As presented at the 99th General Meeting of the American Society for Microbiology, May 1999.

Comparison of the BDProbeTec™ ET System to Ligase Chain Reaction and Polymerase Chain Reaction for Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*

RUTH KENDRICK[1], RL SAUTTER[2], WD LEBAR[1], T RUDOLPH[3]

HCL-Providence Hospital, Southfield, MI[1], Pinnacle Health Systems, Harrisburg, PA[2], Detroit Health Department, Detroit, MI[3]

OBJECTIVE: The BDProbeTec ET System is a new DNA amplification methodology which uses homogeneous strand displacement with an energy transfer detection chemistry for the detection of CT and GC. In an ongoing study, we compare the BD-PT to LCR (Abbott Diagnostics) and PCR (Roche Diagnostics) for the detection of CT and GC.

METHODS: Specimens were obtained from STD clinic patients. Swabs for the BD-PT, LCR and PCR assays were collected from the endocervix of 100 women to date. Urine and urethral specimens were obtained from 39 men. Specimens for BD-PT and LCR were processed within 24 hours of collection. PCR specimens were frozen at -70° C until testing was performed from culture transport medium. Initial results of the 3 assays were then compared.

RESULTS: The agreement of the assays for the detection of CT and GC is shown below.

	CT		GC	
	Swabs	Urines	Swabs	Urines
BD-PT vs LCR	92.6%	100%	100%	93.9%
BD-PT vs PCR	94.8%	94.1%	100%	100%
LCR vs PCR	92.7%	94.8%	100%	94.8%

For detection of CT from swabs, 8 specimens were positive by all 3 assays, 2 positive by BD-PT and LCR, 4 positive by LCR only and 2 positive by BD-PT only. For detection of CT in urine, 5 specimens were positive by all 3 assays and 2 by BD-PT and LCR only. For the detection of GC from swabs, all 11 positive specimens were detected by all 3 assays. For detection of GC in urine, 4 specimens were detected by all 3 assays and 2 by BD-PT and PCR only.

CONCLUSIONS: The detection of CT and GC from swab and urine samples by BD-PT correlates well with other nucleic acid amplification assays.

INTRODUCTION

Chlamydia trachomatis (CT) and *Neisseria gonorrhoeae* (GC) are the most common bacterial sexually transmitted diseases in the United States today. The current methods for detection of CT and GC include culture, enzyme immunoassay, non-amplified and amplified probes. Amplification assays have dramatically increased the sensitivity of detection of these organisms from traditional specimen types (endocervix and urethra) and extended the testing to non-invasive samples (urine). This added sensitivity has also altered the standard for detection of infection from detection of an infected sample to detection of an infected patient.

The BDProbeTec™ ET System is a new DNA amplification methodology which uses homogeneous strand displacement amplification (SDA) with an energy transfer detection chemistry for the detection of CT and GC. In an ongoing study, we compare the BD-PT to LCR (Abbott Diagnostics) and PCR (Roche Diagnostics) for the detection of CT and GC in urogenital specimens.

MATERIALS AND METHODS

PATIENTS: Specimens were obtained from patients attending a STD clinic with clinical or epidemiological history suggestive of chlamydial or gonococcal infection. Swabs for the BD-PT, LCR and PCR assays were collected from the endocervix of 100 women to date. Urine and urethral specimens were obtained from 39 men. Specimens for BD-PT and LCR were processed within 24 hours of collection according to manufacturer's instructions. PCR specimens were frozen at -70° C until testing was performed from culture transport medium.

LCR: The LCR assays (Abbott Diagnostics) for detection of CT and GC were performed according to manufacturer's instructions.

PCR: The Roche *Amplicor* Microwell *Chlamydia trachomatis* and *Neisseria gonorrhoeae* assays were performed according to manufacturer's instructions. An amplification control was included with each specimen tested.

BD-PT: Endocervical, urethral and urine samples were processed according to manufacturer's instructions. All samples were tested within 24 hours of collection.

The BD-PT CT and GC amplified DNA assays are based on the simultaneous amplification and detection of target using amplification primers and a fluorescent labeled detector probe. The SDA reagents are dried in two separate microwell strips. The processed sample is added to the priming microwell which contains the amplification primers, labeled detector probe, and other reagents necessary for amplification. After two incubation steps, the reaction mixture is transferred to the amplification microwell which contains a DNA polymerase and restriction enzyme necessary for SDA. The microwells are sealed to prevent contamination and then incubated in a thermally controlled reader which monitors each reaction for the generation of amplified products. Each sample and control is tested in three discrete microwells: *CT, GC* and the amplification control. In order to identify a sample that may inhibit the SDA reaction, an amplification control is run with each specimen. Results are reported through an algorithm as positive, negative or indeterminate.

Results were analyzed as per cent agreement with PCR and LCR assays.

RESULTS

Comparison of the assays is shown below

	CT (Swab)						CT (Urine)		
BD-PT	+	+	-	+	-	BD-PT	+	+	-
LCR	+	+	+	-	-	LCR	+	+	-
PCR	+	-	-	-	-	PCR	+	-	-
	8	2	4	2	123		5	2	132

	GC (Swab)			GC (Urine)		
BD-PT	+	-	BD-PT	+	+	-
LCR	+	-	LCR	+	-	-
PCR	+	-	PCR	+	+	-
	11	128		4	2	133

The agreement of the assays for the detection of CT and GC is shown below.

	CT		GC	
	Swabs	Urines	Swabs	Urines
BD-PT vs LCR	92.6%	100%	100%	93.9%
BD-PT vs PCR	94.8%	94.1%	100%	100%
LCR vs PCR	92.7%	94.8%	100%	94.8%

DISCUSSION

Amplified nucleic assays for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* offer significant increases in sensitivity when compared to cell culture and other immunologic or non-amplified nucleic assays.

Previous studies in our laboratory have shown that LCR and PCR perform equivalently for the detection of CT and GC from female endocervical and urine samples and male urethral and urine samples when compared to an expanded gold standard. This standard, defined as an infected patient, includes results obtained from cell culture and confirmed amplified nucleic acid assays from multiple specimen sources.

The results of this study demonstrate that the BDProbeTec™ *Chlamydia trachomatis* and *Neisseria gonorrhoeae* assay performs comparably to LCR and PCR for the detection of CT and GC from endocervical, urethral and urine samples.

REFERENCES

1. LeBar WD, and Sautter RL, Abstracts of the Annual Meeting, American Society for Microbiology, 1998.