
LAB ALERT – NEW TEST**NOTIFICATION DATE:** 11/19/2013**EFFECTIVE DATE:** 11/19/2013**STD Panel 1 by NAAT, without Pap****TEST CODE:** STDP1**INTERFACE CODE:** 1004442**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.

STD Panel 1 by NAAT, without Pap provides efficient, accurate and cost-effective testing solutions for multiple STD 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 gonorrhoea*, *Chlamydia trachomatis* and *Trichomonas vaginalis*.

PERFORMED: Monday-Wednesday-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.

Endocervical: APTIMA Combo 2 Unisex Swab Collection Kit (Figure 2)

1. Remove excess mucus from the cervical os and surrounding mucosa using the cleaning swab (white shaft swab in the package with red printing). Discard this swab. Note: To remove excess mucus from the cervical os, a large-tipped cleaning swab (not provided) may be used. Discard swab after use.
2. Insert the specimen collection swab (blue shaft swab in the package with green printing) into the endocervical canal.
3. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling.
4. Withdraw the swab carefully; avoid any contact with the vaginal mucosa.

5. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
6. Carefully break the swab shaft at the scoreline; use care to avoid splashing of the contents.
7. Recap the swab specimen transport tube tightly.

Urine: APTIMA Urine Collection Kit (Figure 3)

1. The patient should not have urinated for at least one hour prior to specimen collection.
2. Direct patient to provide first-catch urine (approximately 20 to 30 mL of the initial urine stream) into a urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity. Female patients should not cleanse the labial area prior to providing the specimen.
3. Remove the cap and transfer 2 mL of urine into the urine specimen transport tube using the disposable pipette provided in the APTIMA Urine collection kit (Figure 3). The correct volume of urine has been added when the fluid level is between the black fill lines on the urine transport tube label.
4. Re-cap the urine specimen transport tube tightly. This is now known as the **processed urine** specimen.

Cytology (Pap) Vials (Figure 4)

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).

STABILITY (FROM COLLECTION TO INITIATION OF TESTING):	APTIMA Swabs: Ambient: 60 days; Refrigerated: 60 days; Frozen: Unacceptable Processed Urine: Ambient: 30 days; Refrigerated: 30 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:	1-4 days
CPT CODE:	87491 (Chlamydia); 87591 (Gonorrhea); 87798 (Trichomonas)
PERFORMING LAB:	med fusion

COLLECTION DEVICES:



Figure 1.
APTIMA Vaginal Swab Collection Kit
Order # B30079



Figure 2.
APTIMA, Swab Collection Kit, Unisex (Endocervical /Urethral)
Order # 11071



Figure 3.
APTIMA, Urine Collection Kit, Unisex
Order #11072



Figure 4.
APTIMA Specimen Transfer Tube - Order # B11700
SurePath - Order # P490527
ThinPrep - Order #P70098

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