ClearPoint DIAGNOSTIC LABORATORIES
Clear Point Diagnostic Laboratories | 2501 South State Highway 121 Business | Suite 1200
| Lewisville, TX 75067-8188
Phone: 972.966.7700 | Fax: 972.966.7799 | www.clearpointlabs.com

NOTIFICATION DATE: 8/22/2013

GO LIVE DATE FOR THIS TEST HAS CHANGED FROM 8/22/2013 TO 9/26/2013

CANDIDA GLABRATA BY QUALITATIVE PCR

TEST CODE: **CGLPCR**

INTERFACE CODE: 1004188

METHODOLOGY: Qualitative Real-Time Polymerase Chain Reaction (PCR)

CLINICAL UTILITY: Vulvovaginal candidiasis (VVC) is caused as a result of overgrowth of Candida spp. present in the normal vaginal flora. Symptoms include irritation, itching, dysuria and discharge. Disruption of the normal vaginal ecology or host immunity such as complicated pregnancy, history of high risk sexual behavior, previous STI, diabetes, HIV infection or antibiotic use are risk factors for VVC. *Candida albicans* is the most common species responsible for 80-90% of the total cases. The most common non-albicans species responsible for VVC is *Candida glabrata*. Together, these two species comprise approximately 93-97% of all vaginal candida infections. The traditional laboratory diagnosis methods of VVC such as direct visualization of yeast cells by microscopy and vaginal culture have limited value. The sensitivity of direct microscopy is 50% and does not provide species identification while cultures have longer turn-around-time. Molecular methods can provide high diagnostic value by simultaneous detection and differentiation of Candida spp. Differentiation of *C albicans* and *C glabrata* is important to guide treatment. *C albicans* is susceptible to principal oral-azole fluconazole while high percentage of *C glabrata* isolates demonstrate decrease susceptibility of fluconazole *in vitro*. Other non-albicans candida infections comprise only 1-3% of the infections.

PERFORMED: Monday-Wednesday-Friday

COLLECTION: Specimen may be submitted using APTIMA® Vaginal Swab Collection Kit. Pap specimen may also be submitted in cytology (Pap) vials: ThinPrep vial or SurePath vial.

Instructions for collection:

Vaginal Specimens (Clinician Collected): 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.

Cytology (Pap) vials:

1. Obtain cervical scrapings using either ThinPrep or SurePath fixative according to the Pap smear collection guidelines.

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Specimen Preparation:

Refer to specimen collection comment for vaginal specimen submission in APTIMA® transport tube.

Cytology (Pap) should be submitted in 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)

Swab specimens:2°C to 30°C for 7 days
Cytology (Pap) : 2°C to 30°C for 7 days
Frozen: 30 days

TRANSPORT: Ambient

REFERENCE RANGE: Target Not Detected (TND)

RESULTS REPORTED: 1-4 days

CPT CODE: 87481

PERFORMING LAB: med fusion

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