TB10 017

MAKE A SLIDE ON THIS 3RD PARTY STUDY!

Comparison of ProbeTec Amplified CT/GC Urine Results Using BD Urine Processing Pouches vs. Sierra Diagnostics DNA/RNA Protect

INTRODUCTION

According to BD, the ProbeTec Urine Processing Pouches (UPP) are designed to remove amplification inhibitors and to stabilize urine specimens for room temperature storage and transport. The UPP may be added at either the collection or testing site, but must be in contact with the proper volume of sample for at least 2 hours prior to further processing.

Unfortunately, Kaiser Regional Laboratory has experienced problems associated with adding UPP:

1) A large volume of gas is generated in urine specimens by the UPP, increasing the pressure in the container if the lid is closed, causing urine to spray from around the lid when opened. If the lid is kept loose, the pressure causes urine to leak around the lid and down the sides. Therefor, the gas generation makes a messy process no matter how one handles the specimen. It would also greatly increase the likelihood of specimens leaking in transit to Regional Lab, so UPP use has not been attempted at the collection sites.
2) The urine must be in contact with UPP for at least 2 hours before further processing, which limits workflow and precludes processing and testing ProbeTec urine specimens on the same shift.
3) Past UPP lot numbers have actually increased inhibition, rather than decreasing it. Fortunately, BD has apparently solved this problem.
4) The UPP is designed for 15-20 ml urine, although up to 60 ml may be used. However, the UPP absorbs approximately 5 ml urine which become bound to the resins in the pouch. Since at least 8 ml is required for testing (enough for 1 test and 1 confirmation), if less than 15 ml is received, diluent must be added to bring the volume up, or the specimen is QNS. When >60 ml urine is received, it needs to be poured off, or multiple UPP added (CLS usually add multiple UPP).
5) UPP costs us $. per box of 100 according to our contract, or $ each. This adds significantly to our cost per test. List price is much higher.
6) BD makes no claims as to UPP compatibility with other urine tests when specimens must be shared for culture, UA, pregnancy testing, etc.

In addition to problems associated with UPP, compliance with collection guidelines (no cleaning, first catch, 20-50 ml urine) has been disappointing. Approximately 20% are still identified as "clean catch" and approximately 50% are either over or under the correct volume.

Because of the perceived UPP and collection shortcomings, the Sierra Diagnostics DNA/RNA Protect urine collection kit was evaluated as an alternative. The kit is provided as a 90 ml urine cup containing 4 ml of preservative. They are packaged singly in sealed plastic bags with a tear off information sheet instructing (English only) the patient to collect first catch urine and highlights the importance of filling the container half full. The product is supposed to stabilize and preserve urine specimens for room temperature storage and transport with no loss or degradation of any nucleic acids present. Sierra Diagnostics also claims that Protect preserved urine specimens may also be used for culture, UA, and pregnancy testing. Achieving the proper 1:10 Protect to urine volume ratio is important. With too much urine added, Protect loses effectiveness, and with too little urine added, the specimen will be inhibitory to amplification.

PROCEDURE

Urine specimens submitted to Regional Laboratory for amplified CT/GC testing are transported in insulated containers with ice packs, and are then refrigerated until processing. Study specimens were aliquoted to screw cap tubes containing DNA/RNA Protect at a 1:10 Protect to urine ratio. UPP were added to the remaining 15-50 ml urine specimens. The UPP specimens were refrigerated until routine testing on the next shift and were completed within 24 hours from arrival at Regional Lab. The Protect aliquot was held at room temperature from <1 hour to 4 days before testing.

Due to ProbeTec supply cost considerations, not all Protect aliquot specimens were tested. Those that were CT and/or GC positive and those that were inhibitory on the routine UPP run were always tested, but only a fraction of the negative specimens were tested.

RESULTS

Table 1.

		Protect CT Results	
		Positive	Negative
UPP CT Results	Positive	23	0
	Negative	0	59

Table 2.

		Protect GC Results	
		Positive	Negative
UPP GC Results	Positive	8	0
	Negative	0	74

Table 3.		*Protect Inhibition Results*	
		Inhibitory	Non-inhibitory
UPP Inhibition	Inhibitory	2	9
Results	Non-inhib.	0	82

There was complete concordance with positive and negative ProbeTec CT/GC results for 82 specimens preserved by either ProbeTec UPP or Sierra Diagnostics Protect (Tables 1 & 2). Another 9 specimens were inhibitory to amplification when preserved with UPP. Of these, only 2 were also inhibitory when preserved with Protect (Table 3). The other 7 UPP inhibitory specimens were non-inhibitory and negative for CT and GC when preserved with Protect. The inhibitory UPP specimens were all CT/GC negative when diluted 1:2 with ProbeTec diluent and retested.

CONCLUSIONS

1. DNA/RNA Protect can replace UPP preservation of urine specimens without compromising CT /GC positive or negative results.
2. DNA/RNA Protect reduces inhibitory ProbeTec results.
3. DNA/RNA Protect does not produce gas or increase the pressure in urine specimens as does UPP, so would not contribute to leaking specimens.
4. DNA/RNA Protect urine specimens preserved at the collection sites could be stored and transported at room temperature without losing sensitivity.
5. DNA/RNA Protect provides urine collection instructions, which could help collection guideline compliance.
6. DNA/RNA Protect could create a whole new set of problems, however, if the containers are over or under filled, and not half full.
7. Refrigerated urine specimens could be preserved at Regional Lab with the correct amount of DNA/RNA Protect to provide the 1:10 dilution ratio.
8. Using DNA/RNA Protect at collection sites would probably increase overall costs of urine amplified CT/GC testing to the NC Kaiser region and would shift Regional Lab preservation costs to the collection sites. The NC Kaiser region policy of collecting urine specimens on all teenagers when they visit a pediatric office, and deciding later whether or not to order amplified CT/GC, exacerbates the cost problem.
9. Using DNA/RNA Protect at Regional Lab could potentially reduce costs, depending on bulk price. Break even cost would be $0.80 per ml. If cost of Protect urine cup with 4 ml preservative is $1.00, then price per ml for bulk should be well under $0.25.
10. QNS specimen reports would be reduced with DNA/RNA Protect used at Regional Lab, since it adds to the urine volume rather than reducing it by 5 ml as does UPP.