

Performance of the BD MAX™ CT/GC/TV for Detection of Chlamydia, Gonorrhoea and Trichomonas

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Disclosures

- Atlas Genetics
- ***BD Diagnostics [provided funding for this study]***
- Beckman Coulter
- Cepheid
- Rheonix
- Roche Molecular

Background

- Most recent WHO estimates of incident STI
 - Chlamydia 105.7 million 4.1% ↑
 - Gonorrhea 106.1 million 21.0% ↑
 - Trichomonas 276.4 million 11.2% ↑
- Platforms suitable to smaller volume labs are needed to keep testing “local”
 - Some level of automation is desirable

BD MAX™ System

- Small platform
- ≤ 24 samples/controls per run
- ≤ 15 min/run hands-on time
- ~ 4 hours per run



Broad menu

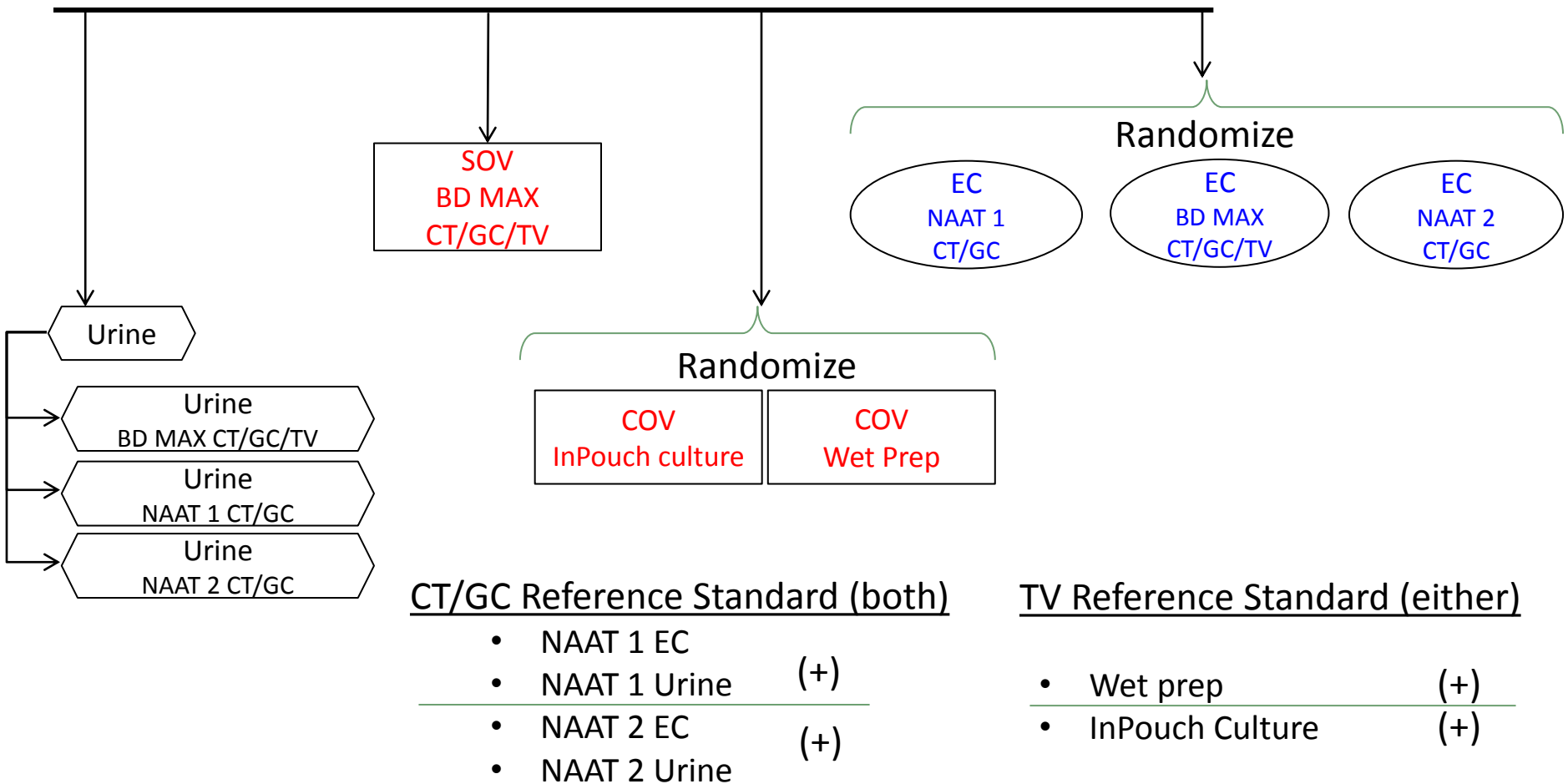
- BD MAX™ MRSA XT
- BD MAX™ StaphSR
- BD MAX™ CDiff
- BD MAX™ GBS
- BD MAX™ Enteric Bacterial Panel
- BD MAX™ Enteric Parasite Panel*
- BD MAX™ CT/GC*
- BD MAX™ CT/GC/TV*
- BD MAX™ GC rtPCR*
- Partner menu:
 - Diagenode™ Enteric Viral Panel*
 - Diagenode™ Respiratory FLU A/B*

