Molecular Diagnostics in the Context of Women's Health;

Introduction to Syndromic Panels and A Cautionary Tale

Sarah Stoner, Eric Beck, Erik Munson

Wisconsin Clinical Laboratory Network
Laboratory Technical Advisory Group

OUTLINE

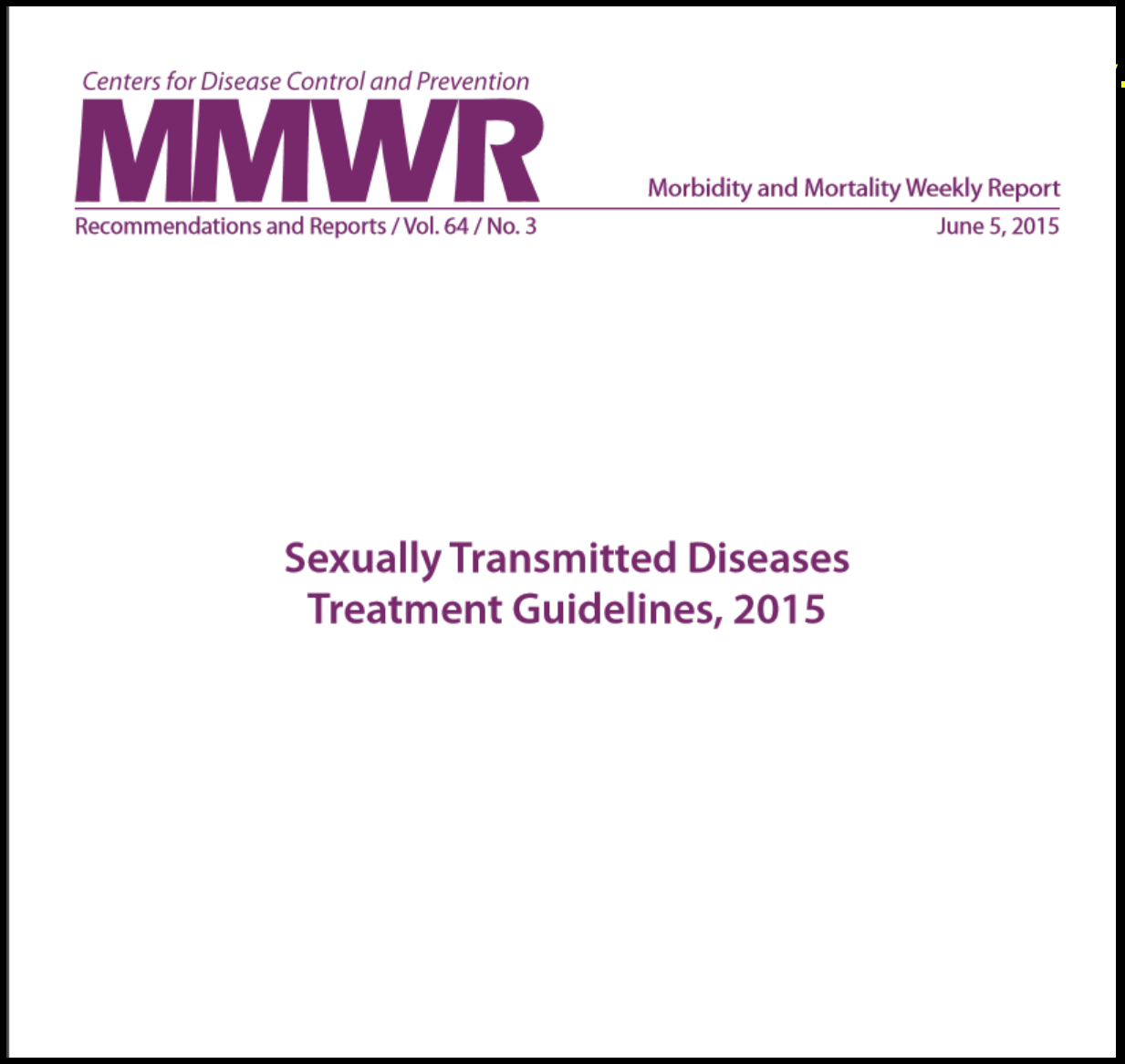
I. Non-ulcerative sexually-transmitted agents

II. Ulcerative STI agents

III. Other issues related to women's health

Streptococcus agalactiae
Human papillomavirus
Bacterial vaginosis

OUTLINE


Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

Recommendations and Reports / Vol. 64 / No. 3

June 5, 2015

Sexually Transmitted Diseases Treatment Guidelines, 2015

-transmitted agents

I-Clicker Warm-up Question

I-CLICKER WARMUP

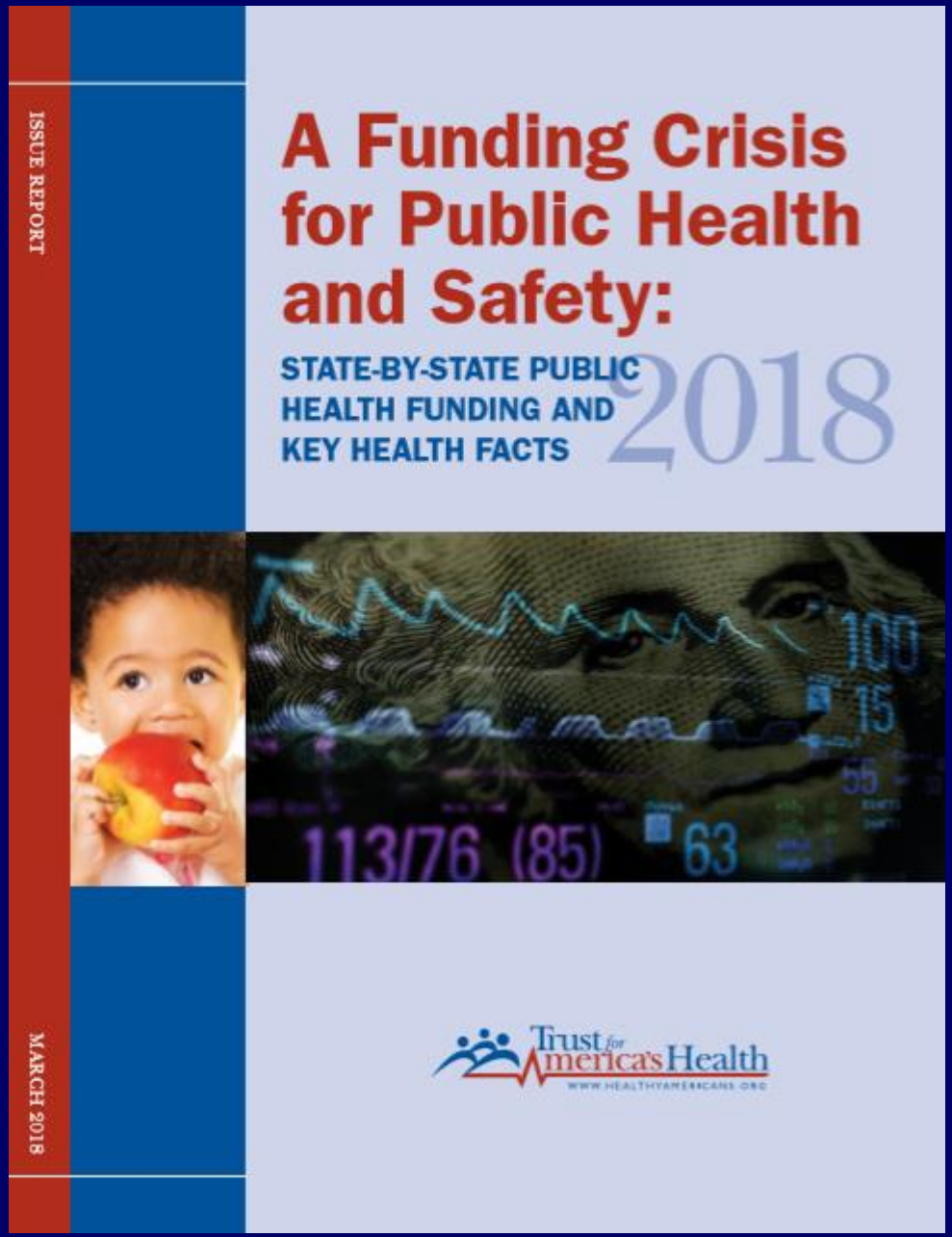
Where does Wisconsin rank in State Public Health Budget (2016-2017 fiscal data) per capita?

A. Top 25%

B. 50th percentile to 75th percentile

C. 25th percentile to 50th percentile

D. Bottom 25%



Introduction

A healthy United States is a strong United States. A prepared nation is a safe nation. But persistent underfunding of the country's public health system has left the nation vulnerable.

