Evaluation of the UriSwab Sponge Collection Device for the Detection of Chlamydia trachomatis in Urine

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Introduction

Sexually Transmitted Infection (STI) screening programs continue to move beyond the confines of the traditional clinical setting and are now performed at a variety of venues including local schools, health fairs, and community centers to name a few. Opportunities for screening in the field have improved markedly with the widespread use of Nucleic Acid Amplification Tests (NAAT) in most diagnostic laboratories with one obvious advantage being the ability to test samples that have been obtained non-invasively. For men, urine can be self-collected in a sterile specimen cup (routine collection) and transported to the laboratory for testing. However, at many screening events where large numbers of samples are collected, problems arise with the manipulation, transport, and storage of the urine cups. In order to alleviate some of these issues, our laboratory undertook a study to evaluate a new sponge-based urine collection and transport device (UriSWAB, Copan Diagnostics) for the detection of Chlamydia trachomatis (CT), Neisseria gonorrhoeae (GC), and Trichomonas vaginalis (TV). The test results obtained from the samples collected using the UriSwab were compared to results generated using routine urine collection cups.

Methods

- Paired urine samples were obtained from young men attending an adolescent clinic or men undergoing Fast Track STI screening at the local STD clinic in Indianapolis, IN
- UriSwab samples were collected by either holding the sponge tipped applicator in the urine stream until saturated or by dipping the sponge directly into a urine cup until saturated. Additional urine was collected in a urine cup (Starplex, Etobicoke, Canada)
- UriSwab and routine urine samples were refrigerated prior to processing
- UriSwab samples were spun in the laboratory at 2000 RPM for 2 minutes to remove urine from the sponge
- Specimen processing and diagnostic testing for CT and GC was performed by PCR (Roche COBAS Amplicor, Indianapolis, IN) according to the package insert for urine, while TV testing has been described previously1
  - κ scores and McNemar’s χ2 (alpha=0.05) were utilized to measure agreement between the UriSwab and urine cup samples

Results

- Paired urine samples were obtained from 228 men including 40 from the adolescent and 188 from the STD clinic.
- 18/228 (7.9%) were positive for CT; 15/18 (83.3%) were positive for CT using the UriSwab and no samples were CT positive from the UriSwab that were not positive using the routine urine sample.
- 4/228 (1.8%) of the samples were positive for GC; each sample type missed one infection.
- There were no TV positive samples in this study population
- The CT results were in good agreement between the two sample types with a κ score of 0.92, p<.001; GC results had moderate agreement with a κ score of 0.66, p<.001
- There was no statistical difference between the two collection methods for CT or GC (p-values >.05)

Conclusions

- The UriSwab performed as well as routine collection for the detection of CT
- No recommendations can be made for the UriSwab for the detection of GC or TV, but preliminary results appear promising for GC
- The UriSwab is easy to transport, store, and process in the laboratory and may facilitate expanded screening opportunities in the field
- Further evaluation of this collection device is warranted, including collection of the UriSwab in the field

Limitations of the study

- Insufficient number of GC positive samples and no TV positives to evaluate UriSwab sufficiently
- The UriSwab was not tested at a screening event in the field
- The UriSwab is currently not available in the United States

References