

# Evaluation of the BDProbeTec™ ET System on Urine and Genital Specimens for the Identification of Chlamydia and Gonorrhea Infections in Adolescents

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## ABSTRACT

■ A new diagnostic test for chlamydia and gonorrhea genital infections was evaluated by comparison with the Abbott LCx assay and culture. The patient population included female patients under 20 years of age attending adolescent, family planning, and obstetric clinics. Most specimen sets included paired urine and cervical swab specimens which were tested by the BDProbeTec ET System as well as by LCx for gonorrhea and chlamydia. Cervical swabs were also streaked on Jembec plates for gonorrhea isolation and inoculated into BGM cells for chlamydia isolation. Gonorrhea isolates were identified by Syva FA reagent as well as by metabolic testing methods. Chlamydia inclusions were identified with Sanofi Diagnostics FA antibody. In urine specimens, the BDProbeTec ET System identified 22 patients as positive for chlamydia. 24 of these patients were positive from at least one specimen site by culture and/or LCx (sensitivity of 91.7%). Of 163 urines from negative patients, 148 were negative and 10 were inhibitory to BDProbeTec ET (specificity of 96.7%). Of 24 evaluable patients positive from at least one specimen site by culture and/or LCx, the BDProbeTec ET System identified 22 patients as positive for chlamydia in swab specimens (sensitivity of 91.7%). Of 169 patients negative from both sites by culture and/or LCx, 160 were negative by BDProbeTec ET (specificity of 94.7%). In urine specimens, the BDProbeTec ET System identified 17 patients as positive for gonorrhea. 20 of these patients were positive from at least one specimen site by culture and/or LCx (sensitivity of 85.0%) Of 169 urines from negative patients, 156 were negative and 10 were inhibitory to BDProbeTec ET (specificity of 98.1%). In swab specimens, the BDProbeTec ET System identified 23 patients as positive for gonorrhea. 22 of these patients were positive from at least one specimen site by culture and/or LCx (sensitivity of 100%, specificity of 99.4%). In conclusion, the BDProbeTec ET System is a highly sensitive and specific test for identifying chlamydia and gonorrhea from urine or cervical swabs in adolescent patients. It has the advantage of identifying specimens containing inhibitors which could cause false negatives.

## OBJECTIVE

Becton Dickinson's BDProbeTec™ ET (BDPT), a new molecular diagnostic test for chlamydia and gonorrhea genital infections, was compared with culture and with Abbott LCx assay for the laboratory diagnosis of genital infections in adolescent patients.

## METHODS

- **Patients:** patients less than 20 years old at ER, teen, family planning and OB clinics
- **Specimens:** paired urine and genital swabs
- **Detection:** BDPT, LCx Assay, and culture (Sanofi FA reagent for chlamydia and Syva FA reagent for gonorrhea culture confirmation)

## DEFINITIONS

**INDETERMINATE:** Amplification inhibition as determined by Amplification Control well. This is an indication that the specimen contained substance(s) which inhibited the amplification process.

**EQUIVOCAL:** "Gray Zone" where results need to be repeated.

**INFECTED PATIENT:** A patient was considered to be infected if any two of the following tests were positive from either swab or urine: culture, BDProbeTec, LCx, or DFA (for chlamydia only)

## DATA

BDPT Compared to Culture/DFA for ID of Chlamydia-Infected Patients				
BDPT Swab	Culture +	Culture -DFA +	Infected Pt Culture-DFA-	Uninfected Pt Culture-DFA-
positive	21	1	5	4
negative	0	1	1	159
indeterminate	0	0	0	0
equivocal	0	0	0	0
BDPT Urine	Culture +	Culture -DFA +	Infected Pt Culture-DFA-	Uninfected Pt Culture-DFA-
positive	20	1	1	1
negative	1	1	2	146
indeterminate	0	0	0	10
equivocal	0	0	0	0

**DATA**

**BDPT Compared to Culture for ID of Gonorrhea-Infected Patients**

BDPT Swab	Culture +	Culture -
positive	20	2
negative	0	171
Indeterminate	0	0
Equivocal	0	1
BDPT Urine	Culture +	Culture -
BDPT urine positive	16	4
BDPT urine negative	2	157
BDPT indeterminate	0	10
BDPT equivocal	0	0

**BDPT Compared to LCx for ID of Chlamydia Infections**

BDPT Swab	LCx swab +	LCx swab -
positive	24	5
negative	1	156
indeterminate*	0	0
equivocal**	0	0
BDPT Urine	LCx urine +	LCx urine -
positive	21	6
negative	2	148
indeterminate*	0	10
equivocal**	0	0

**LCx Compared to Culture/DFA for ID of Chlamydia Infections**

	Culture +	Culture -DFA +	Infected Pt Culture-DFA-	Uninfected Pt Culture-DFA-
LCx swab pos	20	1	4	0
LCx swab neg	0	0	1	161
LCx equiv.**	0	0	0	0
LCx urine pos	17	2	4	1
LCx urine neg	4	0	4	160
LCx equiv.**	0	0	0	0

**BDPT Compared to LCx for ID of Gonorrhea Infections**

BDPT Swab	LCx swab +	LCx swab -
positive	19	1
negative	0	167
indeterminate*	0	0
equivocal**	0	1
BDPT Urine	LCx urine +	LCx urine -
positive	16	4
negative	3	156
indeterminate*	0	10
equivocal**	0	0

**LCx Compared to Culture for ID of Gonorrhea Infections**

	Culture +	Culture -
LCx swab positive	17	2
LCx swab negative	0	169
LCx equivocal**	0	0
LCx urine positive	17	2
LCx urine negative	1	169
LCx equivocal**	0	0

**Accuracy of Amplified Tests in Diagnosing Chlamydia**

Amplified Test	Sensitivity*	Specificity*
BDPT swab	22/22 (100%)	148/153 (96.7%)
LCx Swab	21/21 (100%)	161/165 (97.6%)
BDPT urine	21/22 (95.5%)	149/155 (96.1%)
LCx urine	19/23 (82.6%)	160/164 (97.6%)

## Accuracy of Amplified Tests in Diagnosing Gonorrhea

Amplified Test	Sensitivity**	Specificity**
BDPT swab	20/20 (100%)	171/174 (98.3%)
LCx Swab	17/17 (100%)	169/171 (98.8%)
BDPT urine	16/18 (88.9%)	157/161 (97.5%)
LCx urine	17/18 (94.4%)	169/171 (98.8%)

\*compared to culture and DFA \*\*compared to culture

## Practical Comparison of DNA Detection Methods

BD ProbeTec ET™	Abbott LCx
One small work space	Requires separate processing and amplification areas
Simultaneous chlamydia/ GC detection	Separate chlamydia/GC detection tests
Room temp. urine transport	Refrigerated urine transport
Amplification control	No amplification control
Throughput 180CT&GC/shift	Throughput 40 CT&GC/shift
Daily maintenance: <5 min Weekly: none Monthly: 20 mins	Daily maintenance: 20 mins Weekly: 30 mins Monthly: 30 mins
Specimen spends 135 minutes on instruments	210 minutes on instruments
Hands-on time 2.3 min/spec	Hands-on 3.7 min/spec
Walkaway overnight	Must remove reagents from instrument after test

## CONCLUSIONS

BDPT is a sensitive system for the identification of genital chlamydia and gonorrhea infections with advantages over Abbott LCx:

- Testing for both pathogens is simultaneous rather than consecutive.
- Detection of specimen inhibitors may decrease false negative reports.
- BDPT is faster and more convenient to perform.
- BDPT equipment requires less maintenance than LCX.

