

Comparison of Workflow and Analytical Sensitivity with Urine Specimens between the BD ProbeTec™ ET System and the BD Viper™ System in Extracted Mode.

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REVISED ABSTRACT

The BD ProbeTec™ ET System is a platform for amplification and detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) DNA from swab and urine specimens. Manual specimen processing for this system requires significant hands-on time, and for urine specimens involves prewarm, centrifugation, decanting/resuspension and heat lysis in addition to capping and uncapping. The BD Viper™ System in Extracted Mode* alleviates this workload by automating cell lysis and DNA extraction along with the use of pierceable caps. The purpose of this study was to characterize the functional performance and throughput of the fully automated BD Viper System in extracted mode and compare it to that of the BD ProbeTec ET System. Urine specimens were spiked with 15 CT Elementary Bodies (EBs) and 50 GC particles/mL and processed either manually for the BD ProbeTec ET System or with the ferric oxide-based DNA extraction technology of the BD Viper System. Processed specimens were amplified using the assay chemistries appropriate for each platform and results were evaluated against predetermined thresholds. Hands-on time and time-to-results were determined for both systems based on the processing of 46 specimens and controls. The results from testing spiked urine specimens on the BD ProbeTec ET System and BD Viper System are shown below:

	% Positive	
	BD ProbeTec ET System	BD Viper System
CT	83.3%	100%
GC	100%	100%

The hands-on time for the BD ProbeTec ET System required 174 minutes of technologist time to process 46 specimens and controls prior to running the assays. The hands-on time required for this number of specimens on the BD Viper System in Extracted Mode totaled 31 min. Time-to-results for the BD ProbeTec System was 234 minutes, whereas for the BD Viper System it was 151 minutes. The BD Viper System in Extracted Mode allows for equivalent or better analytical performance in the detection of CT and GC while the enhanced automation provides significant labor release for processing of urine specimens when compared with the BD ProbeTec ET System.

INTRODUCTION

In the United States, *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) are the two most commonly reported sexually transmitted diseases. In 2006, there were over 1 million cases of CT infection and 350,000 cases of GC infection reported to the CDC.¹ Many of these cases are asymptomatic and when left untreated can cause infertility in women and prostatitis in men. Due to the severity and prevalence of these infections, early detection is essential to prevent transmission. Nucleic acid based assays offer enhanced sensitivity and the ability to test a wide range of specimen types.

The BD ProbeTec ET System is a semi-automated platform for amplification and detection of CT and GC DNA from male and female swab and urine specimens. Manual specimen processing for this system requires significant hands-on time, and for urine specimens involves prewarm, centrifugation, decanting/resuspension and heat lysis in addition to capping and uncapping. With the growing shortage of skilled laboratory staff there is a need to alleviate this workload through automation. Here we describe the BD Viper System in Extracted Mode* which eliminates the majority of hands-on time required by the technologist in the processing of both swabs and urine specimens through the use of pierceable caps, chemical lysis, and automated DNA extraction. With the majority of the labor delegated to the robot, the system requires minimal hands-on time providing a 'load and go' workflow which helps maximize laboratory efficiency. The purpose of the present study with urine specimens was to compare the functional performance and throughput of the fully automated BD Viper System in Extracted Mode with that of the semi-automated BD ProbeTec ET System.

METHODS

Equal amounts of in-house collected female and male urine specimens were pooled and spiked with 15 CT EBs and 50 GC particles/mL. The pool was mixed and 3 mL aliquots dispensed into Urine Preservative Transport (UPT) Tubes appropriate to each system. Samples were processed and assayed according to the established protocols developed for both the BD ProbeTec ET System and BD Viper System in Extracted mode. Results were analyzed using the algorithms for the respective platforms and assays. Technologist and instrument run time was recorded for each system based on testing 46 urine samples.

* Product not for sale, for investigational use only in the US.

