

**LAB ALERT – GENERAL COMMUNICATION**

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

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

**WOMEN’S HEALTH PORTFOLIO**

We are pleased to announce the launch of the Women’s Health Vaginal Swab and Pap portfolios. These customized portfolios provide efficient, accurate and cost-effective testing solutions for women’s health using a combination of traditional “Gold Standard” microbiological methodologies and molecular techniques with well-established clinical correlation. This helps physicians get multiple actionable results in a timely manner using clinically-proven technologies.

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.

The following customized women health panels are orderable **with Paps**:

TEST NAME	TEST CODE	INTERFACE CODE	PANEL COMPONENTS	CLINICAL UTILITY	ACCEPTABLE COLLECTION TYPES
SurePath STD Panel 1 by NAAT	SUREPSTDP12P	1004483	<i>Chlamydia</i> <i>Gonorrhea</i> <i>Trichomonas</i>	Molecular testing for patients with multiple STD infections	SurePath
ThinPrep STD Panel 1 by NAAT	THINPSTDP12P	1004487			ThinPrep
SurePath STD Panel 2 by NAAT	SUREPSTDP22P	1004484	<i>Chlamydia</i> <i>Gonorrhea</i> <i>Trichomonas</i> HSV Type 1&2	Molecular testing for patients with multiple STD infections	SurePath
ThinPrep STD Panel 2 by NAAT	THINPSTDP22P	1004488			ThinPrep
SurePath Vaginitis w/STD Panel by NAAT	SUREPVSTDP2P	1004485	<i>Chlamydia</i> <i>Gonorrhea</i> <i>Trichomonas</i> HSV Type 1& 2 <i>Candida albicans/ glabrata</i>	Molecular testing for vaginitis and STD co-infections	SurePath
ThinPrep Vaginitis w/STD Panel by NAAT	THINPVSTDP2P	1004490			ThinPrep
SurePath Comprehensive Vaginitis w/STD/HPV Panel by NAAT	SUREPVSTDH2P	1004486	<i>Chlamydia</i> <i>Neisseria</i> <i>Trichomonas</i> HSV Type 1 & 2 <i>Candida albicans</i> and <i>glabrata</i> + HPV, 16/18 and other HR genotypes	Molecular testing for vaginitis and STD co-infections and cervical cancer profiling	SurePath
ThinPrep Comprehensive Vaginitis w/STD/HPV Panel by NAAT	THINPVSTDH2P	1004489			ThinPrep

The following customized women health panels are orderable **without Paps**:

TEST NAME	TEST CODE	INTERFACE CODE	PANEL COMPONENTS	CLINICAL UTILITY	ACCEPTABLE COLLECTION TYPES
STD Panel 1 by NAAT	STDP1	1004442	<i>Chlamydia</i> <i>Gonorrhea</i> <i>Trichomonas</i>	Molecular testing for patients with multiple STD infections	APTIMA Vaginal Swab APTIMA Endocervical Swab Urine ThinPrep SurePath
STD Panel 2 by NAAT	STDP2	1004443	<i>Chlamydia</i> <i>Gonorrhea</i> <i>Trichomonas</i> HSV Type 1&2	Molecular testing for patients with multiple STD infections	APTIMA Vaginal Swab ThinPrep SurePath
Vaginitis with STD Panel by NAAT	VSTDP	1004444	<i>Chlamydia</i> <i>Gonorrhea</i> <i>Trichomonas</i> HSV Type 1 & 2 <i>Candida albicans/ glabrata</i>	Molecular testing for vaginitis and STD co-infections	APTIMA Vaginal Swab ThinPrep SurePath
Comprehensive Swab <sup>1</sup>	VSTDPNUGENT	1004481	<i>Chlamydia</i> <i>Neisseria</i> <i>Trichomonas</i> HSV Type 1 & 2 <i>Candida albicans</i> and <i>glabrata</i> + BV Nugent Gram Stain <sup>2</sup>	Microbiological and molecular techniques for comprehensive coverage of bacterial vaginosis, vaginitis and STD	Aptima Vaginal Swab + Vaginal Swab Air-Dried Smear <sup>2</sup>

<sup>1</sup> Requires additional Vaginal Swab for Graded Gram Stain

<sup>2</sup> Detects *Lactobacillus*, *G.vaginalis*/*Prevotella*/*Bacteroides* and *Mobiluncus spp.* Morphotypes

**Physicians have flexibility of selecting individual tests to suit their clinical needs. See Ordering Information for individual tests at the end of the Lab Alert.**

**COLLECTION  
INFORMATION:**

**Vaginal Specimens: APTIMA Vaginal Swab Collection Kit**

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.

**Stability/Transport:** Ambient: 60 days; Refrigerated: 60 days; Frozen: Unacceptable

**Collection Devices:**



Figure 1.

APTIMA Vaginal Swab Collection Kit

Order # B30079

**Endocervical: APTIMA® Combo 2 Unisex Swab Collection Kit**

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.

**Stability/Transport:** Ambient: 60 days; Refrigerated: 60 days; Frozen: Unacceptable



Figure 2.

APTIMA, Swab Collection Kit, Unisex (Endocervical /Urethral)

Order # 11071

#### Processed Urine:

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.

**Stability/Transport:** Ambient: 30 days; Refrigerated: 30 days; Frozen: Unacceptable



Figure 3.

APTIMA, Urine Collection Kit, Unisex

Order #11072

#### Cytology (Pap) Vials:

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/Transport:** SurePath: Ambient: 24 hours; Refrigerated/Frozen: Unacceptable  
ThinPrep: Ambient: 1 month; Refrigerated/Frozen: Unacceptable



Figure 4.

APTIMA Specimen Transfer Tube - Order # B11700

SurePath - Order # P490527

ThinPrep - Order # P70098

**NOTE: ADDITIONAL COLLECTION REQUIRED ONLY FOR Comprehensive TEST (VSTDPNUGENT)**

#### Vaginal Swab collection for bacterial Vaginosis: (NUGENT Collection Kit: Order # CPB30175)

1. An air dried smear prepared by rolling a swab over the surface of the vaginal wall. The swab is then rolled over the surface of a microscope slide and the slide is allowed to air dry.

All Tests contained in the panels are individually Orderable.

**ORDERING INFORMATION FOR INDIVIDUAL TESTS:**

Test Code	Interface Codes	Test Name	Acceptable Specimen Types
GCTRNA	1000380	<u>Neisseria gonorrhoeae/Chlamydia trachomatis RNA by TMA</u>	APTIMA Vaginal Swab APTIMA Endocervical Swab Urine ThinPrep SurePath
CTRNA	1000252	Chlamydia trachomatis RNA by TMA	
GCRNA	1000376	Neisseria gonorrhoeae RNA by TMA	
TRICHV	1003711	Trichomonas vaginalis RNA by TMA	
HSVQL	1004215	Herpes Simplex Virus (HSV), 1 and 2 Detection and Typing by Qualitative PCR	APTIMA Vaginal Swab ThinPrep SurePath
CAGPCR	1004189	Candida albicans and Candida glabrata by Qualitative PCR	
CALPCR	1004187	Candida albicans by Qualitative PCR	
CGLPCR	1004188	Candida glabrata by Qualitative PCR	
NUGENT	1003995	Bacterial Vaginosis Nugent Gram Stain	Vaginal Swab Air-Dried Smear

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