DATA SUMMARY

- Range $5.74 per capita to $135.37 per capita
  Mean $35.65 per capita

  Wisconsin is 40th at $14.47 per capita

DATA SUMMARY

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Top Five

DC
Alaska
Hawaii
New York
Iowa

Big (fourteen) Ten

Iowa $68.69
Minnesota $63.96
Nebraska $45.11
Maryland $40.55
New Jersey $25.96
Illinois $25.76
Michigan $12.83
Pennsylvania $12.63
Indiana $12.57
Ohio $12.38

tfah.org/reports

Non-ulcerative Sexually-transmitted Disease

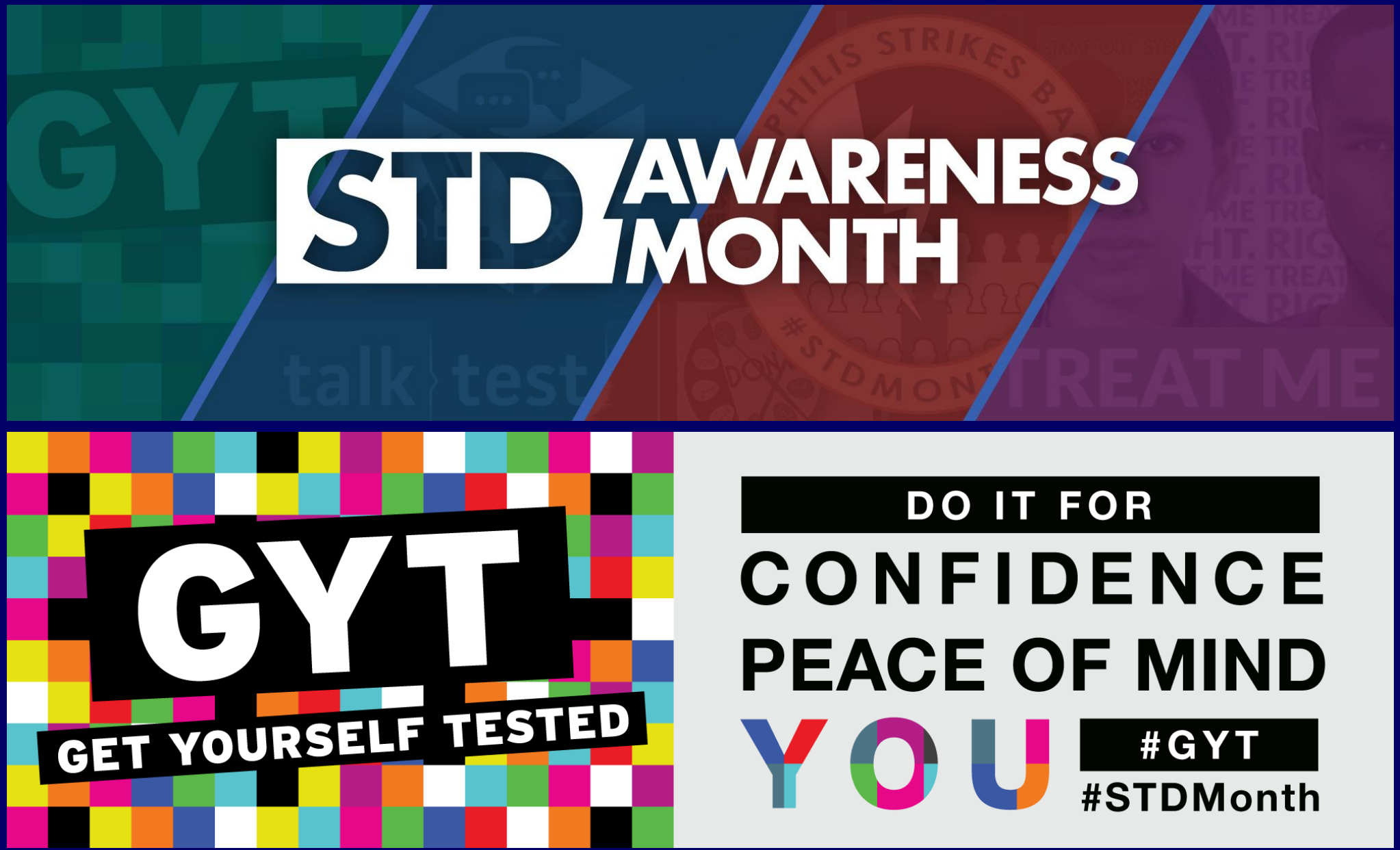
STD AWARENESS MONTH
GYT
GET YOURSELF TESTED
DO IT FOR
CONFIDENCE
PEACE OF MIND
YOU
#GYT
#STDMonth

Table 1

Top 25 Tests by Volume at Five Referral Hospitals

Rank	AKUH, Nairobi	CA, Bangalore	UCH, Ibadan	UMMC, Kuala Lumpur	Denver Health
1	CBC	CBC[a]	CBC	CBC	CBC
2	Urinalysis	Glucose	Electrolytes, urea, and creatinine	Renal function	Basic metabolic panel[b]
3	Urea, electrolytes	Creatinine	Glucose	Liver function	Glucose
4	Stool microscopy	TSH	Urinalysis	Blood glucose	Urinalysis
5	Glucose	Thyroid function	Blood group and crossmatch	Magnesium serum	*Chlamydia* detection
6	C-reactive protein	Renal function	Liver function	Lipid profile	HbA_{1c}
7	Malarial parasites	Urinalysis	Lipid profile	PT/INR	Phosphorus
8	Stool *Helicobacter pylori* antigen	Potassium	Blood film for malaria parasite	APTT	Magnesium
9	Liver function	Liver function	Urine microscopy	Urinalysis	PT/INR
10	Urine microscopy	Platelet count	AFB studies	HbA_{1c}	Comprehensive metabolic panel[c]
11	Surgicals[d]	Urine culture	PT/INR	Blood group	TSH
12	Crossmatch	Lipid profile	Other microscopy	Calcium, phosphorus	Liver function
13	Malaria antigen	PCV	Surgicals	Blood culture[e]	Lipid panel[f]
14	HbA_{1c}	HbA_{1c}	Hb electrophoresis	HBsAg	PTT
15	Lipid profile	Vitamin B_{12}	Cytology	HIV combo	Troponin-I
16	HIV	Hemoglobin	Syphilis	HCV	Urine culture
17	Thyroid function	Sodium	Blood culture	C-reactive protein	Blood group
18	ESR	Vitamin D	ESR	CKMB	Lactate
19	TSH	Blood group	HIV	ESR	Antibody screen
20	Unit packed RBCs	Calcium	Blood group	Thyroid function	Drugs of abuse screen, urine
21	Pregnancy	Coagulation profile	HCV	Syphilis	Cytology
22	Cytology	CBC with ESR	Stool microscopy	Troponin	Syphilis
23	Calcium	Blood culture	HBsAg	Uric acid serum	Surgicals
24	Blood culture	Electrolytes	HbA_{1c}	Lactate	Blood culture
25	Syphilis	ALT	Phosphorus	Urine culture	Pregnancy

Am. J. Clin. Pathol. **151:** 446-451; 2019

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5	Glucose	Thyroid function	Blood group and crossmatch	Magnesium serum	*Chlamydia* detection
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Denver Health
Chlamydia detection
Basic metabolic panel
CBC
Drugs of abuse screen, urine
TSH
Surgicals
HbA_{1C}
Glucose
Comprehensive metabolic panel
Lipid panel
Magnesium
Phosphorus
Liver function
Urinalysis
Urine culture
PT/INR
Troponin-I
PTT
Blood culture
Cytology
Blood group
Antibody screen
Syphilis
Lactate
Pregnancy

Am. J. Clin. Pathol. **151:** 446-451; 2019

I-Clicker Real Question 1

I-CLICKER REAL QUESTION 1

Does your laboratory perform routine screening for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*?

A. Yes, we use a Roche system.

B. Yes, we use a Cepheid system.

C. Yes, we use a Becton Dickinson system.

D. Yes, we use a Hologic system.

E. No / hey, you did not mention our system.

EXTRA-UROGENITAL SCREENING

Gender	Source	n	Detection Rate (%)	
			C. trachomatis	*N. gonorrhoeae*
Female	Pharynx	167	1.2	1.8
	Rectum	51	3.9	2.0
Male	Pharynx	3910	1.0	3.8
	Rectum	1864	7.0	7.0

Courtesy of K. Munson, Ph.D.

EXTRA-UROGENITAL SCREENING

Diagnostic Considerations for Acute Proctitis

Persons who present with symptoms of acute proctitis should be examined by anoscopy. A Gram-stained smear of any anorectal exudate from anoscopic or anal examination should be examined for polymorphonuclear leukocytes. All persons should be evaluated for HSV (by PCR or culture), *N. gonorrhoeae* (NAAT or culture), *C. trachomatis* (NAAT), and *T. pallidum* (Darkfield if available and serologic testing) (see pathogen-specific sections). If the *C. trachomatis* test is positive on a rectal swab, a molecular test PCR for LGV should be performed, if available, to confirm an LGV diagnosis (see LGV) (*394*).

The following screening tests should be performed at least annually for sexually active MSM, including those with HIV infection.

- HIV serology, if HIV status is unknown or negative and the patient himself or his sex partner(s) has had more than one sex partner since most recent HIV test.
- Syphilis serology to establish whether persons with reactive tests have untreated syphilis, have partially treated syphilis, are manifesting a slow serologic response to appropriate prior therapy, or are serofast.
- A test for urethral infection† with *N. gonorrhoeae* and *C. trachomatis* in men who have had insertive intercourse§ during the preceding year (testing of the urine using NAAT† is the preferred approach).
- A test for rectal infection† with *N. gonorrhoeae* and *C. trachomatis* in men who have had receptive anal intercourse§ during the preceding year (NAAT of a rectal specimen is the preferred approach).
- A test for pharyngeal infection† with *N. gonorrhoeae* in men who have had receptive oral intercourse§ during the preceding year (NAAT of a pharyngeal specimen is the preferred approach). Testing for *C. trachomatis* pharyngeal infection is not recommended.

Sexually Transmitted Diseases Treatment Guidelines, 2015

I-Clicker Real Question 2

I-CLICKER REAL QUESTION 2

Does your laboratory perform extra-urogenital screening for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*?

A. Yes, we do.

B. Yes, and it took a bit of work.

C. No, we do not.

D. No, but maybe we should.

I-CLICKER REAL QUESTION 2A

If you answered “no” to the previous question, please select the response that best summarizes the reasoning.

