

Clinical Comparison of the BD ProbeTec™ Amplified DNA Assay and the Abbott LCx for the Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in Endocervical Swabs and Urine Samples

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BACKGROUND AND AIM

Chlamydia trachomatis and *Neisseria gonorrhoeae* infections are the most common sexually transmitted bacterial diseases in the United States. Approximately 4 million new chlamydia cases are estimated to occur each year in the U.S. with worldwide estimates of approximately 50 million new cases annually (1, 2). The incidence of chlamydial infections in women in the U.S. in 1996 was 186.6 per 100,000. The total number of chlamydial infections and gonorrhea cases reported in the U.S. in 1996 were 490,080 and 325,883, respectively (1, 2).

The current methods for detection of *C. trachomatis* and/or *N. gonorrhoeae* include culture, immunoassays, non-amplified probes, and amplified probes. The development of amplified methods has demonstrated two advantages over nonamplified methods: increased sensitivity and applicability to a variety of sample types (3, 4).

The aim of this study was:

1. To compare the BD ProbeTec™ (3,4) and the Abbott LCx assays for the ability to detect *C. trachomatis* and *N. gonorrhoeae* in female endocervical swabs and female/male urine samples.
2. To evaluate the use of an amplification inhibition control.
3. To assess the technical efficiency of each assay and its relationship to cost savings.

MATERIALS AND METHODS

Patient Population. Patient samples were obtained with IRB approval from the North Shore University Hospital Center for Women's Health Care, Manhasset, NY and the Dolan Family Health Center, Huntington, NY.

Sample Collection and Processing. Female endocervical swabs (n=386) and female/male urine samples (n=80) were collected and processed according to each manufacturer's instructions. The order of swab collection (Abbott Uriprobe vs. BD Culturette Direct) was rotated equally between the two swabs during the study.

Sample Testing. Endocervical swabs and urine samples were tested for the presence of both *C. trachomatis* and *N. gonorrhoeae* using the BD ProbeTec™ and the Abbott LCx assays according to each manufacturer's instructions. The amplification control was tested with each BD ProbeTec sample.

Assessment of Technical Efficiency. Technical efficiency was evaluated by determining the hands on time for each assay, the number of repeat or indeterminate results, results per run and instrument maintenance requirements.

RESULTS

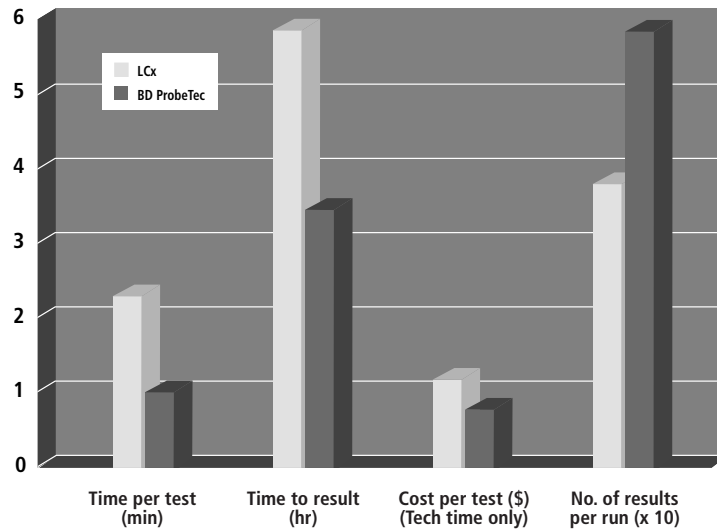
Table 1. Comparison of BD ProbeTec™ and Abbott LCx Results

Method	Source	No. Spec	Pos CT	% Pos	Pos GC	% Pos	CT & GC % Pos
BD ProbeTec	Endocervical	386	5	1.3%	3	0.78 %	2.08 %
Abbott LCx	Endocervical	386	5	1.3 %	3	0.78 %	2.08 %
BD ProbeTec	Urine	80	7	8.75 %	4	5.0 %	13.75 %
Abbott LCx	Urine	80	7	8.75 %	4	5.0 %	13.75 %

Table 2. Assessment of Amplification Inhibition Rates

Specimen Source	# Specimens tested	# Specimens inhibited	% Inhibition
Endocervical	386	3	0.78 %
Urine	80	5	6.25 %

Figure 1. Comparison of Technical Efficiency



SUMMARY OF RESULTS

- Overall concordance of results between the two assays was 100% for the detection of both *C. trachomatis* and *N. gonorrhoeae*.
- C. trachomatis* was detected in 5 endocervical swabs (1.30%) and 7 urine samples (8.75%) for an overall positivity rate of 2.58%. *N. gonorrhoeae* was detected in 3 endocervical swabs (0.77%) and 4 urine specimens (5.0%) for an overall positivity rate of 1.5%.
- The inhibition rate for the BD ProbeTec™ assay was 0.77% (3/386 samples) for endocervical swabs and 6.25% (5/80 samples) for urine specimens.
- The technical time per result, based upon 5 runs per week, was 1.06 min/sample for the BD ProbeTec assay and 2.38 min/sample for the Abbott LCx assay.
- Time to reportable result was 3.5 hr for the BD ProbeTec Assay (58 reportable results) vs 5.45 hr for the Abbott LCx Assay (38 reportable results).

CONCLUSIONS

- The Abbott LCx and BD ProbeTec™ Assays gave comparable results for the detection of *C. trachomatis* and *N. gonorrhoeae* in clinical samples.
- There were four advantages of the BD ProbeTec assay:
 - The ability to detect the presence of amplification inhibitors in samples, particularly in urines, enhancing the negative predictive value of the BD ProbeTec assay.
 - A significantly reduced time to reportable results (BD ProbeTec = 3.5 hr vs Abbott LCx = 5.45 hr)
 - Number of tests completed per run (Abbott LCx = 38 vs BD ProbeTec = 58)
 - The savings in technical time required for the BD ProbeTec assay was estimated, based upon a yearly volume of 12,000 samples (24,000 results) to be approximately \$15,000 per year in technical time.

REFERENCES

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