QUALATATIVE CT/NG BY PCR **4/27/2016**

Test Code: CT DNA PCR- *Chlamydia trachomatis*
NG DNA PCR- *Neisseria gonorrhoeae*

Use: The cobas® CT/NG Test is an *in vitro* nucleic acid amplification test that utilizes the Polymerase Chain Reaction (PCR) and nucleic acid hybridization for the qualitative detection of *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae (NG)* DNA to aid in the diagnosis of chlamydial and gonococcal disease. The test may be used with cervical specimens collected in PreservCyt solution, vaginal swab specimens self-collected in a clinical setting, and male urine from both symptomatic and asymptomatic individuals. Vaginal swabs and urine specimens to be tested should be collected in cobas® PCR Media.

Clinical Significance: Infection with *Chlamydia trachomatis* (CT) is the most frequently reported bacterial sexually transmitted disease (STD) in the United States. CT is the leading bacterial cause of sexually transmitted diseases worldwide, with approximately 89.1 million cases occurring annually. The Centers for Disease Control (CDC) Sexually Transmitted Disease Surveillance 2011 Supplement reports 1,412,791 CT infections in the United States. CT can cause urethritis, cervicitis, proctitis, conjunctivitis, endometritis, and salpingitis; if left untreated, the infection may ascend to the uterus, fallopian tubes, and ovaries causing pelvic inflammatory syndrome, ectopic pregnancy, and tubal factor infertility. Reiter's syndrome (urethritis, conjunctivitis, arthritis, and mucocutaneous lesions) has also been associated with genital CT infection. Many infections remain asymptomatic, and high numbers of infected patients may not seek care. Patients often become re-infected if their sexual partners are not treated. Infants born to infected mothers can develop conjunctivitis, pharyngitis, and pneumonia. The predominant symptoms in men and women are increased discharge and dysuria; women may also present with irregular uterine bleeding.

Neisseria gonorrhoeae (NG) is the causative agent of gonorrhoeae. A total of 321,849 cases of NG infection have been reported to the CDC in 2011 and it is estimated that more than 700,000 persons get new infections each year. Clinical manifestations of NG infections are numerous. In men, acute urethritis presents itself after a 1-10 day incubation period with urethral discharge and dysuria. Only a small proportion of men remain asymptomatic without signs of urethritis. Acute epididymitis is the most common complication, especially in young men. In women, the primary site of infection is the endocervix. There is a high prevalence of coalescence of symptoms with CT, *Trichomonas vaginalis*, and vaginosis; many women remain asymptomatic and therefore do not seek medical care. In symptomatic women increased discharge, dysuria, and intermenstrual bleeding may be observed. Pelvic inflammatory disease can occur in 10%- 20% of women, combined with endometritis, salpingitis, tubo ovarian abscess, pelvic peritonitis, and perihepatitis. Other gonococcal infected sites in men and women are the rectum, pharynx, conjunctiva, and to a lesser degree the disease presents itself as disseminated gonococcal infection. Infants from infected mothers can develop conjunctivitis.

Methodology: The cobas® CT/NG Test for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* is based on 2 major processes: (1) automated sample preparation to obtain nucleic acids, including CT and NG DNA; (2) simultaneous PCR amplification of target DNA sequences using both CT and NG specific primer pairs and real-time detection of cleaved fluorescent-labeled CT and NG specific oligonucleotide detection probes. An Internal Control, containing CT and NG DNA, is added to all samples prior to automated sample preparation and is amplified and detected simultaneously with each sample to monitor the entire process. The intended targets for the cobas® CT/NG Test include all major CT serovars, the Swedish *C. trachomatis* mutant (nvCT), variants that may harbor deletions in the cryptic plasmid or that have no cryptic plasmid at all, and both DR-9A and variant DR-9B sequences of NG.

Normal Range: Negative

Interpretative Data:
Negative: Indicates that neither CT nor NG viral nucleic acid was detected
CT Positive: Indicates that *Chlamydia trachomatis* (CT) viral nucleic acid was detected
NG Positive: Indicates that *Neisseria gonorrhoeae* (NG) viral nucleic acid was detected

Assay Availability: CT/NG assay is batched Monday – Friday, specific days are dependent on volume of tests.

Results Reported: 1 – 3 days

Specimen volume: Vaginal swab specimens collected with the cobas® PCR Female Swab Sample Kit and male urine collected with the cobas® PCR Urine Sample Kit have been validated for use with the cobas® CT/NG Test. For collection of vaginal swabs and urine specimens, follow the respective instructions included with the cobas® PCR Female Swab Sample Kit and cobas® PCR Urine Sample Kit. For collection of PreservCyt specimens, follow the maufacturer's instructions for collecting cervical specimens.

Storage: Vaginal swab specimens collected with the cobas® PCR Female Swab Sample Kit and male urine collected with the cobas® PCR Urine Sample Kit may be stored at 2-30 °C for up to 12 months once the specimens have been stabilized in cobas® PCR Media. Neat male urine is stable at 2-30 °C for up to 24 hours. Cervical specimens collected in PreservCyt vials may be stored at 2-30 °C for up to 6 months after the date of collection. PreservCyt specimens should not be frozen.

Causes for Rejection: Samples collected in non –approved collection media will be rejected. Samples received in the lab without proper identification will be rejected.

Laboratory Contact: For further information, please call the Molecular Diagnostics Laboratory at (501) 526-6439.