

Evaluation of the BD ProbeTec™ Urine Preservative Transport (UPT) for Use With the BD ProbeTec™ ET *Neisseria gonorrhoeae* Amplified Assays

C. AYCOCK¹, E. W. HOOK III^{1,2}, D. FULLER³, J. TALBOTT³, R. BUCKNER³, B. VAN DER POL⁴, J. A. WILLIAMS⁴, C. L. CAMMARATA⁵

¹University of Alabama at Birmingham, Birmingham, AL; ²Jefferson County Department of Health,

³Wishard Health Service-Indiana University School of Medicine; ⁴Indiana University School of Medicine, Indianapolis, IN;

⁵Louisiana State University Health Sciences Center, New Orleans, LA

REVISED ABSTRACT

BACKGROUND. The BD ProbeTec™ ET System (ProbeTec) allows for the detection of *Neisseria gonorrhoeae* (GC) DNA. The system is based on amplification and detection of target DNA using amplification primers with a fluorescent detector probe. In addition to other specimen types, the ProbeTec is cleared for use in testing urine specimens from both symptomatic and asymptomatic males and females for the direct detection of GC using the Urine Processing Kit (UPP).

OBJECTIVE. This study compared the performance of the UPP to the BD ProbeTec™ Urine Preservative Transport (UPT) to transport and store urine specimens for testing on the ProbeTec. This study also investigated untreated (neat) urine, which has no preservatives or additives, as another specimen type for the current GC ProbeTec assay.

METHOD. A total of 953 urine specimens were processed, tested and reported using the UPT device. The lab storage conditions for UPT treated specimens ranged from ≤ 2 days refrigerated (N=122) to ≤ 2 -21 days (N=831) at room temperature. A total of 960 urine specimens stored neat were processed, tested and reported. The transport storage ranged from refrigerated (N=396) to room temperature (N=564)

RESULTS. Seventy specimens were confirmed positive for GC and 883 were negative by UPP. The overall percent agreement (OPA) vs. UPP for specimens refrigerated ≤ 2 days was 98.36% (120/122) while the OPA for specimens stored at room temperature was 99.81% (537/538) for < 2 days, 100% for 3-7 days (217/217), and 100% for 7-14 days (4/4) respectively. Among 564 untreated neat urines stored at room temperatures for up to 8 hours, there were 46 GC confirmed positives and 518 GC negatives with an OPA of 99.29% (560/564) relative to UPP. The examination of 396 untreated neat urine specimens stored refrigerated up to 24 hours yielded 23 confirmed GC positives and 373 GC negatives with an OPA of 99.24% (393/396) relative to UPP.

CONCLUSION. This study illustrates that the ProbeTec UPT is an invaluable aid in the transport and storage of urine specimens for extended periods for GC testing on the BD ProbeTec ET System. The study also confirms that testing of neat urine is an acceptable alternative when the duration of transport is restricted and the temperature is maintained within specified limits.

BACKGROUND

Nucleic acid amplification tests such as the BD ProbeTec™ ET System represent a major step forward in testing for *Neisseria gonorrhoeae* (GC) infections. The system detects target DNA using amplification primers with a fluorescent detector probe in which urine specimens are tested using a Urine Processing Kit (UPP).

OBJECTIVES

To evaluate the performance of the UPP to the UPT for testing on the ProbeTec, using different storage and transport conditions. Neat urine was also investigated as another specimen type for the GC ProbeTec assay.


METHODS

The urine specimens were received and aliquoted into UPTs, plain tubes for the neat testing and a UPP device added to the rest of the urine. The storage and transport of the UPT samples varied from room to refrigerated temperature and held from less than 2 days to 21 days before processing. The neat urine specimens were held up to 24 hours at 2-8°C or up to 8 hours at room temperature prior to processing. The neat and UPT samples were prewarmed before processing and all samples including UPP were then treated equally with processing and testing.


RESULTS

Figure 1. BD ProbeTec Urine Preservation Transport (UPT)*

- For Use with the BD ProbeTec ET System
- Proprietary preservative in automation-compatible tube
- Increased transport flexibility
 - Expected final specimen transport times up to 30 days
 - Range expected to be -20°C to 30°C
- Decreased hands on time
 - No UPP addition
 - Reduced capping/de-capping



Collection kit



Lab

*Product Under Development—not available for sale or use.

Figure 2.

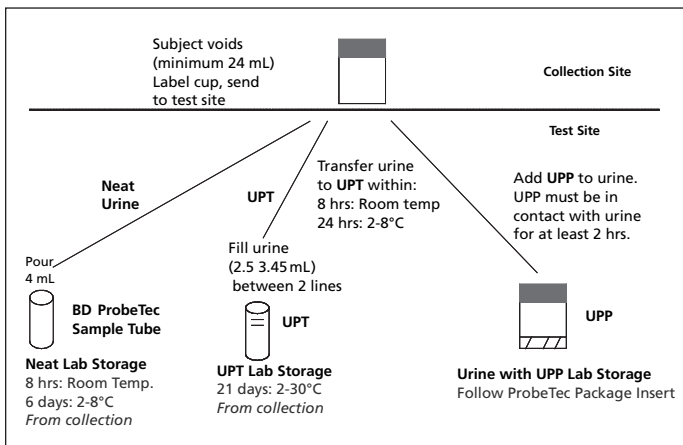
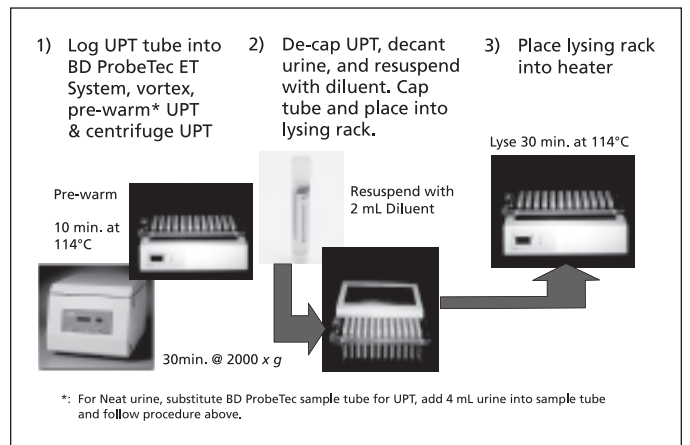