A. No demand from stakeholders

B. Too costly

C. The assay we run does not allow us to offer this testing.

D. Is it time for morning break yet?

Table 1
Commercial molecular diagnostic testing options available in the United States and cleared by the Food and Drug Administration (FDA) for *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, and *Trichomonas vaginalis*

General Format	Method	Distributor	Assay	FDA-Cleared Indications	Notes
DNA amplification	Polymerase chain reaction	Abbott Molecular Incorporated	Abbott RealTime CT/NG[a] (Abbott *m2000* platform)	Endocervical swab Vaginal swab Urethral swab Patient-collected vaginal swab Female urine Male urine	Symptomatic or asymptomatic patients (with exception of endocervical and urethral swabs only indicated on symptomatic patients)
		BD Diagnostic Systems	BD MAX CT/GC/TV[a] assay (BD MAX platform)	Endocervical swab Patient-collected vaginal swab Female urine Male urine	Symptomatic or asymptomatic patients
		Cepheid	Xpert CT/NG[a] (GeneXpert Instrument platform)	Endocervical swab Patient-collected vaginal swab Female urine Male urine	Symptomatic or asymptomatic patients
		Roche Diagnostics Corporation	AMPLICOR CT/NG[a] Test	Endocervical swab Urethral swab Male urine	Symptomatic or asymptomatic patients (with exception of urethral swab only indicated on symptomatic patients)
		Roche Molecular Systems, Incorporated	cobas CT/NG[a] v2.0 Test (cobas 4800 platform)	Endocervical swab Vaginal swab PreservCyt collection Patient-collected vaginal swab Female urine Male urine	Symptomatic or asymptomatic patients
		Roche Molecular Systems, Incorporated	cobas CT/NG[a] (cobas 6800/8800 platform)	Endocervical swab Vaginal swab PreservCyt collection Patient-collected vaginal swab Female urine Male urine	Symptomatic or asymptomatic patients

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General Format	Method	Distributor	Assay	FDA-Cleared Indications	Notes
	Strand displacement amplification	Becton, Dickinson and Company	BD ProbeTec *N gonorrhoeae* (GC) Q^{x} Amplified DNA Assay (BD Viper or Viper LT platforms)	Endocervical swab Urethral swab PreservCyt, SurePath collection Patient-collected vaginal swab Female urine Male urine	Symptomatic or asymptomatic patients
		Becton, Dickinson and Company	BD ProbeTec *C trachomatis* (CT) Q^{x} Amplified DNA Assay (BD Viper or Viper LT platforms)	Endocervical swab Urethral swab PreservCyt, SurePath collection Patient-collected vaginal swab Female urine Male urine	Symptomatic or asymptomatic patients
		Becton, Dickinson and Company	BD ProbeTec ET *C trachomatis* and *N gonorrhoeae*[a] Amplified DNA Assays (BD ProbeTec ET or Viper platforms)	Endocervical swab Urethral swab Female urine Male urine	Symptomatic or asymptomatic patients

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General Format	Method	Distributor	Assay	FDA-Cleared Indications	Notes
RNA amplification	Transcription-medicated amplification	Hologic, Incorporated	Aptima Combo 2 Assay[a] (Panther platform)	Endocervical swab Vaginal swab Urethral swab PreservCyt collection Patient-collected vaginal swab Female urine Male urine	Symptomatic or asymptomatic patients
		Hologic, Incorporated	Aptima Combo 2 Assay[a] (Tigris or semiautomated platform)	Endocervical swab Vaginal swab Urethral swab PreservCyt collection Patient-collected vaginal swab Female urine Male urine	Symptomatic or asymptomatic patients (with exception of patient-collected vaginal swab only indicated on asymptomatic patients)
		Hologic, Incorporated	Aptima *N gonorrhoeae* Assay (Tigris or semiautomated platform)	Endocervical swab Vaginal swab Urethral swab PreservCyt collection Patient-collected vaginal swab Female urine Male urine	Symptomatic or asymptomatic patients (with exception of patient-collected vaginal swab only indicated on asymptomatic patients; with exception of urethral swab only indicated on symptomatic patients)
		Hologic, Incorporated	Aptima *C trachomatis* Assay (Tigris or semiautomated platform)	Endocervical swab Vaginal swab Urethral swab PreservCyt collection Patient-collected vaginal swab Female urine Male urine	Symptomatic or asymptomatic patients (with exception of patient-collected vaginal swab only indicated on asymptomatic patients)

UNCORRECTED PROOF

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I-Clicker Real Question 3

I-CLICKER REAL QUESTION 3

Which of the following is your laboratory's primary means of assessing (female) specimens for *Trichomonas vaginalis*?

A. Wet mount

B. Antigen assays (such as OSOM)

C. Hybridization assays (such as BD Affirm VP III)

D. Nucleic acid amplification

E. We really do a combination of these methods.

OTHER *T. vaginalis* DETECTION

Modality	Performance Indices (%)		
	Sensitivity	Specificity	Reference
Wet mount microscopy	48.1	99.8	1
	47.1	100.0	2
Antigen detection	78-84	99-100	3
	35.1	99.9	4
Nucleic acid hybridization	63.4	99.9	5

[1]J. Clin. Microbiol. **46:** 3368-3374; 2008

[2]Diagn. Microbiol. Infect. Dis. **68:** 66-72; 2010

[3]Sex. Transm. Infect. **86:** 514-519; 2010

[4]J. Clin. Microbiol. **54:** 500-501; 2016

[5]J. Clin. Microbiol. **49:** 866-869; 2011

T. vaginalis ANTIGEN DETECTION

Low-prevalence	High-prevalence
6.4% *C. trachomatis*	11.2% *C. trachomatis*
0.6% *N. gonorrhoeae*	6.1% *N. gonorrhoeae*
4.0% *T. vaginalis* molecular	21.4% *T. vaginalis* molecular
35.1% antigen sensitivity	85.7% antigen sensitivity
99.9% specificity	100.0% specificity
kappa 0.502	kappa 0.904

- Similar symptomatic rate in false-negative antigen patients as true-positive antigen patients ($P \geq 0.17$)

J. Clin. Microbiol. **54:** 500-501; 2016

TESTING OF MALES

Diagnostic method and specimen	Number of specimens				Sensitivity		Specificity		Predictive value (%)	
	True positive	False positive	False negative	True negative	%	95% CI	%	95% CI	Positive	Negative
	Infected patient status algorithm									
Culture	12	0	0	286	100	69.9-100	100	98.3-100	100	100
PCR - Urethral swab	11	13	1	273	91.7	59.8-99.6	95.5	92.2-97.5	45.8	99.6
PCR - Urine	11	9	1	277	91.7	59.8-99.6	96.9	93.9-98.5	55.0	99.6
ATV - Urethral swab	11	38	1	248	91.7	59.8-99.6	86.7	82.1-90.3	22.5	99.6
ATV - Urine	11	23	1	263	91.7	59.8-99.6	91.9	88.0-94.7	32.1	99.6
	Molecular resolved algorithm									
Culture	12	0	30	256	28.6	16.2-44.8	100	98.2-100	100	89.4
PCR - Urethral swab	23	0	19	256	54.8	38.8-69.8	100	98.2-100	100	93.1
PCR - Urine	20	0	22	256	47.6	32.3-63.4	100	98.2-100	100	92.0
ATV - Urethral swab	40	9	2	247	95.2	82.6-99.2	96.5	93.2-98.3	81.7	99.2
ATV - Urine	31	4	11	252	73.8	57.7-85.6	98.4	95.8-99.5	88.6	95.8

Am. J. Obstet. Gynecol. **200:** 188.e1-188.e7; 2009 (adapted)

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General Format	Method	Distributor	Assay	FDA-Cleared Indications	Notes
Detection of *T vaginalis*–specific nucleic acid					
Nucleic acid hybridization	DNA probe	Becton, Dickinson and Company	Affirm VPIII Microbial Identification Test (manual platform)	Vaginal fluid specimens from patients with symptoms of vaginitis/vaginosis	Additional detection of *Candida albicans* and *Gardnerella vaginalis*
DNA amplification	Helicase-dependent amplification	Quidel Corporation	Solana *Trichomonas* Assay (Solana platform)	Vaginal swab Female urine	Symptomatic or asymptomatic patients
	Polymerase chain reaction	BD Diagnostic Systems	BD MAX CT/GC/TV[a] assay (BD MAX platform)	Endocervical swab Patient-collected vaginal swab Female urine	Symptomatic or asymptomatic patients
		Cepheid	Xpert TV (GeneXpert Instrument platform)	Endocervical swab Patient-collected vaginal swab Female urine Male urine	Symptomatic or asymptomatic patients
		GeneOhm Sciences (BD Diagnostics) Canada, Incorporated	BD MAX Vaginal Panel (BD MAX platform)	Vaginal swab	Symptomatic patients; additional detection of bacteria associated with bacterial vaginosis and *Candida* spp. associated with vulvovaginal candidiasis
	Strand displacement amplification	Becton, Dickinson and Company	BD ProbeTec *T vaginalis* (TV) Q[x] Amplified DNA Assay (BD Viper platform)	Endocervical swab Patient-collected vaginal swab Female urine	Symptomatic or asymptomatic patients
RNA amplification	Transcription-mediated amplification	Hologic, Incorporated	Aptima *T vaginalis* Assay (Panther platform)	Endocervical swab Vaginal swab PreservCyt collection	Symptomatic or asymptomatic patients
		Hologic, Incorporated	Aptima *T vaginalis* Assay (Tigris platform)	Endocervical swab Vaginal swab Female urine PreservCyt collection	Symptomatic or asymptomatic patients

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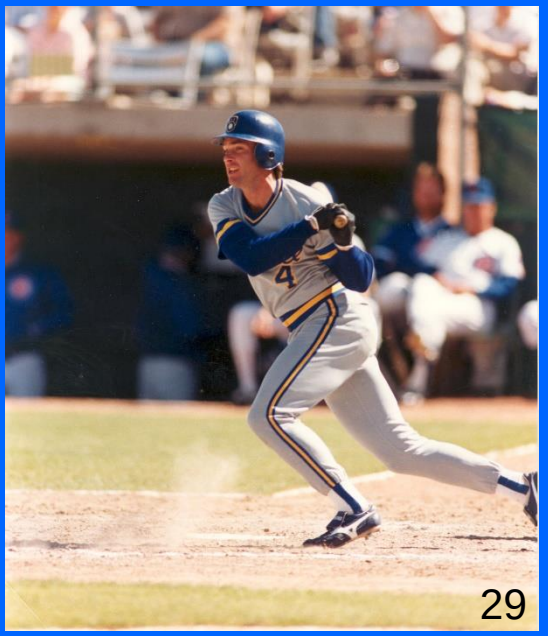
I-Clicker Real Question 4



I-CLICKER REAL QUESTION 4

Does your laboratory perform any laboratory-modified or laboratory-developed testing?

