

Evaluation of the BDProbeTec™ ET System on Urine and Endocervical Specimens for the Identification of Chlamydia and Gonorrhea Infections.

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OBJECTIVES: A new molecular diagnostic test for chlamydia and gonorrhea urogenital infections by Becton Dickinson, BDProbeTec™ ET System (BDPT), was compared with the Abbott LCx (LCx) assay and culture.

METHODS: The patient population included female patients attending emergency, adolescent, family planning, and obstetric clinics. Most specimen sets included paired urine and endocervical swab specimens, which were tested by the BDPT System as well as by LCx for gonorrhea and chlamydia. Endocervical 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 culture inclusions were identified with Kallestad Diagnostics FA antibody.

CHLAMYDIA RESULTS: 32 patients were identified as infected with *Chlamydia trachomatis* (positive culture or DFA or LCx positive from urine or endocervix). Of these, the BDPT identified 31 from swab specimen (sensitivity 96.9%) and 29 from urine (sensitivity 90.6%) 253 of the 262 uninfected patients were negative by BDPT swab testing (specificity 96.6%). Urine specimens were unavailable for 6 patients, and from 13 patients showed inhibition of amplification control so could not be called positive or negative. 239 of 243 remaining uninfected patients were negative by BDPT urine testing (specificity 98.4%).

GONORRHEA RESULTS: 21 patients were identified as infected with *Neisseria gonorrhoeae* (positive culture and/or LCx positive from urine or cervix). Of these, the BDPT identified 21 from swab specimen (sensitivity 100%) and 16/19 positive patients with urine specimens available (sensitivity 84.2%) 273 of the 274 uninfected patients were negative by BDPT swab testing (specificity 99.6%). Urine from 13 patients showed inhibition of amplification control so could not be called positive or negative. 255 of 258 remaining uninfected patients were negative by BDPT urine testing (specificity 98.8%).

CONCLUSIONS: The BDPT system for the identification of endocervical chlamydia and gonorrhea infections is sensitive and specific. Advantages include: a) testing for both pathogens is simultaneous rather than consecutive, b) detection of specimen inhibitors decreases false negative reports, and c) test is faster and more convenient to perform, and d) equipment requires less maintenance than LCx.

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 female patients.

METHODS

- Patients: females 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)

DESCRIPTION OF THE BDPROBETEC TEST

The BD ProbeTec test for detection of chlamydia and gonorrhea infection using genital swabs or first void urine specimens uses amplification of the target organisms' DNA. After an initial processing step, specimens are placed in a heating block for denaturation, and then transferred to a priming plate. Following transfer to the amplification plate, they are placed in the instrument for amplification and detection. The test takes approximately 2.5 hours. The results are printed as positive, negative, equivocal (gray zone), or indeterminate (internal control did not amplify, indicating inhibitor in specimen).

BDPROBETEC ET™ DESCRIBED

- Thermophilic Strand Displacement Amplification (SDA)
- Is an isothermal DNA amplification technology in an instrumented system.
- Based on simultaneous amplification and detection of target DNA by the use of amplification primers along with a fluorescent-labeled detector probe.
- The SDA components in disposable microwell strips react with a processed sample.
- A thermally controlled fluorescent reader incubates the reaction and monitors the real-time formation of amplification products.

RESULTS

BDPT Compared to Culture/DFA for ID of Chlamydia-Infected Patients				
	Culture +	Culture -DFA +	Infected Pt Culture-DFA-	Uninfected Pt Culture-DFA-
BDPT swab pos	28	1	2	9
BDPT swab neg	0	0	1	253
BDPT indet.*	0	0	0	0
BDPT equiv.**	0	0	0	0
BDPT urine pos	27	1	1	4
BDPT urine neg	1	0	2	239
BDPT indet.*	0	0	0	13
BDPT equiv.**	0	0	0	0

RESULTS

BDPT Compared to LCx for ID of Chlamydia Infections		
BDPT Swab	LCx swab +	LCx swab -
Positive	34	6
Negative	3	252
indeterminate*	0	0
equivocal**	0	0
BDPT Urine	LCx swab +	LCx swab -
Positive	24	9
Negative	3	236
indeterminate*	0	13
equivocal**	0	0

BDPT Compared to LCx for ID of Gonorrhea Infections		
BDPT Swab	LCx swab +	LCx swab -
Positive	13	0
Negative	0	124
indeterminate*	0	0
equivocal**	0	0
BDPT Urine	LCx urine +	LCx urine -
Positive	10	2
Negative	0	115
indeterminate*	0	6
equivocal**	0	0

Accuracy of Amplified Tests in Diagnosing Chlamydia-Infected Patient		
Amplified Test	Infected Patient	Uninfected Patient
BDPT swab	96.9%	96.6%
LCx Swab	100%	97.5%
BDPT urine	90.6%	98.4%
LCx urine	71.4%	97.4%

Accuracy of Amplified Tests in Diagnosing Gonorrhea-Infected Patient		
Amplified Test	Infected Patient	Uninfected Patient
BDPT swab	100%	99.6%
LCx Swab	89.5%	99.3%
BDPT urine	84.2%	98.8%
LCx urine	88.2%	99.3%

BDPT Compared to Culture for ID of Gonorrhea-Infected Patients		
BDPT Swab	Culture +	Culture -
Positive	13	0
Negative	0	124
indeterminate*	0	0
equivocal**	0	0
BDPT Urine	Culture +	Culture -
Positive	10	2
Negative	1	115
indeterminate*	0	6
equivocal**	0	0

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.

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