

Clinical Evaluation of the BDProbeTec™ ET System in Detecting *C. Trachomatis* and *N. Gonorrhoeae* in Endocervical and Female Urine Specimens.

M.T. KATANIK¹, M. TUOHY¹, D. WILSON¹, N. MALDEIS², G.S. HALL¹

¹CLEVELAND CLINIC FOUNDATION, CLEVELAND OH, ²BECTON DICKINSON, SPARKS, MD

Abstract

■ We evaluated the BDProbeTec™ ET System (BDPT) (Becton Dickinson, Sparks, MD) for the detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) in endocervical swabs and urine samples. BDPT was compared to culture and The Abbott LCX® (LCX) System (Abbott Laboratories, Abbott Park, IL) for both organisms.

BDPT utilizes a thermophilic Strand Displacement Amplification (tSDA) technology that simultaneously amplifies and detects target DNA while employing the use of an amplification control. LCX uses Ligase Chain Reaction (LCR) amplification technology, which targets specific nucleic acid sequences for GC and plasmid DNA for CT. All testing was performed according to manufacturer's specifications.

INTRODUCTION

We evaluated the BDProbeTec™ ET System (BDPT) (Becton Dickinson, Sparks, MD) for the detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) in endocervical swabs and urine samples. BDPT was compared to culture and the Abbott LCX® (LCX) System (Abbott Laboratories, Abbott Park, IL).

BDPT utilizes a thermophilic Strand Displacement Amplification (SDA) technology that amplifies and detects target DNA while employing the use of an amplification control. LCX uses Ligase Chain Reaction (LCR) amplification technology, which targets specific nucleic acid sequences for GC and plasmid DNA for CT.

Samples in low prevalence populations from the Emergency, Obstetrics and Outpatient Departments at the Cleveland Clinic Foundation were collected from 63 female endocervical specimens. Urine specimens were obtained from 57 of these patients. BDPT results were compared to the gold standard and an enhanced gold standard. The CT gold standard consisted of culture and Direct Fluorescent Antibody (DFA). The enhanced gold standard included culture, DFA and LCX. Likewise, for GC the BDPT System was compared to the gold standard of GC culture, and to the enhanced gold standard of GC culture and LCX.

For endocervical swabs, the sensitivity of the CT BDPT compared to CT culture and DFA was 100% (6/6) with a specificity of 93% (53/57). When comparing CT BDPT to the enhanced gold standard the sensitivity was 100% (6/6) with a specificity of 93% (53/57). For urine specimens, the sensitivity of the CT BDPT compared to the gold standard was 100% (5/5) and specificity was 98% (51/52); compared to the enhanced gold standard sensitivity was 100% (5/5) and specificity was 98% (51/52).

For endocervical swabs, the sensitivity of the GC BDPT compared to GC culture was 100% (1/1) with a specificity of 97% (60/62). When compared to the enhanced gold standard sensitivity was 100% (2/2) and specificity was 98% (60/61). For the urine specimens no sensitivity was determined as there were no positive cultures (gold standard) however, the specificity was 98% (56/57). The sensitivity and specificity were 100% (1/1) and 100% (56/56) respectively when compared to the enhanced gold standard.

We have found the BDProbeTec ET system to be a very user-friendly procedure in our lab. Separate areas for processing and amplification are not required and maintenance of equipment is minimal. The amplification and detection steps run concurrently and are completed in an hour. An amplification control is run with each sample to reduce the likelihood of false negative results. In conclusion, we consider the BDProbeTec ET System to be a sensitive and specific DNA amplification assay for the detection of chlamydia and gonorrhoea infections in females for both endocervical and urine specimens.

METHODS

SPECIMENS: Samples in low prevalence populations from the Emergency, Obstetrics and Outpatient Departments at the Cleveland Clinic Foundation were collected from 63 female endocervical specimens. Urine specimens were obtained from 57 of these patients.

COMPARISONS: BDPT results were compared to the gold standard and an enhanced gold standard. The CT gold standard consisted of culture and Direct Fluorescent Antibody (DFA)*. The enhanced gold standard included culture, DFA* and LCX. Likewise, for GC the BDPT System was compared to the gold standard of GC culture, and to the enhanced gold standard of GC culture and LCX.