RESULTS

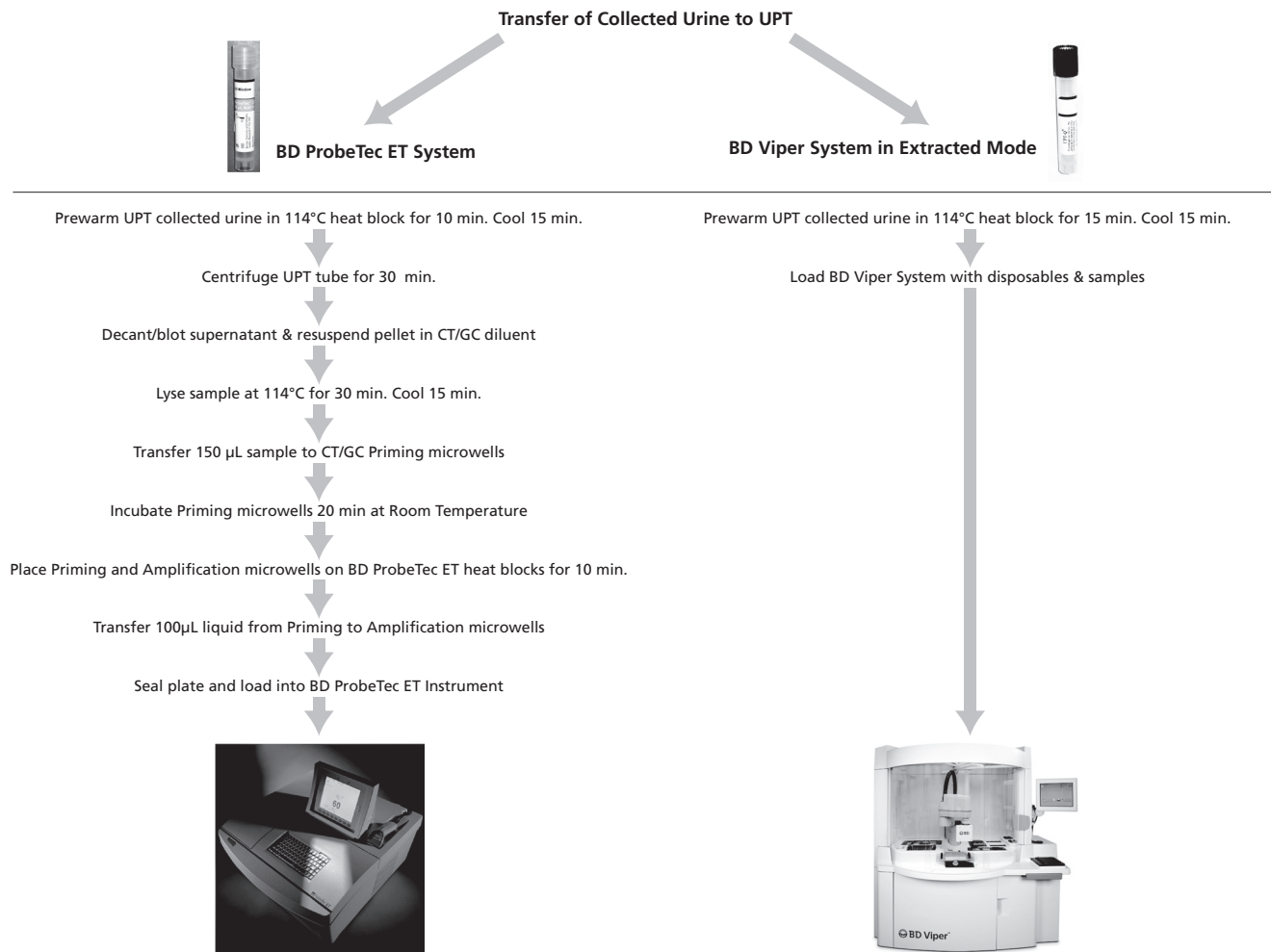


FIGURE 1. Workflow comparison for UPT urine between the BD ProbeTec ET System and the BD Viper System in Extracted Mode. UPT processing for the BD ProbeTec ET System contains several manual steps (including centrifugation and uncapping/recapping), whereas the BD Viper System in Extracted Mode requires only a simple prewarm and cooling step prior to loading samples on the instrument.

