

# Comparison of BDProbeTec™ ET, Abbott LCx®, Roche COBAS AMPLICOR®, and GenProbe PACE 2® Assays for the Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in Female Urine and Swab Specimens

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## INTRODUCTION

■ *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections are the most common sexually transmitted bacterial diseases in the United States. 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 non-amplified methods: increased sensitivity, and applicability to a variety of sample types. This study compared three commercially available amplified probe assays and one non-amplified probe assay for the detection of *C. trachomatis* and *N. gonorrhoeae* in urine and endocervical swab specimens from a female population.

## METHODS

■ We collected urine and endocervical swab specimens from 377 female patients at an urgent care OB-GYN clinic in Indianapolis, IN. The following assays for the detection of *C. trachomatis* (CT) and *N. gonorrhoeae* (NG) were performed: BDProbeTec™ (BD Biosciences, Sparks, MD); Abbott LCx® (Abbott Diagnostics, Abbott Park, IL); Roche COBAS AMPLICOR® (Roche Diagnostic Systems, Indianapolis, IN); and Gen-Probe PACE 2® (Gen-Probe, Inc., San Diego CA). Urine and 4 endocervical swab specimens were collected, transported, and processed according to manufacturer's instructions. The swab specimens were obtained simultaneously to avoid collection bias. Each assay was performed according to manufacturer's instructions for both female urine and female swab specimens with the exception of the PACE 2® assay, which was performed only from swab specimens. The PACE 2® assay is a non-amplified assay for NG and CT while BDProbeTec,™ LCx® and AMPLICOR® are amplified probe assays.

## RESULTS

■ After resolution of discrepant results, 324 (85.9%) were negative by all assays, while 48 (12.7%) were defined as true positives. Thirty-four (9%) patients were positive for *C. trachomatis* while 23(6.1%) were positive for *N. gonorrhoeae*. Nine of 48 (19%) patients were positive for both *C. trachomatis* and *N. gonorrhoeae*. Five specimens were falsely positive: 1 swab and 2 urine specimens for *C. trachomatis* using the Abbott LCx<sup>®</sup> assay, and 1 swab specimen each for both Roche COBAS AMPLICOR<sup>®</sup> and BDProbeTec<sup>™</sup> assays for *N. gonorrhoeae*. The non-amplified PACE 2<sup>®</sup> assay exhibited 92% sensitivity for *N. gonorrhoeae* and 77% sensitivity for *C. trachomatis*. Of the amplified assays for *C. trachomatis*, sensitivities for swab specimens were as follows: LCx 95%, BDProbeTec<sup>™</sup> 98% and COBAS AMPLICOR<sup>®</sup> 100%, while sensitivities for urine specimens were 96% for both LCx and BDProbeTec<sup>™</sup> and 93% for COBAS AMPLICOR<sup>®</sup> (Table 1). Of the amplified assays for *N. gonorrhoeae*, sensitivities for swab specimens were as follows: LCx and BDProbeTec<sup>™</sup> were both 98%, and COBAS AMPLICOR was 97% while the sensitivities for urine were 96% for LCx<sup>®</sup>, 100% for BDProbeTec<sup>™</sup>, and 86% for COBAS AMPLICOR<sup>®</sup> (Table 2).

Table 1. *C. trachomatis* Sensitivity

	PACE 2	BDProbeTec	LCx	COBAS AMPLICOR
SWAB	77%	98%	95%	100%
URINE	N/A	96%	96%	93%

Table 2. *N. gonorrhoeae* Sensitivity

	PACE 2	BDProbeTec	LCx	COBAS AMPLICOR
SWAB	92%	98%	98%	97%
URINE	N/A	100%	96%	86%

## CONCLUSIONS

■ The sensitivity from swab specimens for all three amplified probe assays was comparable, and the sensitivity from urine specimens was comparable with the exception of COBAS AMPLICOR<sup>®</sup> from females. The sensitivity of the non-amplified PACE2<sup>®</sup> assay for *C. trachomatis* was considerably less than the amplified methods. For all amplified probe methods, swabs yielded higher sensitivities than urine specimens except for Abbott LCx<sup>®</sup>, which was 96% for urine and 95% for swabs. The specificity for all assays was 99% or greater (Tables 3 and 4).

Table 3. *C. trachomatis* Specificity

	PACE 2	BDProbeTec	LCx	COBAS AMPLICOR
SWAB	100%	100%	99%	100%
URINE	N/A	100%	99%	100%

Table 4. *N. gonorrhoeae* Specificity

	PACE 2	BDProbeTec	LCx	COBAS AMPLICOR
SWAB	100%	100%	100%	99%
URINE	N/A	99%	100%	100%