for therapeutic success or failure. DNA may persist for 4-6 weeks after treatment.