

Clinical Evaluation of the BD Viper™ System and the BD ProbeTec™ CTQ^x Amplified DNA Assay (CTQ^x) for the Direct Qualitative Screening of *Chlamydia trachomatis* (CT) in Female Endocervical, Female Vaginal, and Female Urine Specimens

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ABSTRACT

INTRODUCTION

The BD ProbeTec™ ET System (PT) and the BD Viper™ System allow for the detection of *C. trachomatis* (CT) and *N. gonorrhoeae* (GC) DNA. The systems are based on simultaneous amplification and detection of target DNA using amplification primers along with a fluorescently-labeled detector probe. The BD ProbeTec ET System is commercially available for the direct, qualitative detection of CT and GC DNA in endocervical swabs, male urethral swabs, and in female and male urine specimens. The BD Viper System under study in this protocol is a fully automated sample processor and fluorescent reader under development for the direct, qualitative detection of CT and GC DNA in endocervical swabs, self-collected vaginal swabs, male urethral swabs, and in female and male urine specimens. The automated system is also based on simultaneous amplification and detection of target DNA using amplification primers along with a fluorescently-labeled detector probe. This BD Viper System integrates a proprietary iron oxide-based paramagnetic particle extraction and SDA technology to detect CT and GC DNA in patient specimens. In this extraction mode, the system includes an extraction control in the extraction tube in order to monitor for extraction failure.

The objective of the study was to examine the performance of female clinical specimens: endocervical swab, neat urine, Urine Preservative Transport (UPT) urine, and a self-collected vaginal swab on the BD Viper™ System (in extracted mode)* combined with the new CTQ^x assay* vs. the patient infected status (PIS) for detection of CT.

METHODS

511 female participants were enrolled from seven sites with both low and high chlamydial prevalence (1.5%–19.2%). Both symptomatic and asymptomatic patients were included. Each participant was asked to provide a urine specimen, four endocervical swabs, and one self-collected vaginal swab. The first endocervical swab was either plated onto GC media for GC culture or was collected as the patient's standard of care swab. The remaining three endocervical swabs were randomized. One endocervical swab and a urine specimen were tested using the BD ProbeTec™ ET System (PT), one endocervical swab and urine specimen was tested using the Gen-Probe APTIMA Combo2 (AC2) assay. The remaining endocervical swab, one vaginal swab, a UPT and a neat urine specimen were tested using the CTQ^x assay on the BD Viper™ System in extracted mode. For comparison, patient infected status (PIS) was defined as positive when there was at least one positive test result from both FDA cleared assays (AC2 and PT) regardless of specimen type (endocervical or urine). In addition to PIS the AC2 swab and urine and the Viper swabs and urine were compared on a rotating basis to estimate percent agreement. Of the 8 results, one was compared to the remaining seven results of which at least two were required to be positive to deem the patient infected.

RESULTS

The sensitivities of the CTQ^x assay, using the BD Viper™ System ranged from 91.8% to 98.0% and specificities from 98.9% to 99.3%, depending on the specimen type. Following is the comparison of the CTQ^x Clinical Specimens vs. patient infected status and percent agreement based on the rotating method:

CTQ ^x Performance Compared to Patient Infected Status					
Specimen Type	N	Sensitivity	95% C.I.	Specificity	95% C.I.
Endocervical Swabs	509	91.8% (45/49)*	(80.4% - 97.7%)	99.3% (457/460)	(98.1% - 99.9%)
Vaginal Swabs	508	98.0% (48/49)	(89.1% - 99.9%)	99.1% (455/459)	(97.8% - 99.8%)
Neat Urine	495	95.8% (46/48)	(85.7% - 99.5%)	98.9% (442/447)	(97.4% - 99.6%)
UPT Urine	511	95.9% (47/49)	(86.0% - 99.5%)	98.9% (457/462)	(97.5% - 99.6%)

* Two of the four subjects where the Viper endocervical swab was negative for CT were also negative in both the reference endocervical swabs (PT and AC2).

CTQ ^x and AC2 Performance Compared to the Rotating Method			
Specimen Type	N	Positive Percent Agreement	Negative Percent Agreement
Viper Endocervical Swab	479	90.0% (45/50; 78.2% - 96.7%)	99.8% (428/429; 98.7% - 100.0%)
Viper Vaginal Swab	479	96.0% (48/50; 86.3% - 99.5%)	99.5% (427/429; 98.3% - 99.9%)
Aptima Combo2 Swab	479	88.0% (44/50; 75.7% - 95.5%)	99.3% (426/429; 98.0% - 99.9%)
Viper Neat Urine	479	94.0% (47/50; 83.5% - 98.7%)	99.3% (426/429; 98.0% - 99.9%)
Viper UPT Urine	479	96.0% (48/50; 86.3% - 99.5%)	99.5% (427/429; 98.3% - 99.9%)
Aptima Combo2 Urine	479	98.0% (49/50; 89.4% - 99.9%)	99.8% (428/429; 98.7% - 100.0%)

CONCLUSIONS

- The CTQ^x assay, using the BD Viper™ System, was highly sensitive and specific for the detection of CT in female clinical specimens when compared to patient infected status and percent agreement.