



## **A New Approach to STD Detection at Doctors Lab.**

*Chlamydia trachomatis* (CT) and *Neisseria gonorrhoea* (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.

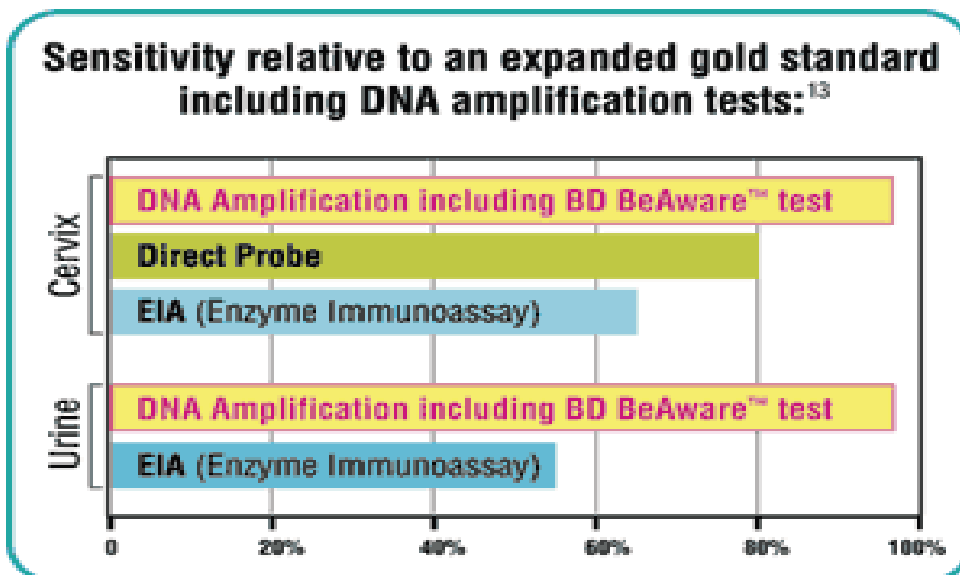
GC causes acute urethritis in males, which if untreated can develop into epididymitis, prostatitis, and urethral stricture. An important complication in females is development of pelvic inflammatory disease, which contributes to infertility.

| <b>ROUTINE ANNUAL SCREENING<br/>FOR CHLAMYDIA (CT) AND/OR<br/>GONORRHEA (GC) IS SUPPORTED BY:</b> |
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| <i>American Medical Association (AMA)</i>   |
| <i>American Academy of Pediatrics (AAP)</i>   |
| <i>The American College of Obstetricians and<br/>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)<br/>– 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 assay for the detection of CT and GC. The assay utilize homogeneous Strand Displacement Amplification (SDA) technology for amplification and fluorescent energy transfer (ET) for detection in endocervical/urethral swabs and urine.

**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 this technique is now available at Doctors Laboratory and the ordering information is provided in the following insert. Besides a convenient screening medium, urine testing can also be recommended for female who had total hysterectomy.
- (3) "ProbeTec ET" kits (pink for female and blue for male) 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 an individual agent, if present.

| <b>Chlamydia AND Gonorrhea Amplified DNA Assay on Urine</b> |   |
|---|---|
| <b>Doctors Lab. Test Code</b>                               | <b>2238 or Urine STD Panel</b>  |
| <b>CPT Codes</b>  | <b>87491 and 87591</b>  |
| <b>Specimen</b>   | <b>Female or Male – The patient should not have urinated for at least an hour before collection. Collect 15-20 milliliters of first voided (not midstream) urine specimen in a sterile, preservative-free urine container supplied by Doctors Laboratory. Tighten lid securely.</b> |
| <b>Stability of collected specimen</b>                      | <b>4-5 days at refrigeration temperature. Freezing is not recommended, but acceptable.</b>  |
| <b>Unsuitable specimens</b>                                 | <b>(1) collected or submitted in a container with a preservative (e.g. Boricult, Vacutainer)<br/>(2) arriving at the Central Lab. 5 days or later after Collection, unless frozen.<br/>(3) kept unrefrigerated</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>   |

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