**APTIMA™ Combo 2 Assay**

*C. trachomatis* and *N. gonorrhoeae* Testing by APTIMA Combo 2

**CLINICAL APPLICATION**

The Gen-Probe APTIMA Combo 2 Assay is a second-generation nucleic acid amplification test (NAAT) for simultaneous detection and differentiation of *C. trachomatis* (CT) and *N. gonorrhoeae* (GC).

The APTIMA assay combines three separate technologies to detect both CT and GC in a single tube. The first step uses oligonucleotides and magnetic microparticles to capture target ribosomal RNA (rRNA) from CT and/or GC. This separates the rRNA from potentially inhibiting substances, isolates it for amplification, and reduces the incidence of false-negative results. The sensitivity of the assay is optimized by Transcription-Mediated Amplification (TMA), which produces up to ten billion copies of target nucleic acid. The Dual Kinetic Assay (DKA) allows the detection of multiple analytes in a single assay.

NAATs have been shown to be more sensitive than non-amplified tests for the detection of CT and GC in asymptomatic patients. The Centers for Disease Control and Prevention (CDC) recommends using NAAT for CT and GC screening of endocervical swabs/male urethral swabs, as well as female and male urine samples.

The sensitivity of the APTIMA Combo 2 Assay for detection of CT has been shown to equal or exceed that of other NAATs. Both CT and GC can be detected in co-infected patients. No cross-reactivity with other nongonococcal Neisseria species has been detected with the APTIMA assay.

The APTIMA Combo 2 Assay is FDA-cleared as a CT/GC screening test for routine CT and GC screening to be extended beyond women undergoing pelvic exam or urethral swab.

SELECTED REFERENCES