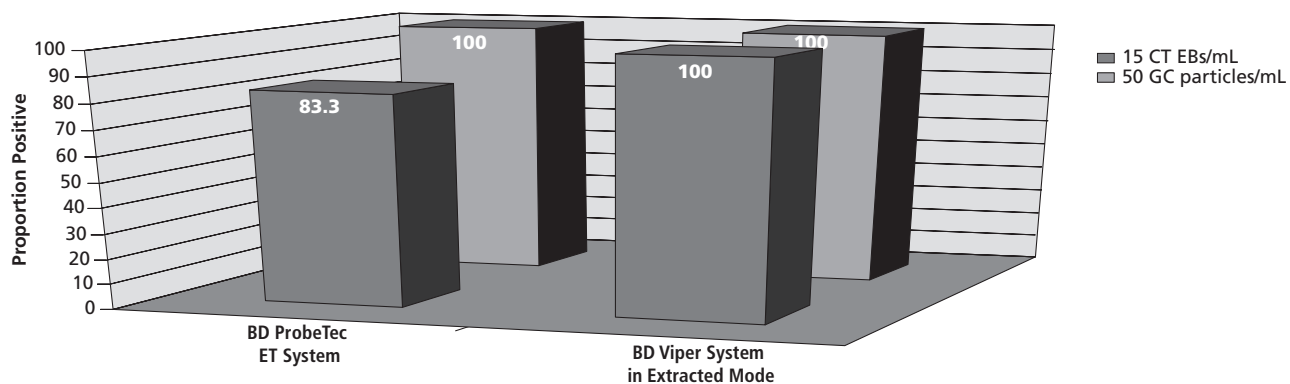


FIGURE 2. Comparison of proportion positive obtained with UPT samples processed and tested using the BD ProbeTec ET System and BD Viper System in Extracted Mode. The BD Viper System in Extracted Mode detected more CT positive specimens at 15 EBs/mL than the BD ProbeTec ET System ($p>0.05$). The proportion positive was the same for GC on both platforms.

RESULTS (continued)

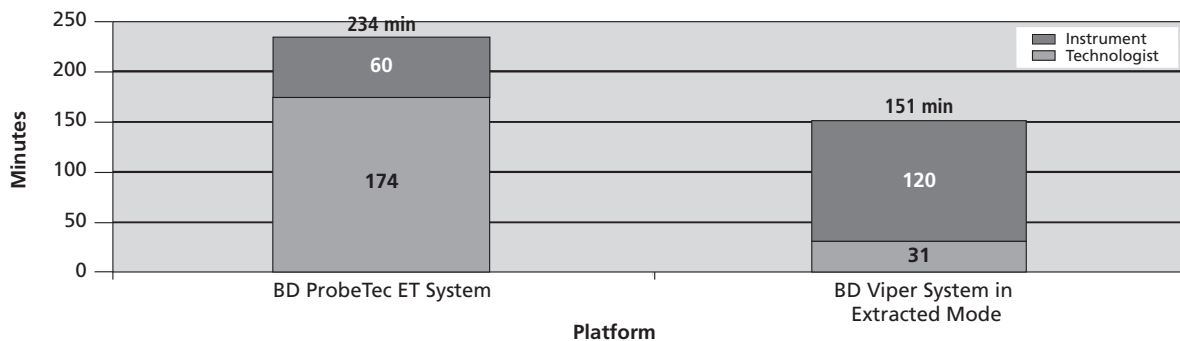


FIGURE 3. Comparison of time required to process 46 UPT samples. UPT samples processed using the BD ProbeTec ET System required 174 minutes of technologist time prior to loading on the instrument for an additional 60 minutes. The BD Viper System in Extracted Mode required 31 minutes of technologist time prior to loading onto the instrument for an additional 120 minutes. For 46 urine specimens, the time to results for the BD ProbeTec ET System was 234 minutes whereas it was 151 minutes for the BD Viper System in Extracted Mode.

