ClearPoint DIAGNOSTIC LABORATORIES

At the ConVergence Center | 2501 South State Highway 121 Business | Suite 1200
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**LAB ALERT – NEW TEST**

**NOTIFICATION DATE:** 11/19/2013
**EFFECTIVE DATE:** 11/19/2013

## Vaginitis with STD Panel by NAAT, without Pap

**TEST CODE:** VSTDP

**INTERFACE CODE:** 1004444

**METHODOLOGY:** Nucleic acid amplification testing (NAAT)

**CLINICAL UTILITY:** Bacterial, yeast, viral and parasitic infections in women typically cause vaginitis, urethritis, and cervicitis. Common symptoms include vaginal discharge, vulvovaginal irritation, and/or dysuria. However, recurrent and/or untreated sexually transmitted infections (STIs) can result in ectopic pregnancy, infertility, and the possible risk of physical and developmental disabilities in fetus, including fetal death in few cases. Healthcare providers must assess the risk of STIs and provide counseling for prevention and treatment for all women of childbearing age. Nucleic acid amplification testing (NAAT) is analytically more sensitive than culture and antigen detection methods and is recommended for targeted STI screening and prevention.

Vaginitis with STD Panel by NAAT, without Pap provides efficient, accurate and cost-effective testing solutions for vaginitis and STD co-infections using molecular techniques with well-established clinical correlation. This helps physicians to get multiple actionable results in a timely manner using clinically-proven technologies. The panel detects *Neisseria gonorrhea, Chlamydia trachomatis, Trichomonas vaginalis,* detects and differentiates between Herpes Simplex Virus 1 and 2, and between *Candida albicans* and *Candida glabrata.*

**PERFORMED:** Monday-Friday

**COLLECTION:**

**Vaginal Specimens: APTIMA Vaginal Swab Collection Kit (Figure 1)**

1. Collect vaginal fluid sample using the Gen-Probe APTIMA® vaginal swab kit by contacting the swab to the lower third of the vaginal wall and rotating the swab for 10 to 30 seconds to absorb fluid.
2. Immediately place the swab into the transport tube and carefully break the swab shaft against the side of the tube.
3. Tightly screw on the cap.
4. The APTIMA Vaginal Swab Collection Kit is the ONLY Collection Kit approved for vaginal specimens. DO NOT use the APTIMA Combo 2 Unisex Swab Collection Kit for collecting vaginal specimens.

**Cytology (Pap) Vials (Figure 2)**

1. Obtain cervical scrapings using either ThinPrep or SurePath fixative according to the Pap smear collection guidelines.
2. Pap (cytology) should be submitted in Cytc ThinPrep vial or SurePath vial, or pre-aliquoted 1mL of either ThinPrep or SurePath liquid cytology media in an APTIMA® Specimen Transfer kit tube (green tube).

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**STABILITY (FROM COLLECTION TO INITIATION OF TESTING):** APTIMA Vaginal Swab: Ambient: 60 days; Refrigerated: 60 days; Frozen: Unacceptable
SurePath: Ambient: 24 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
ThinPrep: Ambient: 1 month; Refrigerated: Unacceptable; Frozen: Unacceptable

**TRANSPORT:** Ambient

**REFERENCE RANGE:** Target Not Detected (TND)

**RESULTS REPORTED:** 2-5 days

**CPT CODE:** 87491 (Chlamydia); 87591 (Gonorrhea); 87798 (Trichomonas); 87529x2 (HSV Type 1& 2); 87481x2 *(Candida albicans/ glabrata)*

**PERFORMING LAB:** med fusion

**COLLECTION DEVICES:**

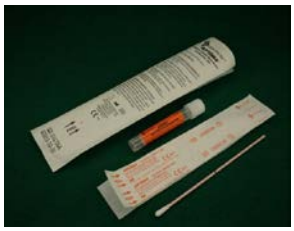

Figure 1.

APTIMA Vaginal Swab Collection Kit

Order # B30079

Figure 2.

APTIMA Specimen Transfer Tube - Order # B11700
SurePath - Order # P490527
ThinPrep - Order #P70098

**CONTACT INFORMATION:** *ClearPoint Client Services: 972-966-7700 | Fax: 972-966-7799*