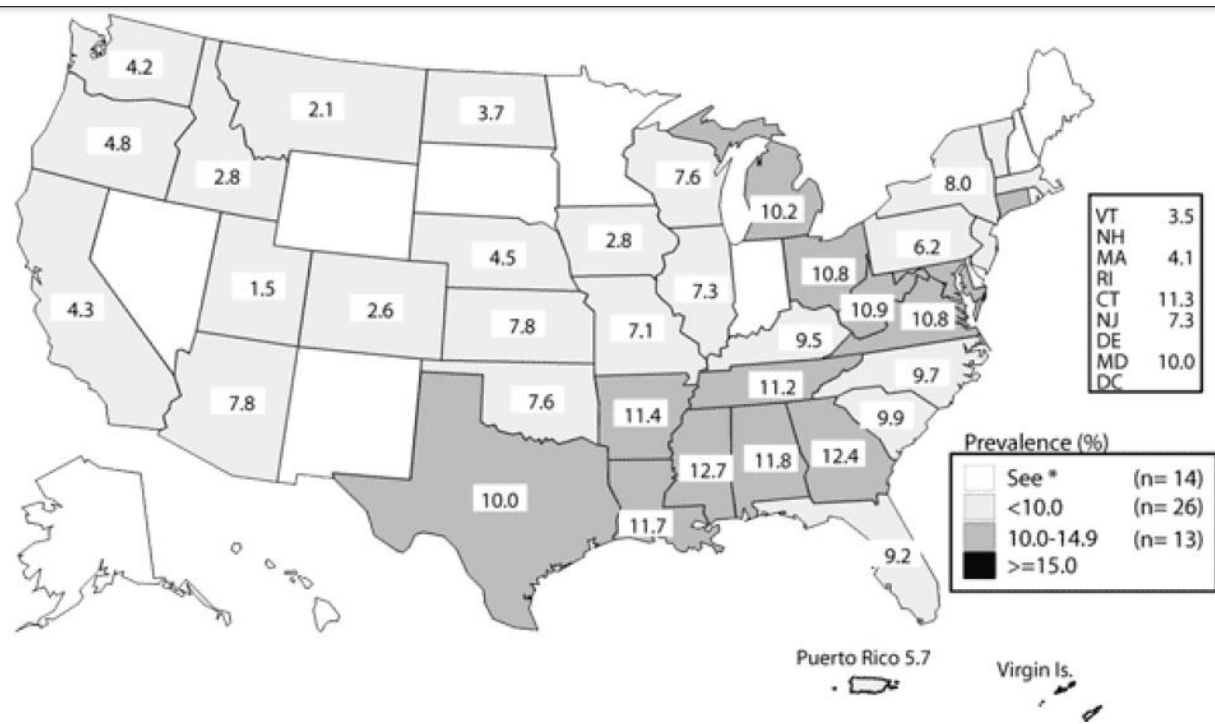


HCM530  
Case Study 6

**Case Study Testing for Chlamydia**

Chlamydia trachomatis is a prevalent sexually transmitted organism, and is known to cause serious complications in women, such as pelvic inflammatory disease, infertility, and ectopic pregnancy. The Centers for Disease Control (CDC) therefore recommends annual screening for all sexually active women age 15-25 (among this group the prevalence rate is estimated to be 25%) (Chernesky, 1999). The value of screening men has not been determined, as men have no sequelae and often have no symptoms of infection. Public health agencies are reluctant therefore to direct money and other resources toward screening of males, even though it has been considered that asymptomatic men may be an important reservoir of chlamydial infection, and the source of infection and complications for women. Overall prevalence for Chlamydia in men in the United States is 7% (Shillinger et al, 2005). The U.S. Department of Labor produced statistics related to U.S. prevalence of Chlamydia for men in the 16-24 age group in 2003 (Figure 1).



**Figure 1.** Chlamydia — Prevalence among 16- to 24-year-old men entering the National

Job Training Program by state of residence: United States and outlying areas, 2003

*\*Fewer than 100 men residing in these states and entering the National Job Training Program were screened for chlamydia in 2003. Note: The overall chlamydia prevalence among male students entering*

*the National Job Training Program for the period July-December 2003 was 8.0%. SOURCE: U.S. Department of Labor*

The technology for Chlamydia screening using urine samples became available in 1999. Chernesky and colleagues (1999) compared three point of care urine tests and the commonly known leukocyte dipstick test (used for urinalysis) against a reference standard of positivity determined by ligase chain reaction (LCR) assay (LCx), and a confirmed Chlamydiazyme assay (EIA). The LCR and EIA are the previously known “gold standard” methods of Chlamydia testing using urethral (men) or endocervical (women) specimens. Results with sensitivities and specificities appear in Table 1 below:

TABLE 1. Diagnostic performances of three rapid tests and LE dipstick assay compared to those of two reference standards for detection of *C. trachomatis* with FVU specimens from men.

Rapid test	Standard	% Sensitivity	% Specificity
Testpack Chlamydia (Abbott)	EIA <sup>a</sup>	76.4 (42/55) <sup>b</sup>	93.2 (68/73)
	LCR <sup>c</sup>	70.9 (44/62)	95.5 (63/66)
Surecell Chlamydia (Kodak)	EIA	67.3 (37/55)	97.3 (71/73)
	LCR	62.9 (39/62)	100 (66/66)
Clearview Chlamydia (Unipath)	EIA	76.4 (42/55)	95.9 (70/73)
	LCR	67.7 (42/62)	95.5 (63/66)
LE dipstick (Boehringer)	EIA	88.6 (39/44)	89.0 (65/73)
	LCR	87.5 (42/48)	92.4 (61/66)

*a Specimens positive by the Chlamydiazyme EIA confirmed with Chlamydia blocking reagent.*

*b Values in parentheses are number of positive specimens/number of specimens tested.*

*c Specimens positive by LCR by the LCx Chlamydia assay as confirmed by the presence of three or more EBs by fluorescent-antibody staining.*

This study shows that rapid chlamydial antigen tests performed reasonably well with first-voided urine specimens, and that the LE dipstick, which had the highest sensitivity, would be very helpful in screening large numbers of infected male patients (Chernesky et al, 1999).

**Case Questions:** Answer the case questions, with research from your book, CDC, NIH and other quality sources to determine answers and solutions. You are to write a 2-3 page paper in APA formatting that addresses the following questions. Note: A minimum of two references should be used, which should include your textbook and the CDC, and others that support your responses in your paper. This is a paper, so your answer should not be numbered, but rather it should use titles and subtitles.

1. What are the elements of a good screening program for the problem of Chlamydia infection in men?
2. What is a reference standard? What is meant by “gold standard?” What is the expected sensitivity and specificity of the reference standard?

3. What is meant by the term “point of care testing?” Why is the concept useful in health care planning?
4. Knowing that the disease prevalence rate for women is 25% and for men is 7%, how does this impact positive predictive value for each gender?
5. What is the health care impact for men of false positives?
6. What are the screening implications of using urine instead of urethral swabs (men) and endocervical swabs (women)?
7. What is the value of the research finding that the simple LE dipstick has the highest sensitivity for screening?