Figure 3. BD ProbeTec™ UPT* Workflow — Laboratory



| | | | Positive | | Negative | | Overall | |
|--------------------|------------------------|-----|-------------------|-------------------|---------------------|-------------------|---------------------|-------------------|
| Analysis | Neat Transport Storage | N | | | | | | |
| GC Neat vs. GC UPP | Refrigerated | 396 | 95.83% (23/24) | (78.88% - 99.89%) | 99.46% (370/372) | (98.08% - 99.93%) | 99.24% (393/396) | (97.80% - 99.84%) |
| | Room Temp | 564 | 100.0% (46/46) | (92.29% - 100.0%) | 99.23% (514/518) | (98.3% - 99.79%) | 99.29% (560/564) | (98.19% - 99.81%) |

| | | | Positive | | Negative | | Overall | |
|-------------------|-----------------------|-----|-------------------|-------------------|---------------------|-------------------|---------------------|-------------------|
| Analysis | UPT Transport Storage | N | | | | | | |
| GC UPT vs. GC UPP | Refrigerated | 394 | 100% (24/24) | (85.75% - 100.0%) | 99.19% (370/372) | (97.65% - 99.83%) | 99.24% (391/394) | (97.79% - 99.84%) |
| | Room Temp | 559 | 100.0% (46/46) | (92.29% - 100.0%) | 100.0% (513/513) | (99.28% - 100.0%) | 100.0% (555/559) | (99.34% - 100.0%) |

| Analysis | UPT Lab Storage | UPT Lab Storage Bin | N | Positive | | Negative | | Overall | |
|-------------------|-----------------|---------------------|-----|----------------------|-------------------|------------------|-------------------|------------------|-------------------|
| | | | | | | | | | |
| GC UPT vs. GC UPP | Refrigerated | < = 2 days | 122 | 100.0% (15/15) | (78.20% - 100.0%) | 98.13% (105/107) | (93.41% - 99.77%) | 98.36% (120/122) | (94.20% - 99.80%) |
| | Room Temp | < = 2 days | 538 | 100.0% (45/45) | (92.13% - 100.0%) | 99.80% (492/493) | (98.88% - 99.99%) | 99.81% (537/538) | (98.97% - 16.0%) |
| | | 3 - 7 days | 217 | 100.0% (10/10) | (69.15% - 100.0%) | 100.0% (207/207) | (98.23% - 100.0%) | 100.0% (217/217) | 98.31% - 100.0% |
| | | 7 - 14 days | 72 | No data for PPA rate | | 100.0% (72/72) | (95.01% - 100.0%) | 100.0% (72/72) | (95.01% - 100.0%) |
| | | 14 - 21 days | 4 | No data for PPA rate | | 100.0% (4/4) | (39.76% - 100.0%) | 100.0% (4/4) | (39.76% - 100.0%) |

| Method | UPP Lab Storage | Initial Indeterminate Rate | Initial Indeterminate Rate CI | Resolved Indeterminate Rate | Resolved Indeterminate Rate CI |
|--------|-----------------|----------------------------|-------------------------------|-----------------------------|--------------------------------|
| GC UPP | R | 3.4% (9/267) | (1.6% - 6.3%) | 2.2% (6/267) | (0.8% - 4.8%) |
| | T | 1.4% (10/705) | (0.7% - 2.6%) | 0.9% (6/705) | (0.3% - 1.8%) |

| Method | UPT Lab Storage | Initial Indeterminate Rate | Initial Indeterminate Rate CI | Resolved Indeterminate Rate | Resolved Indeterminate Rate CI |
|--------|-----------------|----------------------------|-------------------------------|-----------------------------|--------------------------------|
| GC UPT | R | .08% (1/124) | (0% - 4.4%) | 0.8% (1/124) | (0% - 4.4%) |
| | T | 1.3% (11/850) | (0.6% - 2.3%) | 1.1% (9/850) | (0.5% - 2%) |

| Method | Neat Transport Storage | Initial Indeterminate Rate | Initial Indeterminate Rate CI | Resolved Indeterminate Rate | Resolved Indeterminate Rate CI |
|---------|------------------------|----------------------------|-------------------------------|-----------------------------|--------------------------------|
| GC Neat | F | 0.2% (1/105) | (0% - 1.4%) | 0% (0/405) | (0% - 0.9%) |
| | T | 0.2% (1/569) | (0% - 1%) | 0% (0/569) | (0% - 0.6%) |

CONCLUSION

- The ProbeTec UPT is an invaluable aid in the transport and storage of urine specimens for extended periods for GC testing on the BD ProbeTec ET system. The study also confirms that Neat urine is an acceptable alternative when length of time of transportation is restricted and temperature is within specified limits.