A. Yes, we do/have.

B. Yes; it would please me greatly to share with audience.

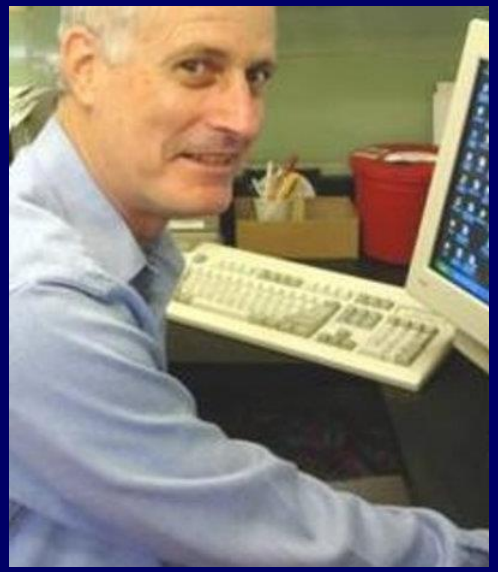
C. No, we do not.

D. No, but please tell me more about LDT.

REGULATORY ELEMENTS

- College of American Pathologists

- Extensive verification study



  Large n
  Ensure sufficient “positives”
  Consider predicate device
  Consider cross-reactive specimens

  Multiple operators; multiple days

REGULATORY ELEMENTS

- College of American Pathologists
- Extensive verification study
- Verification report

Background; literature review
Methods (specimens)

Accuracy
Precision (concordance; coefficient of variation)
Analytical specificity (interfering substances)
Analytical sensitivity (limit of detection)
Establish/verify reference range

REGULATORY ELEMENTS

- College of American Pathologists
- Extensive verification study
- Verification report
- Comment on patient report (COM.40850)

"Performance characteristics of…screening have been determined by Really Good Wisconsin Laboratory and published (J. Clin. Microbiol. 51:xxxx-xxxx; 2013). Although not FDA-approved, the FDA has determined this approval is not necessary."

ORDERING PRACTICES

Testing Modality	Percentage of Female Genital Swabs		
	2004-2007	2008-2010	*P* value
Any wet mount preparation	66.2	57.7	< 0.0002
Point-of-care wet mount preparation	27.8	22.4	< 0.0002
Any assessment for *Trichomonas vaginalis*	66.2	83.6	< 0.0002
Chlamydia trachomatis/*Neisseria gonorrhoeae* TMA	80.4	83.7	< 0.0002

WMJ **111:** 39-42; 2012

ORDERING PRACTICES

Testing Modality	Percentage of Female Genital Swabs		
	2004-2007	2008-2010	*P* value
Any wet mount preparation	66.2	57.7	< 0.0002
Point-of-care wet mount preparation	27.8	22.4	< 0.0002
Any assessment for *Trichomonas vaginalis*	66.2	83.6	< 0.0002
Chlamydia trachomatis/*Neisseria gonorrhoeae* TMA	80.4	83.7	< 0.0002

Testing Modality	Percentage Positive		
	2004-2007	2008-2010	*P* value
Any wet mount preparation	5.5	4.5	0.054
Any assessment for *Trichomonas vaginalis*	5.5	7.9	< 0.0002

WMJ **111:** 39-42; 2012

"You know, ever since we started doing your new Trich test, we still notice guys with obvious urethritis, but still have negative results for chlamydia, gonorrhea, and Trich. I really think that it's *Mycoplasma*; can you test for this?"

R. Gremminger, M.D.
circa 2010

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MINIREVIEW

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Molecular Diagnostics Update for the Emerging (If Not Already Widespread) Sexually Transmitted Infection Agent *Mycoplasma genitalium*: Just About Ready for Prime Time

ABSTRACT *Mycoplasma genitalium* is an important and emerging agent of sexually transmitted infection in females and males, carrying the potential for postinfection genital tract sequelae. Past efforts to identify this organism on a routine basis, which were problematic due to the fastidious nature of the bacterium and its antigenic intricacies, have recently become supplemented by molecular diagnostics. A number of these assays are available commercially. This minireview describes the format and performance indices of a number of *M. genitalium* DNA- and RNA-based amplification assays; many of these assays have contributed to an improved clinical and epidemiologic understanding of this organism.

KEYWORDS *Mycoplasma genitalium*, PCR, molecular diagnostics, transcription-mediated amplification

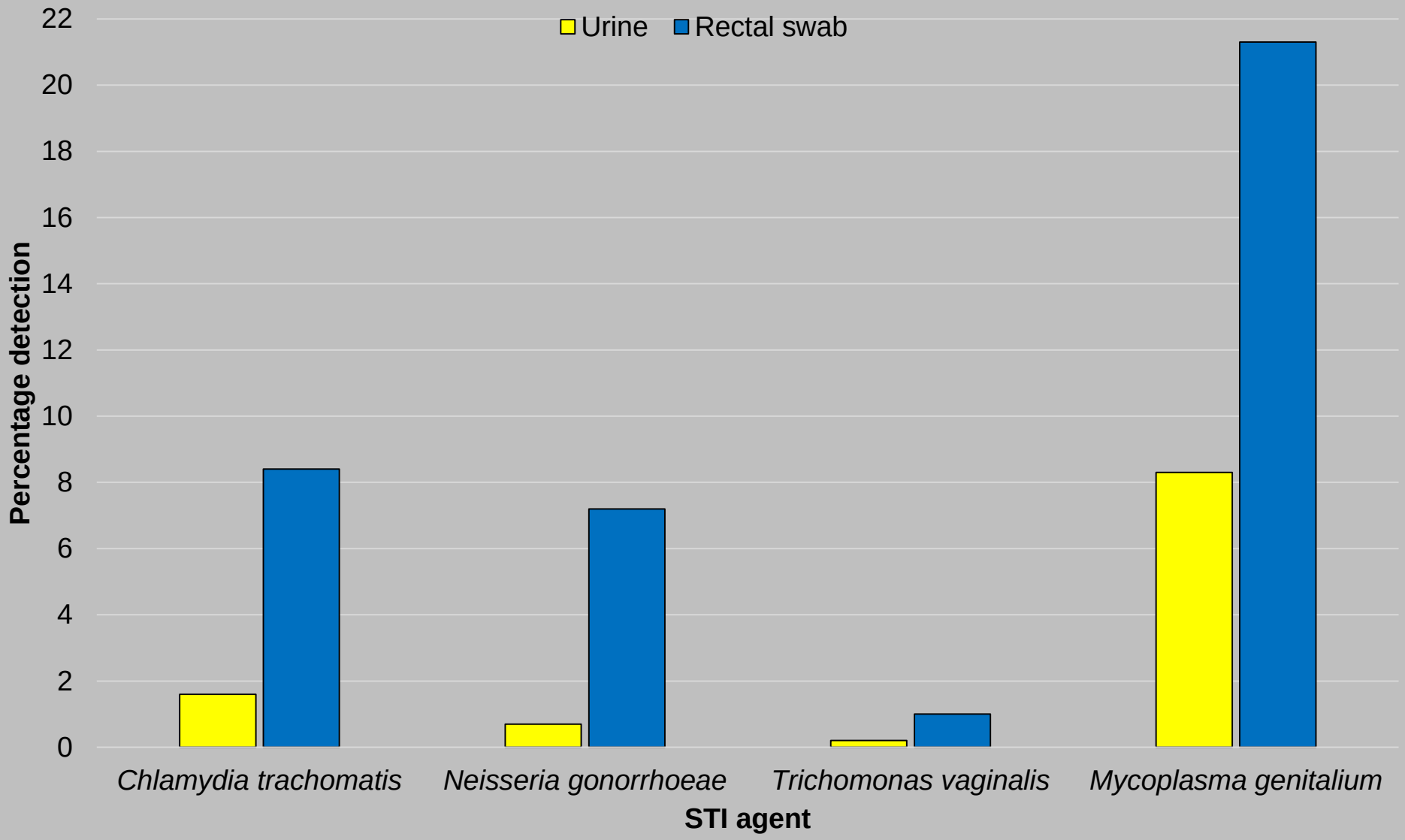
J. Clin. Microbiol. **55:** 2894-2902; 2017