*Not available for use in the US.

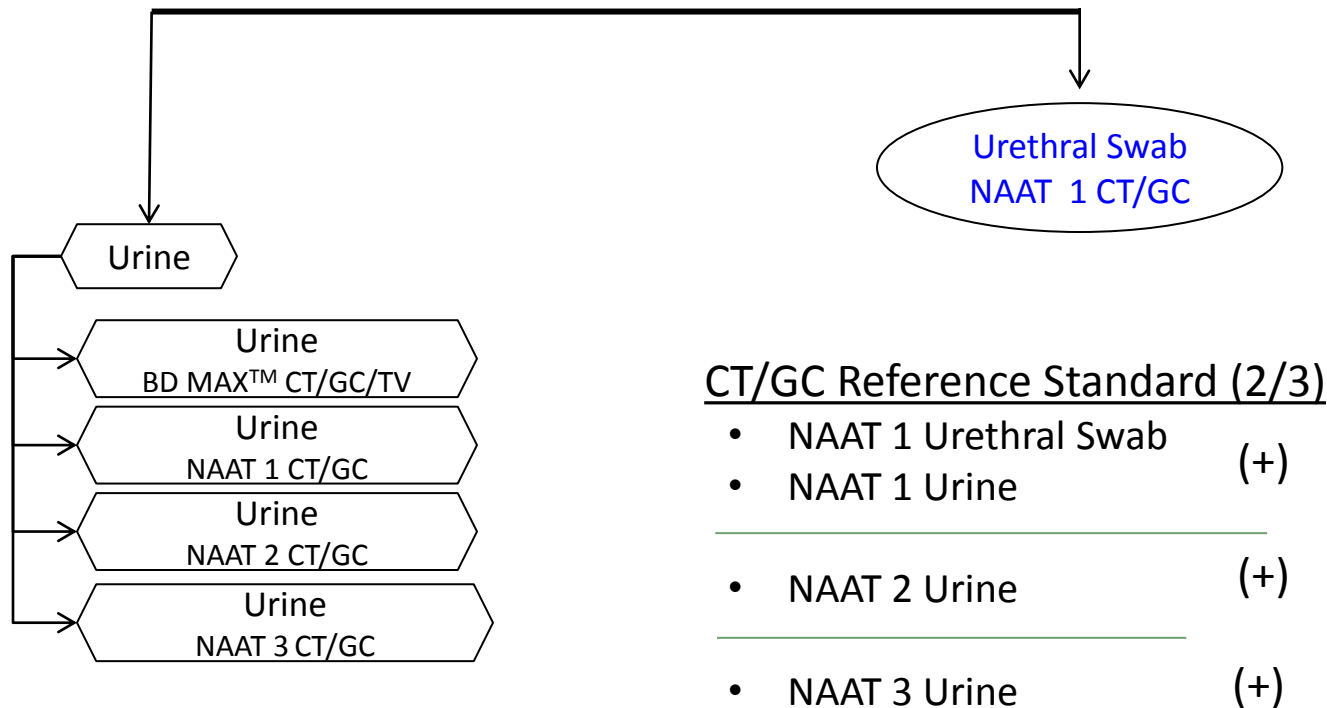
Study Design – Patient Samples

- 8 US Recruitment sites, 4 US BD MAX™ System testing sites
- Women
 - Urine
 - 1 self-obtained vaginal swab (SOV)
 - 2 clinician-obtained vaginal swabs (COV)
 - 3 endocervical swabs (EC)
- Men
 - Urethral swab
 - Urine

Study Design – Women



Study Design – Men



Results* – Chlamydia

Specimen Type	(+)/n**	Sensitivity (95% CI)	Specificity (95% CI)
Vaginal swab	127/1746 (7.2%)	99.2% (95.7-99.9%)	98.6% (98.0-99.1%)
Endocervical swab	124/1740 (7.1%)	96.8% (92.0-98.7%)	99.3% (98.7-99.6%)
Female Urine	128/1758 (7.3%)	92.2% (86.2-95.7%)	99.5% (99.0-99.8%)
Male Urine	177/803 (22.0%)	96.6% (92.8-98.4%)	99.5% (98.6-99.8%)

*Results presented represent all study sites

**Total PIS +/Total enrolled

Results* – Gonorrhea

Specimen Type	(+)/n**	Sensitivity (95% CI)	Specificity (95% CI)
Vaginal swab	39/1746 (2.2%)	94.9% (83.1-98.6%)	99.8% (99.5-99.9%)
Endocervical swab	39/1733 (2.3%)	94.9% (83.1-98.6%)	99.9% (99.7-100%)
Female Urine	41/1758 (2.3%)	95.1% (83.9-98.7%)	99.7% (99.3-99.9%)
Male Urine	107/812 (13.2%)	99.1% (94.9-99.8%)	100% (99.5-100%)

*Results presented represent all study sites

**Total PIS +/Total enrolled

Results* – Trichomonas

Specimen Type	(+)/n**	Sensitivity (95% CI)	Specificity (95% CI)
Vaginal swab	152/1048 (14.5%)	96.1% (91.7-98.2%)	98.9% (98.0-99.4%)
Endocervical swab	152/1039 (14.6%)	93.4% (88.3-96.4%)	99.3% (98.5-99.7%)
