

Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* from Endocervical Swabs: A Comparative Evaluation of Three Commercial Kits

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ABSTRACT

BACKGROUND: Several nucleic acid amplification (NAA)-based kits are commercially available for the detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC). A parallel evaluation of the BD ProbeTec ET and the Roche Cobas Amplicor was performed and compared in respect to validity, cost-per-test, hands-on time and turnaround time.

METHODS: A total of 703 endocervical swabs were collected at Vanderbilt's STD clinic. These samples were tested for both CT and GC using the BD Probetec ET, Roche Cobas Amplicor and the GenProbe Pace 2 system.

RESULTS: The test results were compared in respect to performance, timeliness, and cost. The positivity rate of the ProbeTec, Cobas Amplicor and Pace 2 was 7.4%, 7.1% and 5.1% for CT and 1.9%, 1.7% and 1.6% for GC.

Using a repeatedly positive result from any three tests as an evaluation standard, the sensitivity of the ProbeTec, Cobas Amplicor and Pace 2 was 96.3%, 92.6% and 66.7% for CT and 100%, 92.3% and 84.6% for GC, respectively. Hands-on time for all three procedures were similar, yet a lower turnaround time (TAT) was noted for the ProbeTec and Pace 2 (4 hours) as compared to the Cobas Amplicor (almost 6 hours). The cost-per test was lower with Pace 2 than either of the amplified tests, Cobas Amplicor and ProbeTec.

CONCLUSION: Although amplified tests do propose a higher cost-per-test, increases in sensitivity and savings in hands-on and turnaround time make the BD ProbeTec assay advantageous for a mid-volume laboratory.

INTRODUCTION

Improvements in detection of CT and GC include nucleic acid amplification as opposed to older probe hybridization technologies. There are many commercially available nucleic acid amplification platforms available. Currently, at Vanderbilt University's Clinical laboratory we are using the Gen-Probe PACE 2 system. While these kits work efficiently, there are new more sensitive methods for detecting both CT and GC in endocervical swabs, urethral swabs and urine.

METHODS

Evaluation of Specimens. A total of 703 endocervical swabs collected at Vanderbilt's STD clinic between September 10, 2003 and January 23, 2004 were included in the study. Swab samples were collected in each manufacturer's required collection media CT and GC testing. All endocervical swabs were tested by the Pace 2, the Cobas Amplicor and the ProbeTec using the manufacturer's guidelines. Samples were repeated if there was a low positive or indeterminate result.

Test Sensitivity Comparison. Fifty-four samples tested positive by at least one of the three compared methods. This was used to calculate a test sensitivity for all methods.

Cost, Test Turn-Around-Time, and Hands-On Time Analysis. A cost and time comparison was performed to detect differences between methods.

Table 1. Test Sensitivity

Test Method	<i>Chlamydia trachomatis</i>	<i>Neisseria gonorrhoeae</i>
PACE	36/54 (66.7%)	11/13 (84.6%)
Amplicor	50/54 (92.6%)	12/13 (92.3%)
ProbeTec	52/54 (96.3%)	13/13 (100%)

Table 2. Improved Diagnosis by Switch from PACE to ProbeTec

Test Method	<i>Chlamydia trachomatis</i>	<i>Neisseria gonorrhoeae</i>
Sensitivity enhancement	29.7% (66.6 → 96.4)	15.4% (84.6 → 100)
Detection Rate enhancement*	2.3% (5.1 → 7.4)	0.3% (1.6 → 1.9)
Annual additional cases identified**	219	29

*Based on 703 specimens detected in the study.

**Based on an estimation of total test volume of 9,500 at VUMC.

Figure 1. Maximum Test Volumes per 8-hour shift and Cost-per-Test.

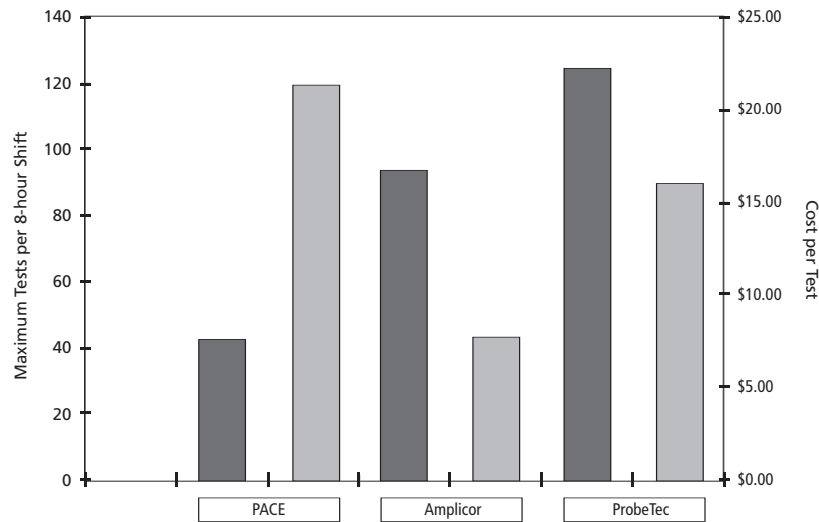
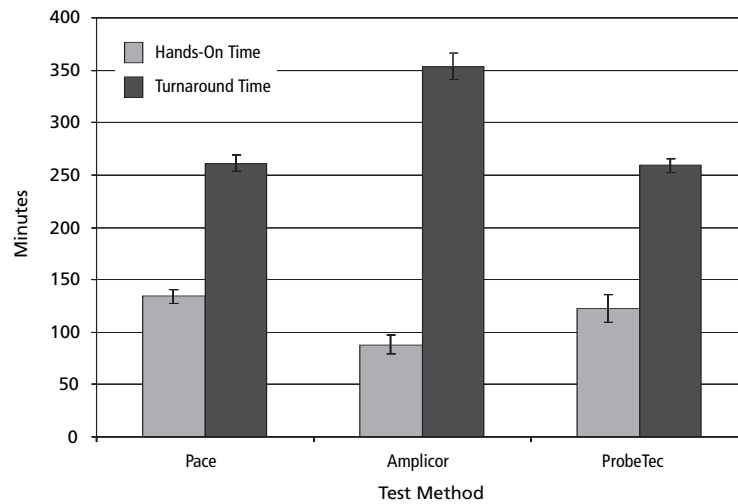


Figure 2. Hands-On Time and Turn-Around-Time (TAT) Comparison.



CONCLUSIONS

- The test sensitivity of the amplified tests (ProbeTec and Cobas Amplicor) was much higher than the non-amplified test (Pace 2).
- Hands-on time was similar between all test methods, but Turnaround time was longer for the Cobas Amplicor (almost 6 hours) than the Pace 2 and ProbeTec (4 hours).
- The amplified test methods (Cobas Amplicor and ProbeTec) had higher costs than the non-amplified test (Pace 2).
- The switch from non-amplified PACE to amplified ProbeTec will improve patient care outcome by preventing 219 chlamydial and 28 gonococcal infections from being untreated annually at VUMC.