



UriSponge™ facilitate urine collection and transportation for the detection of STD with the Anyplex™ II STI-7e assay.

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Background

Dedicated molecular urine collection devices are not compatible with all molecular assays and are not supporting bacteria culture. Copan UriSponge™ consists of a leak-proof screw-cap tube with 3 sponges containing preservative salts attached to a plastic stick to absorb and retain urine samples during transport and prevent bacterial overgrowth. Urines collected in UriSponge™ were previously compared to urine samples transported in dry containers for the detection of sexual transmitted pathogens with a Multiplex Real-time PCR assays.

Objective

The objective of this study was to validate the performance of urine transported in UriSponge™ for the detection of STI with the Seegene Anyplex™ II STI-7e v1.1 assay

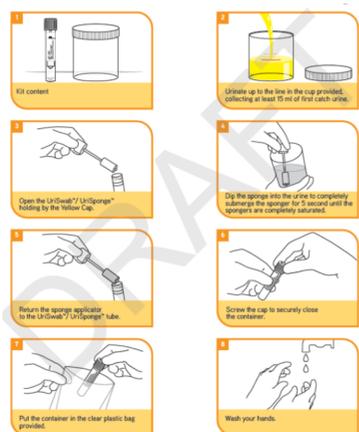
Materials

UriSponge™



Sponge Electronic Microscopy image containing salts

UriSponge™ collection procedure



Methods

Urine, collected with UriSponge™ from 2991 patients attending a STD clinic in Milan, were used in this study.

A first catch urine was collected in a sterile cap, the UriSponge™ was immersed it into the urine until saturated and stored back in its own tube.

Prior testing, UriSponge™ samples were centrifuged at 3000 RPM for 10 minutes, de-capped the tubes and discarded the sponges, reduce the urine volume to 2 ml, vortexed and loaded the urine tubes on the Nimbus for nucleic acids extraction.

Nucleic acids were amplified with the Anyplex II STI-7e assay for the detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis*, *Mycoplasma genitalium*, *Mycoplasma hominis*, *Ureaplasma urealyticum*, and *Ureaplasma Parvum*.



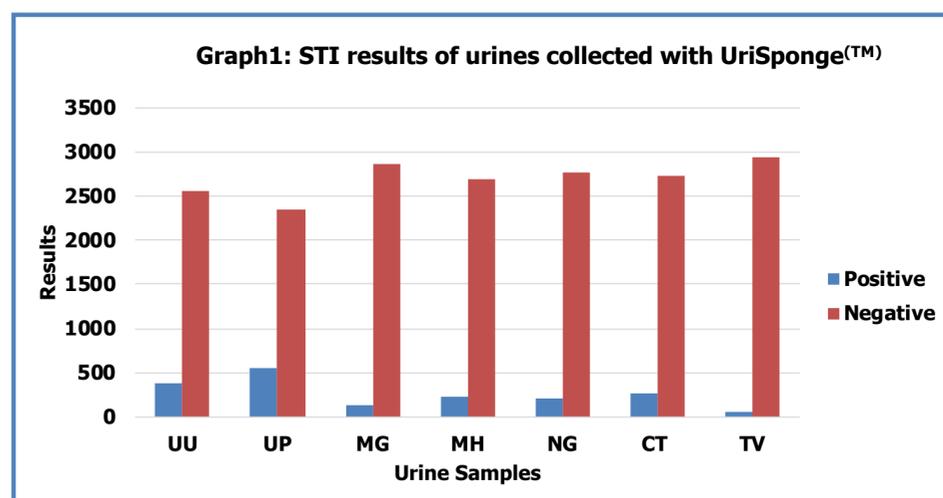
Seegene nucleic acids extraction and real-time PCR detection system.

Results

In the 2991 UriSponge™ samples tested, were detected 267 (8.02%) *Chlamydia trachomatis*, 220 (7.35%) *Neisseria gonorrhoeae*, 59 (1.97%) *Trichomonas vaginalis*, 129 (4.31%) *Mycoplasma genitalium*, 232 (7.75%) *Mycoplasma hominis*, 430 (14.5%) *Ureaplasma urealyticum* and 640 (21.4%) *Ureaplasma Parvum* positive. (Graph 1).

The positivity rate of each sexual transmitted pathogens was comparable to data obtained from a previous study comparing urine samples stored in sterile containers and to urine stored in UriSponge™.

The Seegene automated Nimbus system samples processing workflow facilitated the testing of urine collected and stored in the UriSponge™ device.



Conclusions

Good performance was obtained with urine collected and transported with the UriSponge™ for the detection of STI with the Seegene Anyplex™ II STI-7e assay.

The Copan UriSponge™ proved to be an excellent device for the collection of urine for STI detection.

UriSponge™ is an optimal device for both point of care urine collection and home urine collection and transport for STI screening programs.

UriSponge™ eliminates the use of large leaking urine containers or the use of needles and has the advantage of supporting culture back up for *Neisseria gonorrhoeae* antimicrobial susceptibility testing.

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