*DFA was used to adjudicate discrepant results.

CULTURE: For CT—two McCoy shell vials (Viomed Labs) were inoculated and incubated for 48 hours at 37 degrees in 6% CO₂. One vial was stained at 48 hours, the second vial blind subbed and stained after another 48-hour incubation. Stains were done using Bartel's Anti-Chlamydiae Mouse Monoclonal FITC Conjugate. For GC—culture was performed by swabbing a Martin-Lewis Plate and incubation for 72 hours at 37 degrees and 6% CO₂. Identification by Quadferm® (bio Merieux Vitek), serological confirmation by Gonogen™ (Becton Dickinson).

DFA: The chlamydia culture transport media (M4 media, Micro Test Inc., Lilburn, GA) was centrifuged and the pellet stained using Bartel's Anti-Mouse Monoclonal FITC Conjugate.

DEFINITIONS

POSITIVE ENHANCED RESULT:

- CT enhanced gold standard—culture or DFA positive and/or LCX positive in both urine and swab.
- GC enhanced gold standard—culture positive and/or LCX positive in both urine and swab.

NEGATIVE ENHANCED RESULT:

- For both CT and GC—negative by all methods.
- For CT—positive by BDProbeTec, negative by culture and DFA and/or LCX negative in both urine and swab.
- For GC—positive by BDProbeTec, negative by culture and/or LCX negative in both urine and swab.

RESULTS

CHLAMYDIA: For endocervical swabs, the sensitivity of the CT BDPT compared to CT culture and DFA was 100% (6/6) with a specificity of 93% (53/57). When comparing CT BDPT to the enhanced gold standard the sensitivity was 100% (6/6) with a specificity of 93% (53/57). For urine specimens, the sensitivity of the CT BDPT compared to the gold standard was 100% (5/5) and specificity was 98% (51/52); compared to the enhanced gold standard sensitivity was 100% (5/5) and specificity was 98% (51/52).

GONORRHOEAE: For endocervical swabs, the sensitivity of the GC BDPT compared to GC culture was 100% (1/1) with a specificity of 97% (60/62). When compared to the enhanced gold standard sensitivity was 100% (2/2) and specificity was 98% (60/61). For the urine specimens no sensitivity was determined as there were no positive cultures (gold standard) however, the specificity was 98% (56/57). The sensitivity and specificity were 100% (1/1) and 100% (56/56) respectively when compared to the enhanced gold standard.

NOTE: None of the 63 swabs tested by BDPT were found to be inhibitory. One urine, tested for chlamydia, out of 57 (1.8%) was found to be inhibitory by BDPT. Upon relysing and retesting, the specimen resulted as a true positive.

Table 1

BDPT CHLAMYDIA RESULTS		
SAMPLES	GOLD STANDARD	ENHANCED GOLD STANDARD
BDPT SWABS	SENS.= 100% (6/6)	SENS.= 100% (6/6)
	SPEC.= 93% (53/57)	SPEC.= 93% (53/57)
BDPT URINES	SENS.= 100% (5/5)	SENS.= 100% (5/5)
	SPEC.= 98% (51/52)	SPEC.= 98% (51/52)

Table 2

BDPT GC RESULTS		
SAMPLES	GOLD STANDARD	ENHANCED GOLD STANDARD
BDPT SWABS	SENS.= 100% (1/1)	SENS.= 100% (2/2)
	SPEC.= 97% (60/62)	SPEC.= 98% (60/61)
BDPT URINES	SENS.= NA (0/1)	SENS.= 100% (1/1)
	SPEC.= 98% (56/57)	SPEC.= 100% (56/56)

CONCLUSION

We have found the BDProbeTec ET system to be a very user-friendly procedure in our lab. Separate areas for processing and amplification are not required and maintenance of equipment is minimal. The amplification and detection steps run concurrently in a closed, contamination free environment and are completed in an hour. An amplification control is run with each sample to reduce the likelihood of false negative results. In conclusion, we consider the BDProbeTec ET System to be a sensitive and specific DNA amplification assay for the detection of chlamydia and gonorrhoea infections in females for both endocervical and urine specimens.