Comparison of Urine collected in Dry container to urine collected, transported and preserved in the Copan UriSwab for the detection of STDs with the Seeplex® STD6 ACE assay

A.Archenti¹, P.Biagiola¹, D.Pasquali¹, F.Spaggiari¹, R.Casa¹, S.Razeti²
¹ ASL di Milano, Laboratorio di Prevenzione ² Arrow Diagnostics Srl

Background

Commercial molecular assays of sexual transmitted disease (STD) have dedicated urine collection devices that are not compatible for all molecular assays and are not supporting bacteria culture. Copan produces the UriSwab, a liquid based collection (LBM) device for urine specimen collection, transportation and storage device used for bacteria culture with manual and Walk Away Specimens Processor (WASP) automation plating methods. UriSwab, consists of a leak-proof screw-cap tube with 3 sponges on a plastic stick used to absorb and retain urine during transport. The sponges contains boric acid and sodium formate stabilizers that are incorporated during sponge production to prevent bacterial overgrowth. UriSwab can be used for urine collection, including self-collection, transport and storage for STD screening with molecular assays.

Objectives

The objective of this study were to compare Urine collected in Dry Container to urine collected, transported and stored in UriSwab for the detection of Trichomonas vaginalis (TV), Mycoplasma hominis (MH), Mycoplasma genitalium (MG), Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG) and Ureaplasma urealyticum (UU) with the Seeplex® STD6 ACE assay.

Materials

COPAN UriSwab collection and processing procedure

Methods

Duplicate urines (n=217) were collected from patients attending a Milan STD clinic. A urine sample was collected in a dry container as per routine method and another urine sample in UriSwab device. Prior nucleic acid extraction, 5 ml of urine from the dry container were transferred into a tube. Urines samples tubes, dry container and in UriSwab, were centrifuged at 3000g for 20 minutes; supernatant from both samples was discarded, the cell pellets were eluted in 200ul of PBS. Nucleic acids were extracted with the QIAamp DNA Mini kit (Qiagen) as recommended in the package insert for the first 97. The QIAcube (Qiagen) was used for the extraction of the other 120 urine samples in both transport containers. Three microliters of purified nucleic acid for all duplicate samples were tested as per recommended procedures with the Seeplex® STD6 ACE assay.

(Seegene, distributed by Arrow Diagnostics, Genova, Italy).

Results

In the 217 urine tested in duplicate, transported in dry container and UriSwab, were found 138 negative and 70 positive with 95.8% concordance and 9 discordant (4.2%) results; positive included 3 TV, 31 MH, 2 MG, 19 CT, 10 NG, and 33 UU.

In the discordant urine in dry container had 1 MH, 1 MG positive while UriSwab had 1 TV, 2 NG and 2 UU positive. No inhibition was detected in both containers.

As of March 12 we implemented the use of the UriSwab device for the transportation of urine samples for STDs detection and up to June 27.

We have tested additional 750 urine samples.

Conclusions

Good agreement was found between Copan UriSwab and the dry containers for transporting and storing urines for STIs detection with the Seeplex® STD6 ACE assay.

The UriSwab is leak-proof, is easy-to-transport and store at room temperature, prevents overgrowth and stabilizes bacteria and nucleic acids, and facilitates self-collection.

The Copan UriSwab can be used for the collection and transport of urine for bacteria culture and nucleic acid extraction for STI screening with molecular assays.