



Comparison of Anyplex™ II STI-7 assay to the Allplex™ CT/NG/MG/TV Assay for the detection of sexually transmitted infections from urine specimens collected with UriSwab™

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Background

Sexual transmitted infections are playing an important role in genital infections. *Chlamydia trachomatis* (CT) *Neisseria gonorrhoeae* (NG), *Mycoplasma genitalium* (MG) and *Trichomonas vaginalis* (TV), have been associated vaginal infections, cervicitis and urethritis that can lead to complications like pelvic inflammatory diseases, ectopic pregnancy and infertility. Other pathogens like *Mycoplasma hominis* (MH), *Ureaplasma urealyticum* (UU) and *Ureaplasma parvum* (UP) are residing in the genital tracts but are not always associated to active infections. Seegene introduced the new Allplex™ CT/NG/MG/TV Assay for sexual transmitted infections detection.

Objective

The objective of this study was to compare the performance of the Anyplex™II STI-7e v1.1 assay that detects CT, NG, TV), MG, MH, UU), and UP, to the Allplex™ CT/NG/MG/TV Assay for the detection of STI from urines samples

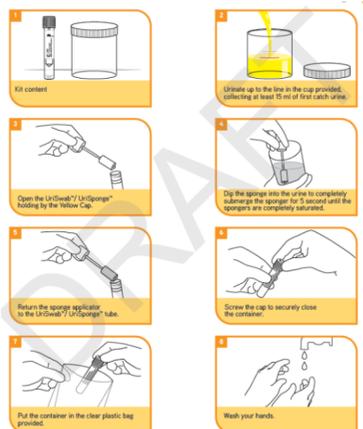
Materials

UriSponge™



Sponge Electronic Microscopy image containing salts

UriSponge™ collection procedure



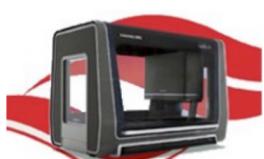
Methods

In this study were used 201 Urine samples collected from patients attending an STD clinic in Milan.

A first catch urine was collected in a sterile cap, the UriSponge™ (Copan Italia, Brescia, Italy) was immersed into the urine until the sponges were saturated and stored back in its own tube.

Prior testing, UriSponge™ samples were centrifuged at 3000 RPM for 10 minutes, after de-capping the tubes, discarding the sponges and reducing the urine volume to 2 ml, the urine samples were vortexed and loaded on the Nimbus and 200 ul of urine was used for nucleic acids extraction.

Nucleic acids were analyzed with the STI-7e and CT/NG/MG/TV assays on the CFX96 (Bio-Rad) real-time PCR detection system. Results from both assays were compared, concordant results were considered negative or positive, discordant results were retested in duplicate.

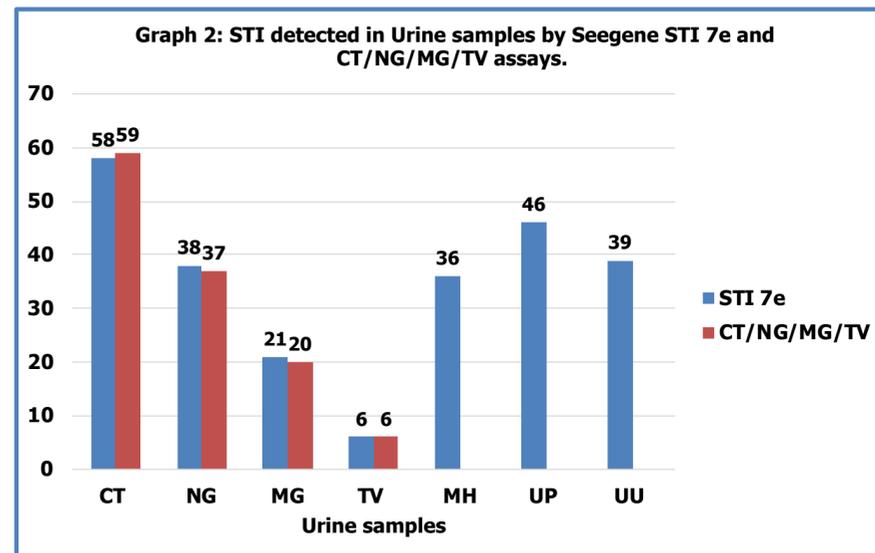
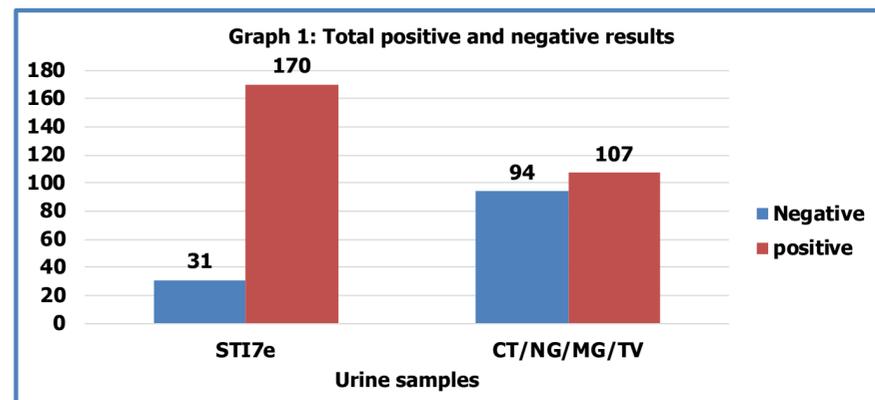


Seegene nucleic acids extraction and real-time PCR detection system.

Results

In the 201 urine samples tested STI-7e detected 31 negative and 170 positive while CT/NG/MG/TV detected 94 negative and 107 positive samples (Graph 1).

When comparing the positive results: STI-7e detected 1 NG and 1 MG positive not detected by CT/NG/MG/TV while CT/NG/MG/TV detected 1 CT and 1 NG missed by STI-7e. Results were not statistically significant ($p > 0.05$). Anyplex II STI-7e detected additional 36 MH, 46 UP and 39 UU not included in the Allplex™ CT/NG/MG/TV assay.



Conclusions

In this study an excellent agreement was demonstrated between Seegene Anyplex™II STI-7e v1.1 and by Allplex™ CT/NG/MG/TV assays for the detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Mycoplasma genitalium* in urine samples collected with Copan UriSponge™.

The new Seegene Allplex™ CT/NG/MG/TV assay eliminates the detection of MH, UU, and UP, included in the STI-7, that may be present in colonized patients.

Furthermore Copan UriSponge™ proved to be an excellent device for the collection and transport of urine samples for STI detection with molecular assays and can be used for culturing all the *Neisseria gonorrhoeae* positive urine samples for antimicrobial resistance testing.

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