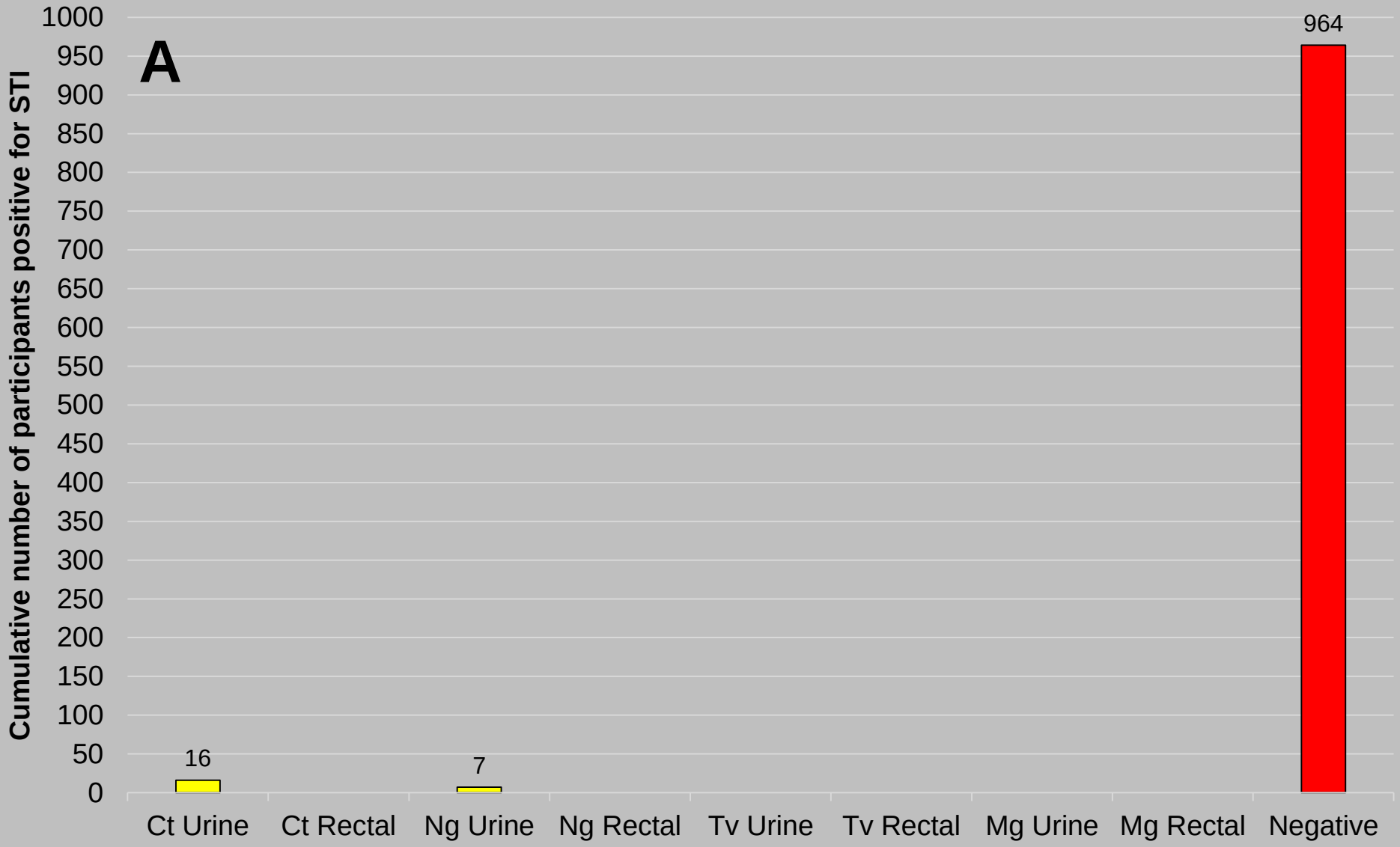
DETECTION % BY LOCATION

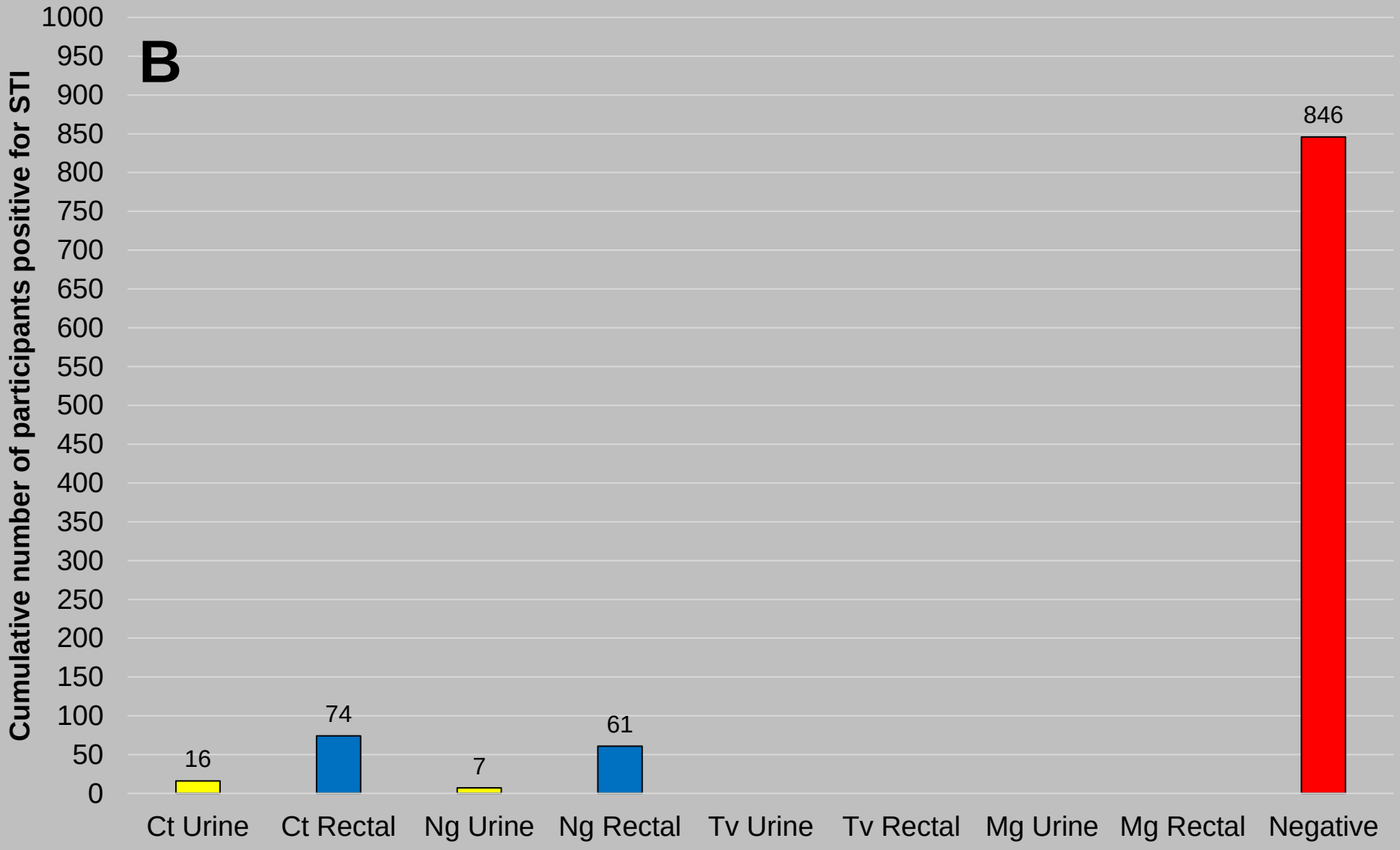
Location	n	*Chlamydia*	*Neisseria*	*Trichomonas*	*M. genitalium*	
					Overall Detection	Sole Detection[a]
Outpatient OB/GYN #1	406	6.9	0.5	6.7	10.6	85.7
ER/urgent care #1	309	13.3	3.9	20.1	20.4	65.1
Outpatient OB/GYN #2	238	4.2	2.5	7.1	14.7	82.9
ER/urgent care #2	123	4.9	2.4	10.6	13.8	64.7
Urban family care #1	133	3.8	0.8	12.0	13.5	61.1
Suburban family care #1	88	4.6	0.0	6.8	6.8	83.3
ALL LOCATIONS	2478	6.2	1.4	9.0	11.4	72.0

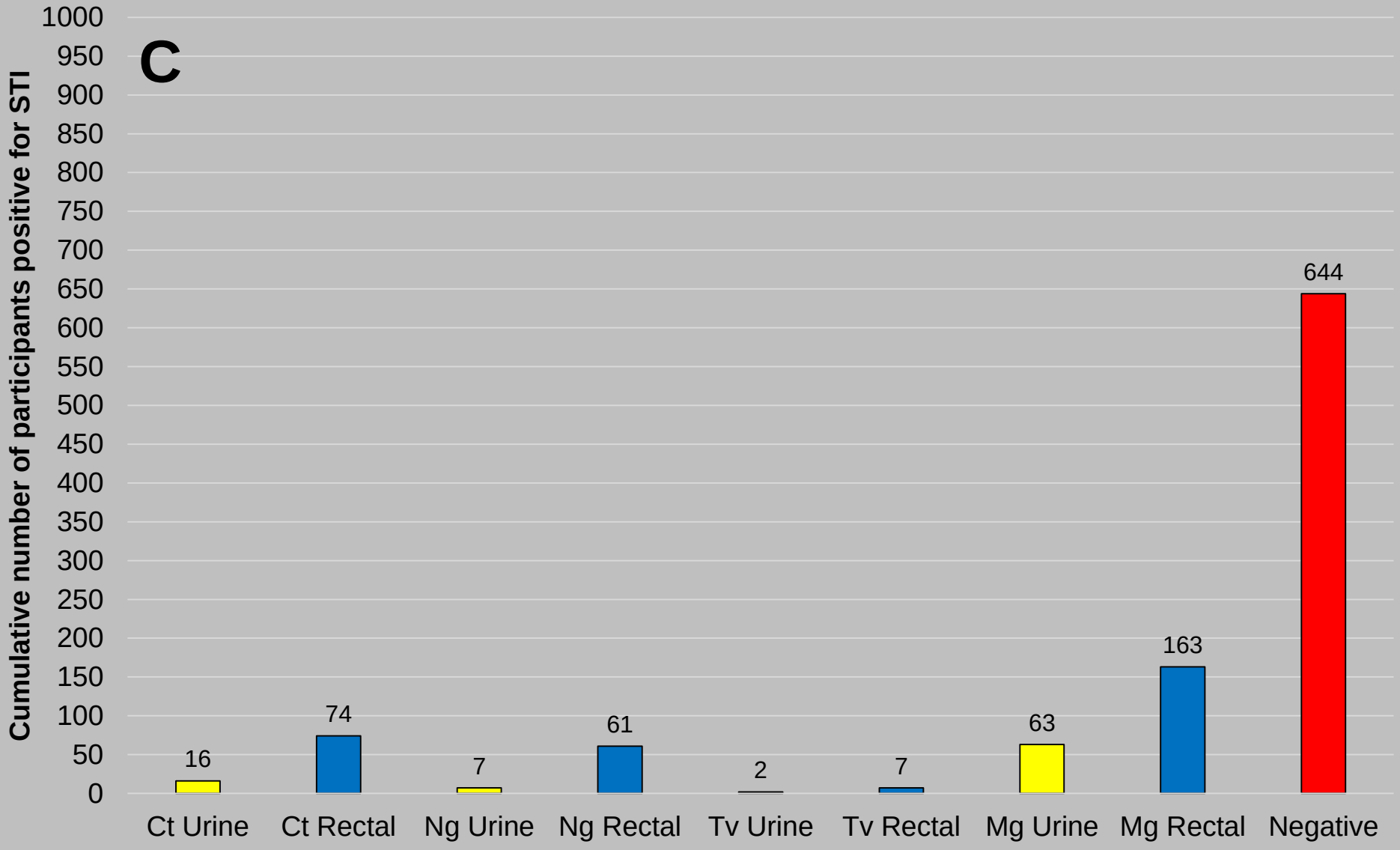
[a]Percentage of *M. genitalium* detections not involving co-detection with another agent

