Evaluation of the IUO Alinity m STI Assay at a Veterans Administration Hospital

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Background

- Trichomonas, chlamydia, and gonorrhea are common sexually transmitted infections (STI).
- *Mycoplasma genitalium* is a less commonly suspected cause of cervicitis, urethritis, proctitis, and asymptomatic carriage in the oropharynx.
- The Investigational Use Only Alinity m STI assay is an in vitro reverse transcriptase PCR assay for qualitative detection of *Neisseria gonorrhoeae* (NG), *Chlamydia trachomatis* (CT), *Trichomonas vaginalis* (TV), and *Mycoplasma genitalium* (MG).
- We performed an evaluation of the IUO Alinity m STI against test of record comparator methods.

Methods

- The women's health clinic and infectious disease consultants at the Durham VA hospital collected paired samples from patients with concern for a STI using the IUO Alinity m STI assay and the standard of care testing method.
- The Cepheid Xpert TV and Xpert CT/NG panels were the routine testing method for endocervical and urine samples.
- Gonorrhea cultures were performed for rectal and oropharyngeal samples.
- Due to supply shortages, many samples were externally tested using the Aptima Combo 2 (CT/NG) and Aptima Trichomonas vaginalis assays by Hologic.
- Aliquots of positive urine samples stored in Cepheid and Aptima urine collection kits from an external VA hospital were also tested using Alinity m STI.
- The Aptima MG assay was used to confirm positive and negative MG results from Alinity m STI.
- External controls containing inactivated CT, NG, TV, and MG were diluted in STI-negative urine and tested using Alinity m STI for a reproducibility evaluation.

Accuracy

Urine		Cepheid PCR		Hologic TMA (Panther)		Correlated positives
		Positive	Not Detected	Positive	Not Detected	
Alinity STI	CT detected	3	1*	5	1*	8
	NG detected	3	0	4	0	7
	TV detected	2	0	10	0	12
	MG detected	0	NA	2	0	2
	Not Detected	0	41	NA	MG Not Det (4)***	
	Total-pos	8		21		29
	Total-neg		41**		1-MG only	

* High CN (Crossing point)-probable contamination, did not confirm positive by Quest.

**Of 41 Negative urines, 27 were tested by Xpert CT/NG assay only (no TV testing performed). 14 of the Negative urines were tested by Cephied Xpert CT/NG and TV assays. 1 additional sample was sent to Quest for MG only. No CT, NG or TV testing was performed.

***4 of 42 STI-negative samples were tested for MG (Quest). These all confirmed negative.

Non-urine		Cepheid PCR		Hologic TMA (Panther)		GC culture-Negative
		Positive	Not Detected	Positive	Not Detected	
Alinity STI	CT detected	2	0	1	0	NA
	NG detected	0	0	0	0	NA
	TV detected	0	0	0	0	NA
	MG detected	NA	NA	2	0	NA
	Not Detected (All targets)	0	23 endocervical	NA	1-urethral MG only	4-rectal 6-oral
	Total-pos	2		3		
	Total-neg		23		1	10

Urine Reproducibility

Target	# Trial 1 positive	# Trial 2 positive
CT	6	5
NG	5	5
TV	11	11
MG	2	2
Total	24	23

Target	# Trial 1 negative	# Trial 2 negative
CT	5	5
NG	5	5
TV	4	4
MG	4	4
Total	18	18

Conclusions

- The Alinity m STI assay performed well compared to standard of care testing methods.
- Due to an insufficient number of non-urine (extragenital, vaginal, urethral) samples, a full concordance evaluation for these sample types was unable to be completed.
- Alinity m STI assay is a promising platform to use for STI testing. No tests positive by comparator were negative on Alinity m STI.

Acknowledgements

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The Alinity m STI assay is pending 510k clearance and is not yet available for use in the United States. IUO Alinity m STI reagents were provided to the DVAMC Microbiology Laboratory by Abbott Molecular (Des Plaines, IL) for the completion of this study.