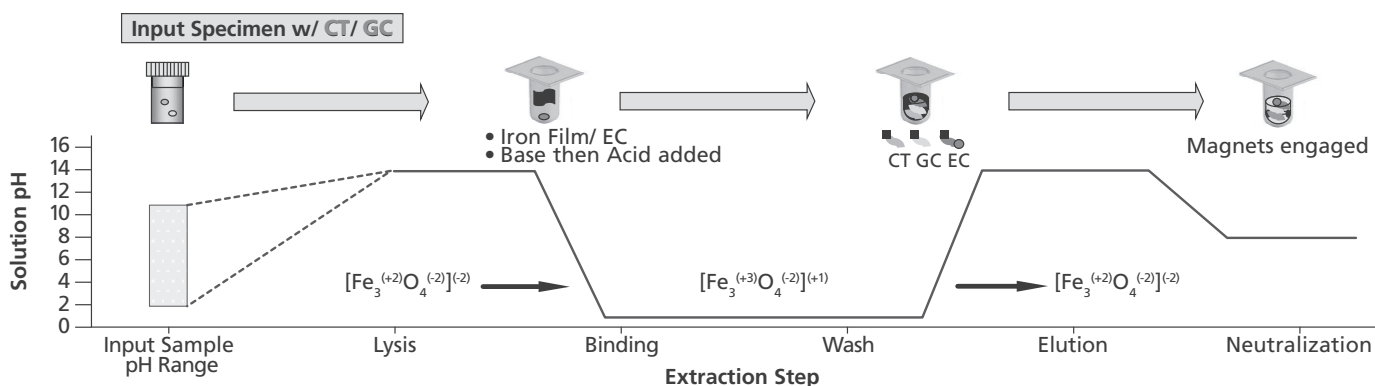


FIGURE 4. Flowchart of BD Viper System Extraction Principle. The extraction module involves pH and iron oxide chemistry. Cell lysis occurs with KOH addition. Subsequent addition of acid induces a positive charge on the iron allowing the bacterial DNA to bind. Magnets pull the iron to the side of the tube for the wash step. A two-step elution results in a final eluate with a pH = 9 that is transferred to priming and amplification wells.

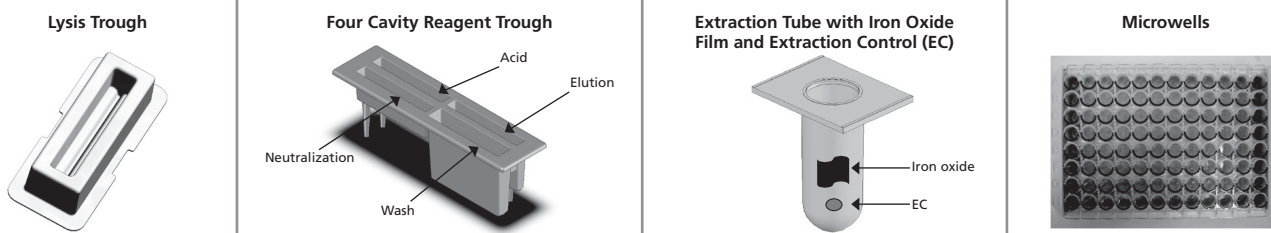


FIGURE 5. Consumable Reagents used with the BD Viper System in Extracted Mode. All extraction reagents are packaged in single use aliquots with a pierceable seal to prevent spillage and contamination. The BD Viper System punctures the seals automatically and disposes of unused reagents at the end of the run.

CONCLUSIONS

- The BD Viper System in Extracted Mode detected 17% more positive urine specimens spiked at 15 CT EBs/mL than the BD ProbeTec ET System. Performance with GC spiked urine at 50 particles/mL was similar across both platforms.
- The Time to Results for 46 urine specimens on the BD Viper System in Extracted Mode was 151 minutes versus 234 minutes on BD ProbeTec ET System.
- The BD Viper System in Extracted Mode offers significant labor release within the CT/GC testing laboratory through the use of unit dose reagents, pierceable seals and caps and automated DNA extraction. Further studies are required in order to characterize clinical performance.

REFERENCE

¹ <http://www.cdc.gov/std/stats/trends2006.htm>