

## **Chlamydia/Gonorrhea Detection at Doctors Lab.**

*Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) infections are the most common sexually transmitted bacterial diseases in the United States.

CT causes cervicitis, urethritis, salpingitis, proctitis and endometritis in women and urethritis, epididymitis and proctitis in men. Chlamydia can also be transmitted in the birth canal, potentially resulting in infant conjunctivitis and/or chlamydial pneumonia in newborns.

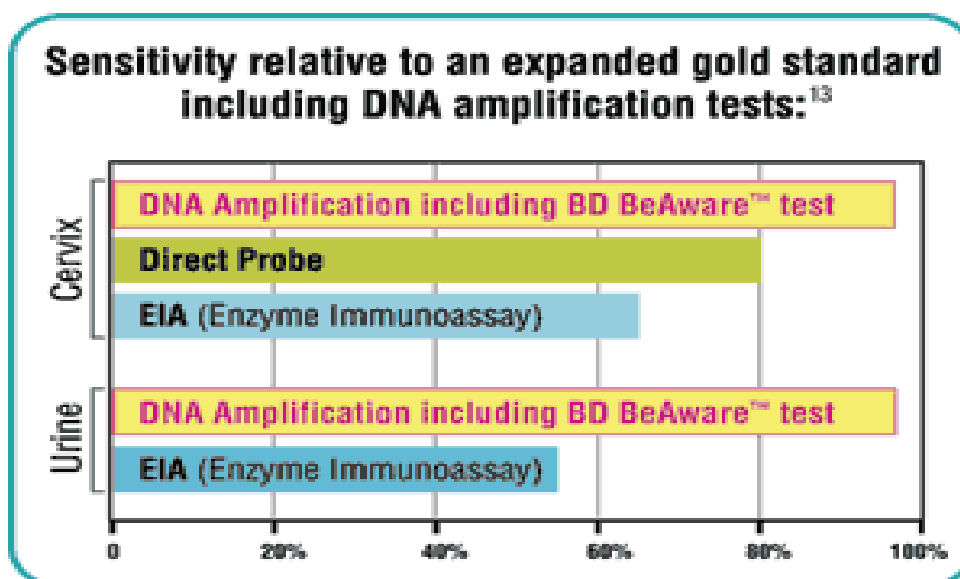
GC causes acute urethritis in males, which if untreated, can develop into epididymitis, prostatitis, and urethral stricture. An important complication in females is development of pelvic inflammatory disease, which contributes to infertility.

<b>ROUTINE ANNUAL SCREENING FOR CHLAMYDIA (CT) AND/OR GONORRHEA (GC) IS SUPPORTED BY:</b>
<i>American Medical Association (AMA)</i>
<i>American Academy of Pediatrics (AAP)</i>
<i>The American College of Obstetricians and Gynecologists (ACOG)</i>
<i>American Social Health Organization (ASHA)</i>
<i>Centers for Disease Control and Prevention (CDC)</i>
<i>U.S. Preventative Services Task Force</i>
<i>National Committee on Quality Assurance (NCQA) – HEDIS 2000</i>

**Considering that up to 75% of women and 50% of men who have Chlamydia and/or Gonorrhea have no symptoms, routine screening and early, effective treatment are the keys to reducing the high prevalence of CT/GC and the incidence of PID.**

The current methods for detection of CT and/or GC include culture, immunoassays, non-amplified probes, and amplified probes. Amplified methods have demonstrated two advantages over non-amplified

methods: increased sensitivity, and ability to test urine specimens, in addition to endocervical/urethral swabs. The following frame illustrates sensitivity of amplified assays compared to non-amplified probes or EIA.



After evaluating four brands, Doctors Laboratory, Inc. has chosen B-D's "ProbeTec" brand amplified probe assays for the detection of CT and GC. The assays utilize homogeneous Strand Displacement Amplification (SDA) technology for amplification and fluorescent energy transfer (ET) for detection in endocervical/urethral swabs and urine.

Specimen collection and submission instructions are included in the following insert and available poster. Additional clinical information about CT may be requested from Doctors Lab..

**IMPORTANT NOTES:**

- (1) ProbeTec is currently approved by FDA for endocervical/urethral and urine only. For all other sources cultures are recommended, using M-4 tube for CT and culture swab for GC.
- (2) Urine specimen testing by ProbeTec technique is also available from Doctors Laboratory, which may be ideal for screening targeted population. Information for urine testing is available separately, and may be requested from a Client Relations Specialist..
- (3) "ProbeTec ET" kits are not interchangeable with any other collection kit, nor are they suitable for any test other than ProbeTec assay, and should not be submitted as such.
- (4) Following recommendations of experts to screen for both CT and GC, and a review of historical ordering pattern of our clients, Doctors Laboratory will not offer single CT or GC assay but a combination CT/GC assay which will identify and confirm the presence of either CT or GC in a specimen.

<b>Chlamydia AND Gonorrhea Amplified DNA Assay</b>	
<b>Doctors Lab. Test Code</b>	<b>8998 or STD-1 Panel</b>
<b>CPT Codes</b>	<b>87491 and 87591</b>
<b>Specimen</b>	<b>Female – Endocervical swab collected with PINK “ProbeTec ET” Kit</b>  <b>Male - Urethral swab collected with BLUE "ProbeTec ET" kit</b>
<b>Stability of collected specimen</b>	<b>4-6 days at refrigeration or room temperature</b>
<b>Unsuitable specimens</b>	<b>(1) Not Endocervical or urethral</b> <b>(2) Not in "ProbeTec ET” Kit</b> <b>(3) Male swab in female kit or female swab in male kit (except after hysterectomy)</b> <b>(4) Frozen specimen</b>
<b>Testing Schedule</b>	<b>Monday to Friday</b>
<b>Turn Around Time</b>	<b>1 day (Reported Tuesday to Saturday)</b>
<b>Normal Range</b>	<b>Negative for Chlamydia and Gonorrhea</b>