

# Comparison of Three Nucleic Acid Amplification Tests for the Detection of *Chlamydia trachomatis* in Urine Specimens

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## ABSTRACT (revised)

Traditionally culture and immunoassays have been performed for the detection of sexually transmitted diseases, specifically *C. trachomatis* (CT). However, these assays may often require invasive specimen collection methods, such as female cervical and male urethral swabs. Recently, new methods using nucleic acid amplification tests (NAATs) have been approved for testing CT using a urine sample. The Abbott LCx,<sup>™</sup> BD ProbeTec<sup>™</sup> ET and Gen-probe Aptima<sup>™</sup> Combo 2 are all tests which implement nucleic acid amplification urine testing for CT. Our objective was to compare the sensitivity and specificity of these assays using urine samples. In an ongoing study, urine specimens were collected from both symptomatic and asymptomatic males and females from various school based clinics. These samples were processed, according to each of the manufacturer's directions, and tested for CT. The gold standard for a positive result was defined as any two positive NAATs. 506 samples were tested for CT by all three methods. CT was positive by LCx in 72 (14.2%), by ProbeTec in 72 (14.2%), and by Combo 2 in 75 (14.8%). The sensitivities for CT by LCx, ProbeTec, and Combo 2 were 96.0%, 96.0% and 100%, respectively. The specificities for CT by LCx, ProbeTec, and Combo 2 were 99.1%, 100% and 98.8%, respectively. The Abbott LCx,<sup>™</sup> BD ProbeTec<sup>™</sup> ET and Gen-probe Aptima<sup>™</sup> Combo 2 methods are highly sensitive and specific in the detection of CT in urine specimens. With high sensitivity and specificity, these NAATs can be recommended for use with urine, and should be used widely for non-invasive screening of *C. trachomatis*.

## BACKGROUND

- Invasive specimen collection methods are required for many traditional STD testing assays, specifically for *Chlamydia trachomatis* (CT).
- Culture and immunoassays are some of these traditional tests.
- Nucleic acid amplification tests (NAATs) have recently been approved for CT testing for use with a urine sample.
- The Abbott LCx,<sup>™</sup> BD ProbeTec<sup>™</sup> ET and Gen-probe Aptima<sup>™</sup> Combo 2 assays are all such NAATs.

## METHODS

- Urine specimens collected from various school based health clinics were processed for each of the three testing methods according to the manufacturer's directions.
- After processing, the samples were tested by all three methods for CT.

- The results were recorded for each test and the gold standard for a positive result was defined as any two positive NAATs.
- Sensitivity, specificity, positive and negative predictive values (PPV, NPV) were determined.

## RESULTS

- 72/506 (14.2%) specimens tested positive for CT by LCx.
- 72/506 (14.2%) specimens tested positive for CT by ProbeTec.
- 75/506 (14.8%) specimens tested positive for CT by Combo 2.
- 75 specimens were considered to be true positives (2 positive NAATs).

Results: Comparison Data			
ABBOTT	BD	GEN-PROBE	TOTAL
Positive	Positive	Positive	69
Positive	Positive	Negative	0
Positive	Negative	Positive	3
Negative	Positive	Positive	3
Positive	Negative	Negative	4
Negative	Positive	Negative	0
Negative	Negative	Positive	5
Negative	Negative	Negative	422

Results		
	Sensitivity	Specificity
ABBOTT	96.0%	99.1%
BD	96.0%	100%
GEN-PROBE	100%	98.8%

Results		
	+ Predictive Value	- Predictive Value
ABBOTT	94.7%	99.3%
BD	100%	99.3%
GEN-PROBE	93.8%	100%

Results — Abbott LCx		
N=506	True Positive	True Negative
Positive Test	72	4
Negative Test	3	427

Results — BD ProbeTec		
N=506	True Positive	True Negative
Positive Test	72	0
Negative Test	3	431

Results — Gen-probe Combo 2		
N=506	True Positive	True Negative
Positive Test	75	5
Negative Test	0	426

## CONCLUSIONS

- The Abbott LCx,™ BD ProbeTec™ ET and Gen-probe Aptima™ Combo 2 assays are highly sensitive and specific for the detection of CT in urine specimens.
- These NAATs can be all recommended for non-invasive screening of *C. trachomatis* using urine specimens.