J. Clin. Microbiol. **54:** 432-438; 2016

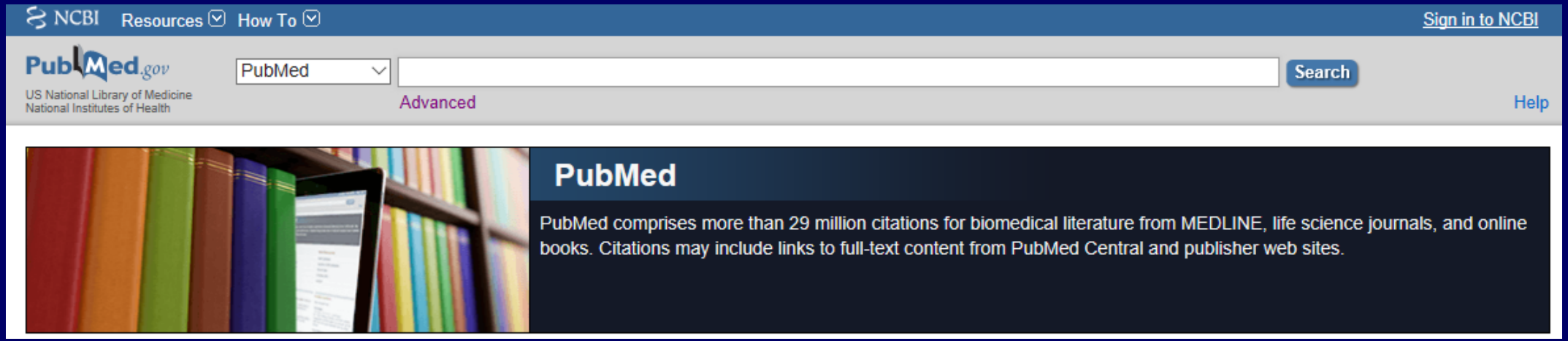

Urine
Rectal swab
22
20
18
16
14
12
10
8
6
4
2
0
Percentage detection
Chlamydia trachomatis
Neisseria gonorrhoeae
Trichomonas vaginalis
Mycoplasma genitalium
STI agent


A
Cumulative number of participants positive for STI
1000
950
900
850
800
750
700
650
600
550
500
450
400
350
300
250
200
150
100
50
0
16
7
964
Ct Urine
Ct Rectal
Ng Urine
Ng Rectal
Tv Urine
Tv Rectal
Mg Urine
Mg Rectal
Negative


B
Cumulative number of participants positive for STI
1000
950
900
850
800
750
700
650
600
550
500
450
400
350
300
250
200
150
100
50
0
16
74
7
61
846
Ct Urine
Ct Rectal
Ng Urine
Ng Rectal
Tv Urine
Tv Rectal
Mg Urine
Mg Rectal
Negative


C
Cumulative number of participants positive for STI
1000
950
900
850
800
750
700
650
600
550
500
450
400
350
300
250
200
150
100
50
0
16
74
7
61
2
7
63
163
644
Ct Urine
Ct Rectal
Ng Urine
Ng Rectal
Tv Urine
Tv Rectal
Mg Urine
Mg Rectal
Negative


ROAD
HAZARD
AHEAD


NCBI
Resources
How To
Sign in to NCBI
PubMed.gov
US National Library of Medicine
National Institutes of Health
PubMed
Search
Advanced
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ROAD
FLOODED


ROUGH
ROAD


DANGER


UFO
PRESENCE

J Infect Chemother (2012) 18:494–500
DOI 10.1007/s10156-011-0362-7

ORIGINAL ARTICLE

CAUTION I

Evaluation of Seeplex® STD6 ACE Detection kit for the diagnosis of six bacterial sexually transmitted infections

Abstract Traditionally, the diagnosis of bacterial sexually transmitted infection (STI) has been dependent on the isolation of the causative pathogens by culturing endocervical or urethral swab specimens on selective media. While such procedures typically provide excellent diagnostic accuracy, they are often time-consuming and expensive. Amultiplex polymerase chain reaction (PCR) assay, based on a semi-automated detection system, was evaluated for the detection of six STI causative organisms. The Seeplex® STD6 ACE (auto-capillary electrophoresis) Detection assay employed six pairs of dual priming oligonucleotide (DPO™) primers specifically targeted to unique genes of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Mycoplasma genitalium*, *Ureaplasma urealyticum*, *Mycoplasma hominis*, and *Trichomonas vaginalis*. A total of 739 specimens (304 cervical swabs and 435 urine samples) collected for 4 months were tested, and results were compared to those obtained with a combined monoplex PCR. The concordance between the multiplex PCR and monoplex PCR assay was 100% for both sensitivity and specificity. We also tested for the presence of two pathogenic bacteria (*C. trachomatis* and *N. gonorrhoeae*) and compared the results obtained with the multiplex PCR and BD ProbeTec duplex strand displacement amplification (SDA). The results of the multiplex PCR and duplex SDA were 99.7% concordant for *C. trachomatis* and 100% concordant for *N. gonorrhoeae*. The multiplex PCR assay using the Seeplex® STD6 ACE Detection kit proved to be a novel cost-effective and fast diagnostic tool with high sensitivity and specificity for the simultaneous detection of six STI pathogens.

Keywords Diagnosis · Sexually transmitted infection · Bacterial and parasite infection · Multiplex PCR

SUBOPTIMAL REFERENCE METHOD

Monoplex PCR assay

In contrast to multiplex PCR, only one pair of primers was used to detect the target organism in the monoplex PCR using Seegene DPO™ technology [12]. PCR amplification was performed with the Seeplex® *C. trachomatis* Detection kit, Seeplex® *N. gonorrhoeae* Detection kit, Seeplex® *M. genitalium* Detection kit, Seeplex® *U. urealyticum* Detection kit, Seeplex® *M. hominis* Detection kit, and Seeplex® *T. vaginalis* Detection kit (Seegene) respectively, according to the manufacturer's instructions. The internal control was present in the PCR mixture. Therefore, the internal control was used as the sole check for possible PCR inhibition.

Table 1 Comparison of results between multiplex polymerase chain reaction (PCR) and monoplex PCR ($n = 739$)

Target pathogen	Monoplex PCR	Multiplex PCR	
		Positive	Negative
Chlamydia trachomatis	Positive	40	0
	Negative	0	699
Neisseria gonorrhoeae	Positive	32	0
	Negative	0	707
Mycoplasma genitalium	Positive	2	0
	Negative	0	737
Ureaplasma urealyticum	Positive	157	0
	Negative	0	582
Mycoplasma hominis	Positive	82	0
	Negative	0	657
Trichomonas vaginalis	Positive	7	0
	Negative	0	732

J. Infect. Chemother. **18:** 494-500; 2012

Original research article

CAUTION II

INTERNATIONAL JOURNAL OF STD & AIDS

International Journal of STD & AIDS
2016, Vol. 27(14) 1275–1282
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DOI: 10.1177/0956462415615775
std.sagepub.com
SAGE

Multiplex PCR testing for nine different sexually transmitted infections

Abstract

Current sexually transmitted infection (STI) testing is not optimal due to delays in reporting or missed diagnoses due to a lack of comprehensive testing. The FilmArray® (BioFire Diagnostics, LLC, Salt Lake City, Utah) is a user-friendly, fully automated, multiplex PCR system that is being developed for rapid point-of-care use. A research-use-only STI panel including multiple PCR primer sets for each organism was designed to detect *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Treponema pallidum*, *Trichomonas vaginalis*, *Mycoplasma genitalium*, *Ureaplasma urealyticum*, *Haemophilus ducreyi*, and herpes simplex virus (HSV) types 1 and 2. Standard clinical testing included Gram stain, nucleic acid amplification, wet mount examination, herpes simplex virus culture, and syphilis IgG. Standard clinical tests were not available for all the organisms tested by the FilmArray STI panel. Two hundred and ninety-five clinical specimens from 190 subjects were directly compared to standard testing. Urine ($n = 146$), urethral/cervical swabs (31), oral swabs (60), rectal swabs (43), and ulcer swabs (15) were tested. Among the tested samples, FilmArray detected *C. trachomatis* in 39 (13%), *N. gonorrhoeae* in 20 (7%), *T. vaginalis* in nine (3%), HSV 1 in five (2%), HSV 2 in five (2%), *U. urealyticum* in 36 (12%), *M. genitalium* in eight (3%), and *T. pallidum* in 11 (4%). Concordance between the FilmArray STI panel and standard nucleic acid amplification testing for *C. trachomatis* was 98% and for *N. gonorrhoeae* was 97%. Multiplex PCR STI testing has the potential to improve public health by providing rapid, sensitive, and reliable results within the clinic or nearby laboratory.

Keywords

FilmArray, sexually transmitted diseases, sexually transmitted infections, STI, diagnostic test performance, multiplex PCR

NO REFERENCE METHOD

Table 1. Standard clinical testing methods employed at the [redacted] clinic at the time of the study. Urethral Gram stains were used in patients with suspected urethritis, in addition to nucleic acid amplification testing (NAAT). NAAT for *T. vaginalis* was not employed as a standard clinical test due to the expense and low prevalence of this disease in the patient population. Amplification testing for *M. genitalium* and *U. urealyticum* were not commercially available at the time of the study. *H. ducreyi* has not been identified in this population.