Female Urine	154/1047(14.7%)	92.9% (87.7-96.0%)	99.3% (98.5-99.7%)

*Results presented represent all study sites

**Total PIS +/Total enrolled

Results* – Mixed Infections

Specimen Type	CT (+)/n Sensitivity	GC (+)/n Sensitivity	TV (+)/n Sensitivity
Vaginal swab	25/26 96.2%	15/16 93.8%	18/18 100%
Endocervical swab	25/26 96.2%	16/16 100%	17/18 94.4%
Female Urine	25/27 92.6%	17/18 94.4%	17/19 89.5%
Male Urine	30/33 90.9%	33/34 97.1%	---

*Results presented represent all study sites

Summary

- Rates of treatable STI remain high
 - CT: 7% in women, 22% in men
 - GC: 2% in women, 13% in men
 - **TV: 14% in women**
 - The BD MAX™ CT/GC/TV assay is the first true multiplexed commercial assay for all 3 organisms
- Sensitivity & specificity was high for all organism across all specimen types
- The BD MAX CT/GC/TV assay performed well in the presence of mixed infections

Application

- Combined TV with CT/GC is useful in many settings and may provide time/cost savings
- Testing locally may also save time and reduce costs and is therefore desirable in some settings
 - A platform designed for smaller volume labs can facilitate this

My collaborators

- James Williams Indiana University
- DeAnna Fuller Eskenazi Health Services
- Tom Davis Eskenazi Health Services
- Grace Daniel University of Alabama at Birmingham
- Ned Hook University of Alabama at Birmingham
- Stephanie Taylor Louisiana State University

THANKS FOR YOUR ATTENTION