NPHL Investigates Specimen Integrity in Urine STD Screening

by Nathan Birch, M.D.

Although the development of amplified assays has increased the detection rate in at-risk populations at least one major un-foreseen problem has appeared: the potential submission of falsified specimens. *(1,2)*. First generation amplification technologies utilized material collected on a swab from either the cervix or urethra. Such an approach necessitated appropriate examination equipment and trained medical personnel. The advent of high sensitivity amplification procedures expanded the range of specimen types to include urine *(3)*. Urine amplification testing not only offered a non-invasive means of specimen collection, but also eliminated the need for a private examination room and medical personnel. Consequently, institutions with a high prevalence of disease and limited medical facilities, such as state penitentiaries and youth correctional facilities, can provide routine STD testing with the expectation that expanded screening will reduce the number of sub-clinical infections and ultimately the number of new cases *(4)* Detection of C/GC in urine using an amplified assay was implemented in 2001 as a pilot project at the NPHL. Since introductions of the amplified assay, the overall percentage of positive results increased from 3.8 to 5.8% (see accompanying article by Peter Iwen, Ph.D.).

Between 95 and 99% of random urine specimens submitted to the clinical laboratory for urinalysis testing are yellow in color *(5)*. Interest in determining the validity of urine specimens developed when NPHL technologist noted a substantial number of colorless urine specimens submitted for C/GC amplification. Alteration of urine used in screening for drugs of abuse is a wellknown problem. However, falsification of urine specimens submitted for C/GC amplification testing has not been previously described. Therefore, no procedures were in place for the detection of potentially manipulated specimens.

No single test is able to validate or refute a specimen as urine or not. Therefore to characterize the sample as compatible with urine or not, the criteria derived from the studies of Cook etal. were used . A specimen with a urine creatinine of < 5 mg/dL and a specific gravity of < or = to 1.001 was judged to be incompatible with urine. Approximately 8% of all specimens submitted during a six week evaluation period were determined to be inconsistent with urine.

The motivation for the submission of falsified specimens from clients who have been offered optional STD screening at no cost is unknown. Discussions with staff from submitting institutions indicate that the suspicion of random drug testing was the most likely reason for the apparent submission of water in place of urine. The consensus of the institutional staff was that patient education and reassurance would provide the most effective and cost efficient method of reducing the substitution rate.

The widespread use of urine C/GC testing methodology in the arena of public health with limited funding, makes reducing the number of altered specimens a priority. An understanding of the patient population served and coordination with submitting facilities will likely provide an inexpensive and timely solution. Alternatively, other approaches used by drug screening programs such as temperature monitoring, on-site specific gravity measurements, and direct observation could be instituted.

Knowledge of specimen manipulation is necessary to effectively implement a urine based C/GC screening program.

References

1. Stamm, W. E. *Sex Transm Dis* **2001**, *28*, 684-9; de Barbeyrac, B.; Rodriguez, P.; Dutilh, B.; Le Roux, P.; Bebear, C. *Genitourin Med* **1995**, *71*, 382-6.
2. Marrazzo, J. M.; White, C. L.; Krekeler, B.; Celum, C. L.; Lafferty, W. E.; Stamm, W. E.; Handsfield, H. H. *Ann Intern Med* **1997**, *127*, 796-803.
3. Rietmeijer, C. A.; Yamaguchi, K. J.; Ortiz, C. G.; Montstream, S. A.; LeRoux, T.; Ehret, J. M.; Judson, F. N.; Douglas, J. M. *Sex Transm Dis* **1997**, *24*, 429-35.
4. Gantzer, M. L. *Clin Lab News* **1998**, 14-16.
5. Cook, J. D.; Caplan, Y. H.; LoDico, C. P.; Bush, D. M. *J Anal Toxicol* **2000**, *24*, 579-88.