Organism	Standard testing
Chlamydia trachomatis	NAAT (Roche Amplicor)
Neisseria gonorrhoeae	a) Urethral Gram stain, b) NAAT (Roche Amplicor)
Treponema pallidum	a) Syphilis IgG (Captia), b) RPR staging of all IgG positives c) TP-PA tie breaker, if necessary (reverse sequence syphilis screening)
Trichomonas vaginalis	Wet mount examination
HSV1	HSV culture
HSV2	HSV culture
Mycoplasma genitalium	None
Ureaplasma urealyticum	None
Haemophilus ducreyi	Clinical examination, Gram stain

RPR: rapid plasma reagin; HSV: herpes simplex virus.

Int. J. STD AIDS **27:** 1275-1282; 2016

LOW NUMBERS

Table 1. Standard clinical testing methods employed at the [redacted] clinic at the time of the study. Urethral Gram stains were used in patients with suspected urethritis, in addition to nucleic acid amplification testing (NAAT). NAAT for *T. vaginalis* was not employed as a standard clinical test due to the expense and low prevalence of this disease in the patient population. Amplification testing for *M. genitalium* and *U. urealyticum* were not commercially available at the time of the study. *H. ducreyi* has not been identified in this population.

Organism	Standard testing
Chla	
Neis	
Trep	
Trich	
HSV	
HSV	
Myc	
Urea	
Hae	
RPR	

Table 4. Results for specimens (by type) tested by the FilmArray STI panel. Two hundred and ninety-five specimens from 190 subjects were selected for testing on the FilmArray device. The table header shows the total number of samples tested for each specimen type. The table body shows the number of tested specimens that were positive by the FilmArray.

Organism	Urine $n=146$	Urethral/cervical swab $n=31$	Rectal swab $n=43$	Oral swab $n=60$	Ulcer swab $n=15$	Total $n=295$
Chlamydia trachomatis	23	5	10	1	0	39
Neisseria gonorrhoeae	9	1	6	4	0	20
Treponema pallidum	2	0	2	2	5	11
Trichomonas vaginalis	5	3	0	1	0	9
HSV1 or HSV2	5	1	2	1	1	10
Mycoplasma genitalium	5	1	1	1	0	8
Ureaplasma urealyticum	9	9	10	8	0	36
Haemophilus ducreyi	0	0	0	0	0	0
Total	58	20	31	18	6	133

Int. J. STD AIDS **27:** 1275-1282; 2016

APMIS
ACTA PATHOLOGICA, MICROBIOLOGICA
ET IMMUNOLOGICA SCANDINAVICA

APMIS 123: 879–886

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DOI 10.1111/apm.12430

CAUTION III

Evaluation of the new AmpliSens multiplex real-time PCR assay for simultaneous detection of *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Mycoplasma genitalium*, and *Trichomonas vaginalis*

In this study, we performed an evaluation of the new CE-marked multiplex real-time AmpliSens N.gonorrhoeae/C.trachomatis/M.genitalium/T.vaginalis-MULTIPRIME-FRT PCR assay compared to APTIMA tests, i.e., APTIMA COMBO 2 assay, APTIMA *Trichomonas vaginalis* assay (FDA-approved), and two different APTIMA *Mycoplasma genitalium* assays (research use only; one of them only used for discrepancy analysis). Vaginal swabs (n = 209) and first-void urine (FVU) specimens from females (n = 498) and males (n = 554), consecutive attendees (n = 1261) at a dermatovenerological clinic in Sweden, were examined. The sensitivity of the AmpliSens PCR assay for detection of *C. trachomatis* (6.3% prevalence), *M. genitalium* (5.7% prevalence), *N. gonorrhoeae* (0.3% prevalence), and *T. vaginalis* (0.08% prevalence) was 97.5% (95% confidence interval (CI): 91.2–99.6%), 81.9% (95% CI: 70.7–89.7%), 100% (95% CI: 40.2–100%) and 100% (95% CI: 16.5–100%), respectively. The specificity of the AmpliSens PCR assay was 100% (95% CI: 99.6–100%) for all agents. The analytical sensitivity and specificity for *N. gonorrhoeae* detection was excellent, i.e., 55 international gonococcal strains detected and 135 isolates of 13 non-gonococcal Neisseria species were negative. In conclusion, the multiplex real-time AmpliSens N.gonorrhoeae/C.trachomatis/M.genitalium/T.vaginalis-MULTIPRIME-FRT PCR assay demonstrated high sensitivity and excellent specificity for the detection of *C. trachomatis*, *N. gonorrhoeae*, and *T. vaginalis*, and excellent specificity but suboptimal sensitivity for *M. genitalium* detection.

Key words: Sexually transmitted infections; AmpliSens; APTIMA COMBO 2 assay; APTIMA *Trichomonas vaginalis* assay; APTIMA *Mycoplasma genitalium* assay.

DISCREPANCY PREPONDERANCE

Table 2. True positive and negative results and the results obtained using the AmpliSens multiplex real-time PCR assay, divided into specimen type

True results[1]	AmpliSens result	No. of samples			
		Chlamydia trachomatis	*Neisseria gonorrhoeae*	*Mycoplasma genitalium*	*Trichomonas vaginalis*
Vaginal samples					
+	+	12	0	13	0
–	–	197	209	192	209
+	–	0	0	4	0
–	+	0	0	0	0
Total		209	209	209	209
FVU, females					
+	+	28	2	22	1
–	–	469	496	472	497
+	–	1	0	4	0
–	+	0	0	0	0
Total		498	498	498	498
FVU, males					
+	+	38	2	24	0
–	–	515	552	525	554
+	–	1	0	5	0
–	+	0	0	0	0
Total		554	554	554	554
Overall results					
+	+	78	4	59	1
–	–	1181	1257	1189	1260
+	–	2	0	13	0
–	+	0	0	0	0
Total		1261	1261	1261	1261

APMIS **123:** 879-886; 2015

PERFORMANCE INDICES

Diagnostic method and specimen	Number of specimens: True positive	False positive	False negative	True negative	Sensitivity: %	95% CI	Specificity: %	95% CI	Predictive value (%): Positive	Negative
	Infected patient status algorithm									
Culture	12	0	0	286	100	69.9-100	100	98.3-100	100	100
PCR - Urethral swab	11	13	1	273	91.7	59.8-99.6	95.5	92.2-97.5	45.8	99.6
PCR - Urine	11	9	1	277	91.7	59.8-99.6	96.9	93.9-98.5	55.0	99.6
ATV - Urethral swab	11	38	1	248	91.7	59.8-99.6	86.7	82.1-90.3	22.5	99.6
ATV - Urine	11	23	1	263	91.7	59.8-99.6	91.9	88.0-94.7	32.1	99.6
	Molecular resolved algorithm									
Culture	12	0	30	256	28.6	16.2-44.8	100	98.2-100	100	89.4
PCR - Urethral swab	23	0	19	256	54.8	38.8-69.8	100	98.2-100	100	93.1
PCR - Urine	20	0	22	256	47.6	32.3-63.4	100	98.2-100	100	92.0
ATV - Urethral swab	40	9	2	247	95.2	82.6-99.2	96.5	93.2-98.3	81.7	99.2
ATV - Urine	31	4	11	252	73.8	57.7-85.6	98.4	95.8-99.5	88.6	95.8

Am. J. Obstet. Gynecol. **200:** 188.e1-188.e7; 2009 (adapted)

In vitro CHALLENGE *C. trachomatis*

Elementary Bodies	TMA Result		PCR Result
	Light Units (x1000)	Interpretation	
200	1217	detected	detected
20	1111	detected	detected
2	1062	detected	not detected
0.2	878	detected	not detected
0.02	288	detected	*not tested*
0.002	12	not detected	*not tested*
0.0002	14	not detected	*not tested*
0.00002	13	not detected	*not tested*

J. Med. Microbiol. **54:** 357-360; 2005

I-Clicker Real Question 5

I-CLICKER REAL QUESTION 5

Does your laboratory test for organisms such as *Mycoplasma hominis* and *Ureaplasma urealyticum*?

A. Yes, routinely

B. Yes, but we do not get requests for these very often.

C. No, we do not offer this testing.

D. Sort of; this is a send-out test.

Mycoplasmataceae PATHOGENICITY

CAUTION IV

Disease	Causality by:		Comments
	U. urealyticum	*M. hominis*	
NGU	+++	-	*Ureaplasma* proportion unknown
Prostatitis	++	-	no evidence for chronic prostatitis
Epididymitis	+++	-	particularly in HIV-positive
Urinary calculi	++	-	largely animal studies
Pyelonephritis	-	+++	acute cases and exacerbations
Reiter's disease	+	-	more *Ureaplasma* data needed
Involuntary infertility	+	-	role in sperm motility

Mandell Principles and Practice of Infectious Diseases, 5th edition

Mycoplasmataceae PATHOGENICITY

Disease	Causality by:		Comments
	U. urealyticum	*M. hominis*	
Low birth weight	-	-	causal relation unproved
Chorioamnionitis	++	-	quoted as “few cases”
Repeated stillbirth/ spontaneous abortion	-	-	causal relation unproved
Involuntary infertility	+	-	also role in sperm motility
Postpartum fever	+	+++	*M. hominis* major cause
Postabortal fever	-	+++	*M. hominis* proportion unknown
PID	-	++	probably small proportion
Vaginitis/vaginosis	-	-	*M. hominis* association with vaginosis
Cervicitis	-	-	NONE
Bartholin abscess	-	-	*M. hominis* involvement doubtful

Mandell Principles and Practice of Infectious Diseases, 5th edition

Diseases Characterized by Urethritis and Cervicitis

Urethritis

T. vaginalis can cause NGU in heterosexual men, but the prevalence varies substantially by region of the United States and within specific subpopulations. In some instances, NGU can be acquired by fellatio (i.e., oral penile contact), sometimes because of specific pathogens such as HSV, Epstein Barr Virus, and adenovirus (*476*); data supporting other *Mycoplasma* species and *Ureaplasma* as etiologic agents are inconsistent. Diagnostic and treatment procedures for these organisms are reserved for situations in which these infections are suspected (e.g., contact with trichomoniasis, urethral lesions, or severe dysuria and meatitis, which might suggest genital herpes) or when NGU is not responsive to recommended therapy. Enteric bacteria have been identified as an uncommon cause of NGU and might be associated with insertive anal intercourse (*476*). The importance of NGU not caused by defined pathogens is uncertain; neither complications (e.g., urethral stricture and epididymitis) nor adverse outcomes in sex partners have been identified in these cases.

