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

COMPREHENSIVE SWAB PANEL

TEST CODE: VSTDPNUGENT

INTERFACE CODE: 1004481

METHODOLOGY: Nucleic acid amplification testing (NAAT) and Gram Stain

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.

Comprehensive Swab Panel provides efficient, accurate and cost-effective testing solutions for women health using a combination of traditional "Gold Standard" microbiological methodologies and molecular techniques with well-established clinical correlation. The panel detects *Neisseria gonorrhea, Chlamydia trachomatis, Trichomonas vaginalis,* Herpes Simplex Virus 1 and 2, and *Candida albicans* and *Candida glabrata* using nucleic acid amplification tests. Nugent Scoring using graded gram stain detects the semi-quantitate the *Lactobacillus, G.vaginalis/Prevotella/Bacteroides* and *Mobiluncus spp.* morphotypes and provides laboratory evidence for the presence or absence of bacterial vaginosis. The graded gram stain is considered the gold standard for recognition of bacterial vaginosis. The presence of yeast, trichomonas organisms, and/or clue cells are also be noted on the report. This helps physicians to get multiple actionable results in a timely manner using clinically-proven technologies.

PERFORMED: Monday-Friday

COLLECTION: **The Comprehensive Panel requires <u>TWO SWABS</u>:**

A. 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.

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B. Vaginal Swab using NUGENT Collection Kit (Order # B30175)

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.

STABILITY (FROM COLLECTION TO INITIATION OF TESTING): APTIMA Vaginal Swab: Ambient: 60 days; Refrigerated: 60 days; Frozen: Unacceptable
NUGENT Slide: 7 days

TRANSPORT: Ambient

REFERENCE RANGE: Target Not Detected (TND) for NAAT; Normal for NUGENT

RESULTS REPORTED: 3-6 days

CPT CODE: 87491 (Chlamydia); 87591 (Gonorrhea); 87798 (Trichomonas); 87529x2 (HSV Type 1& 2); 87481x2 *(Candida albicans/ glabrata);* NUGENT: 87205

PERFORMING LAB: med fusion

COLLECTION DEVICES:

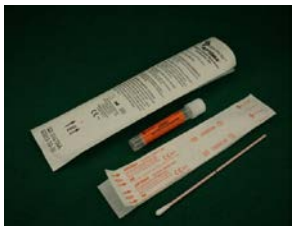

Figure 1.

APTIMA Vaginal Swab Collection Kit

Order # B30079

NUGENT Collection Kit: Order # CPB30175

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