Detection of *Chlamydia trachomatis* and *Neisseria gonorrheae* by the Abbott RealTime PCR *Chlamydia trachomatis/Neisseria gonorrheae* (CT/NG) Assay

Summary & Explanation of the Test:

The Molecular Diagnostics laboratory at UTMC performs an FDA-approved Qualitative assay (Abbott RealTime PCR *Chlamydia trachomatis/Neisseria gonorrheae* assay) for detection of *Chlamydia trachomatis* & *Neisseria gonorrheae* (CT & NG).

CT and NG infections are the most common sexually transmitted bacterial diseases in the United States. Approximately 4 million new chlamydia cases occur each year. CT is a gram-negative, intracellular bacterium that causes cervicitis, urethritis, salpingitis, proctitis and endometritis in women and urethritis, epididymitis and proctitis in men. Many chlamydial infections in women are asymptomatic and remain untreated which can ultimately result in infertility.

NG organisms are gram-negative, oxidase positive diplococci which cause acute urethritis, epididymitis, and prostatitis in males and cervicitis in females. Cervicitis can lead to pelvic inflammatory disease which contributes to infertility, particularly because infections are frequently Asymptomatic.

The current methods for detection of CT and/or NG include culture, immunoassays, non-amplified probes, and amplified probes. Culture of NG can be difficult because the organism does not survive long outside its host and is highly susceptible to adverse environmental conditions.

Amplified methods such as real time PCR have two advantages over non-amplified methods: increased sensitivity, and applicability to a variety of sample types. For NG, optimized culture methods continue to be the "gold standard" for diagnosing gonococcal infections but the amplified probe method has been accepted as the "platinum standard" for laboratory diagnosis of CT and NG infections. The new Abbot assay utilizes Real Time PCR to amplify and detect specific CT/NG nucleic acid sequences using fluorescently labeled nucleic acid probes and is reported as a Qualitative result.

Turn-Around-Time: 1-4 days

Sample Requirements:

The approved specimen types are male and female urine, male urethra, endocervical and vaginal. As a part of the FDA approval, a new, simple, specimen collection kit (Abbott *m*ulti-Collect Specimen Collection Kit) **is required** and contains everything necessary for submission of all sample types. This kit will be **provided free of charge** by our Molecular Diagnostics Laboratory (phone: 419-383-5636).

Results Reporting:

1) organisms detected: Positive 2) organisms not detected: Negative 3) Indeterminate: Indeterminate

For any questions regarding *Chlamydia trachomatis & Neisseria gonorrheae* testing, other types of molecular diagnostics questions or to obtain free CT/NG specimen collection kits please contact the UTMC Molecular Diagnostics Laboratory (phone: 419-383-5636). More information is also available on our website at: http://www.utoledo.edu/med/depts/path/moldx/index.html