

# Evaluation of the Abbott Alinity m STI assay for diagnosis of the primary causes of sexually transmitted infections in the United States

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## BACKGROUND

Sexually transmitted infections can lead to urethritis, cervicitis, pelvic inflammatory disease, and premature birth. The objective of our study was to evaluate the clinical and analytical performance of the Abbott Alinity m STI assay which detects *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), *Trichomonas vaginalis* (TV), and *Mycoplasma genitalium* (MG). Risk factors for infection with these pathogens are similar, and symptomatic infection can be indistinguishable, supporting use of a 4-plex test as an efficient diagnostic modality.

## METHODS

Sensitivity and specificity were determined by comparison with the Hologic Panther Aptima assay for CT, NG and TV in specimens from a female and male adult outpatient population in a metropolitan region in the Northeast United States, collected as urine or genital swabs in Aptima transport medium. Co-detection of *M. genitalium* was evaluated in samples positive and negative for other sexually transmitted pathogens. Analytical sensitivity was determined through serial dilution of analytical standards from Microbiologics (St. Cloud, MN) in negative swab and urine matrix to determine the limit of detection.

**The Abbott Alinity m STI assay provides a robust, high throughput, multiplex sample-to-answer, nucleic acid amplification test for detection of major STI pathogens (CT, NG, TV, and MG).**

## RESULTS

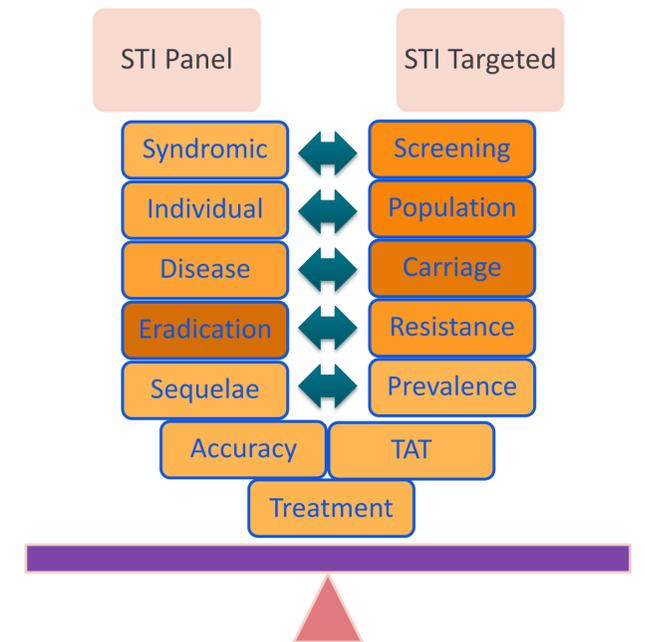
Sensitivity and specificity for CT, NG and TV were 100% (91-100%, 95% C.I.) and 99% (95-100%); 100% (89-100%) and 100% (97-100%); and 96% (82-100%) and 100% (97-100%), respectively, compared with Hologic Panther determination. Rare discrepant showed either very low relative light units (RLU, Panther) and/or high CT values (Alinity m) near the assay cutoffs for positivity. Assays were performed on samples collected in Aptima transport media.

Co-infection with MG was detected in 24%, 25%, 11% and 9% of samples that were positive for CT, NG, or TV; or negative for all three pathogens, respectively.

Limit of detection (95% detection threshold) for urine and swab matrix for CT, NG, TV, and MG were  $\leq 5$  and  $\leq 1$  copies/mL;  $\leq 5$  and  $\leq 5$  copies/mL;  $\leq 0.5$  and  $\leq 0.5$  copies/mL and  $\leq 500$  and 250 copies/mL, respectively.

## DISCLOSURE/ACKNOWLEDGEMENT

Abbott Molecular provided Alinity m STI reagents and Microbiologics control material used in our method evaluation study. The Abbott m STI assay is not FDA approved.



## CONCLUSIONS

The Abbott Alinity m STI assay appears to have excellent analytical performance and identifies pathogens accurately compared with a well-established comparator. Multiplex capability on high throughput, flexible instrumentation offers a compelling new testing modality for sexually transmitted infections.

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