Cervicitis

C. trachomatis
N. gonorrhoeae
T. vaginalis
M. genitalium (persistent)

Sexually Transmitted Diseases Treatment Guidelines, 2015

PELVIC INFLAMMATORY DISEASE

- Upper female genital tract inflammatory disorders

  Endometritis
  Salpingitis
  Tubo-ovarian abscess
  Pelvic peritonitis

- *N. gonorrhoeae*, *C. trachomatis* many cases
- Vaginal organisms (*G. vaginalis*, anaerobes, enteric GNR, *H. influenzae*, *S. agalactiae*)
- Some associations with *M. hominis*, *U. urealyticum*, *M. genitalium*

Sexually Transmitted Diseases Treatment Guidelines, 2015

PELVIC INFLAMMATORY DISEASE

- Most-specific diagnostic criteria:

  Histopathologic evidence of endometritis
  Thickened, fluid-filled tubes (MRI, sonography)
  Laparoscopic findings consistent with PID

- Supplemental findings include:

  C. trachomatis, *N. gonorrhoeae* cervical infection
  Abnormal cervical mucopurulent discharge
  Increased leukocytes in vaginal fluid
  Elevated C-reactive protein

Sexually Transmitted Diseases Treatment Guidelines, 2015

PARTICIPANTS: 19% ♀; 81% ♂

Table 4. Results for specimens (by type) tested by the FilmArray STI panel. Two hundred and ninety-five specimens from 190 subjects were selected for testing on the FilmArray device. The table header shows the total number of samples tested for each specimen type. The table body shows the number of tested specimens that were positive by the FilmArray.

Organism	Urine $n=146$	Urethral/cervical swab $n=31$	Rectal swab $n=43$	Oral swab $n=60$	Ulcer swab $n=15$	Total $n=295$
Chlamydia trachomatis	23	5	10	1	0	39
Neisseria gonorrhoeae	9	1	6	4	0	20
Treponema pallidum	2	0	2	2	5	11
Trichomonas vaginalis	5	3	0	1	0	9
HSV1 or HSV2	5	1	2	1	1	10
Mycoplasma genitalium	5	1	1	1	0	8
Ureaplasma urealyticum	9	9	10	8	0	36
Haemophilus ducreyi	0	0	0	0	0	0
Total	58	20	31	18	6	133

Int. J. STD AIDS **27:** 1275-1282; 2016

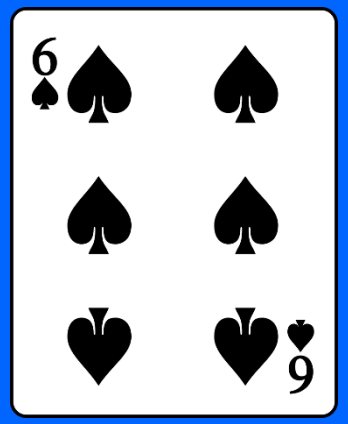
PARTICIPANTS: 304 ♀; 435 ♂

Table 1 Comparison of results between multiplex polymerase chain reaction (PCR) and monoplex PCR ($n = 739$)

Target pathogen	Monoplex PCR	Multiplex PCR	
		Positive	Negative
Chlamydia trachomatis	Positive	40	0
	Negative	0	699
Neisseria gonorrhoeae	Positive	32	0
	Negative	0	707
Mycoplasma genitalium	Positive	2	0
	Negative	0	737
Ureaplasma urealyticum	Positive	157	0
	Negative	0	582
Mycoplasma hominis	Positive	82	0
	Negative	0	657
Trichomonas vaginalis	Positive	7	0
	Negative	0	732

21.2% detection from female
26.2% detection from male urine

J. Infect. Chemother. **18:** 494-500; 2012



I-Clicker Real Question 6

I-CLICKER REAL QUESTION 6

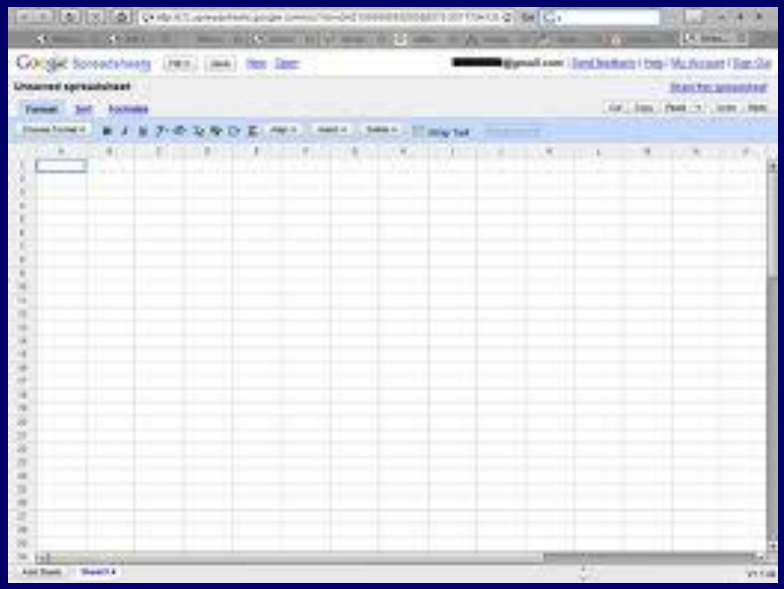
If you are a laboratory that performs laboratory-modified or developed testing, how has reimbursement been?

A. Better than I thought it would be

B. About as expected

C. My boss calls me into the office weekly; I get yelled at.

D. I need a crash course on this.




COST
CLINICAL
NEED

OUTPATIENT

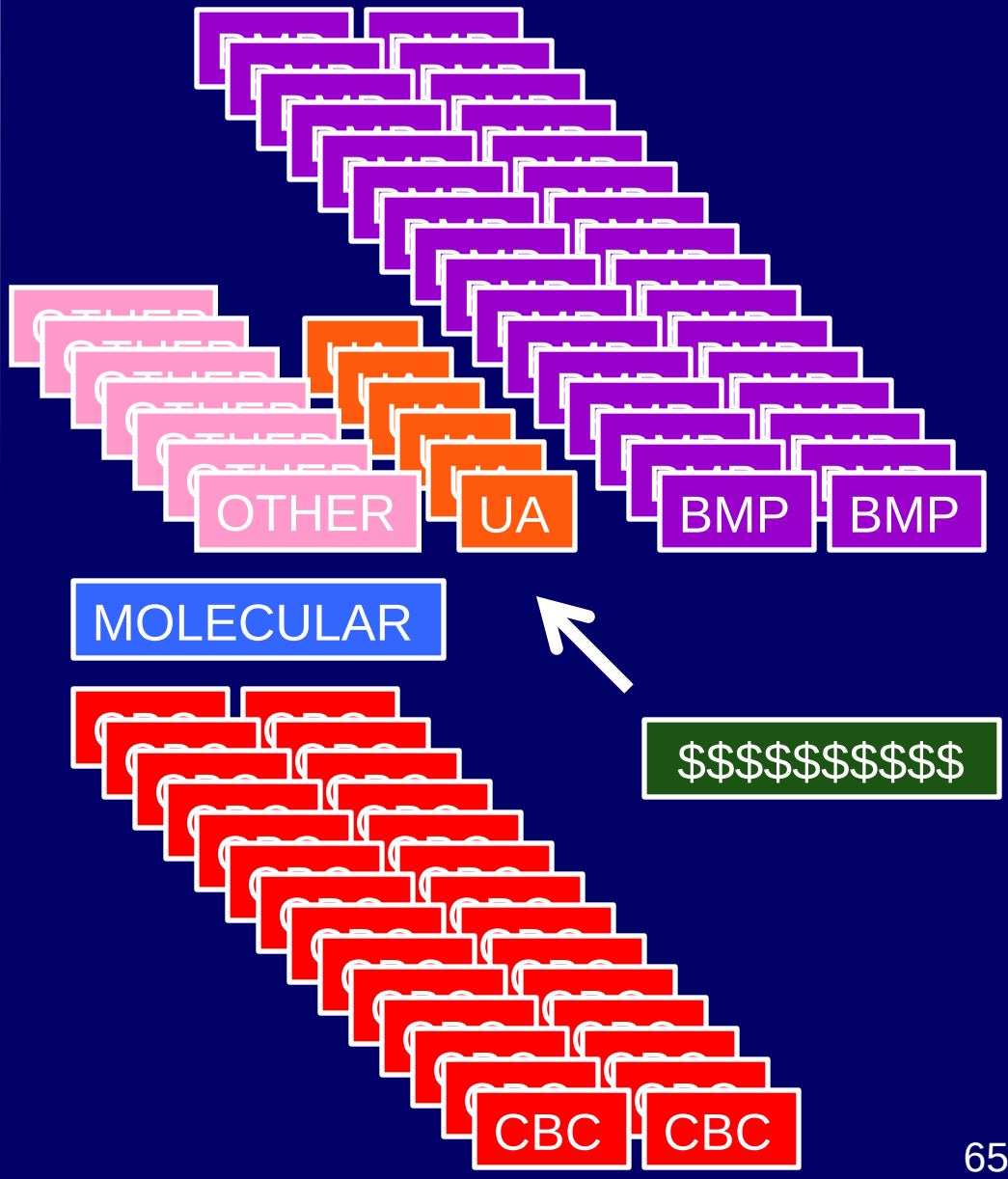
MOLECULAR ← $$$$$$$$$$

CBC ← $$$$$$$$$$

BMP ← $$$$$$$$$$

UA ← $$$$$$$$$$

INPATIENT



COST/REIMBURSEMENT

Method	Microscopy	Molecular
Reagent co$t	$0.54	$11.81
Direct co$t (labor)	$3.81	$17.84
Reimbur$ement	$5.96	$51.25

No additional capital

No additional specimen collection

No additional training

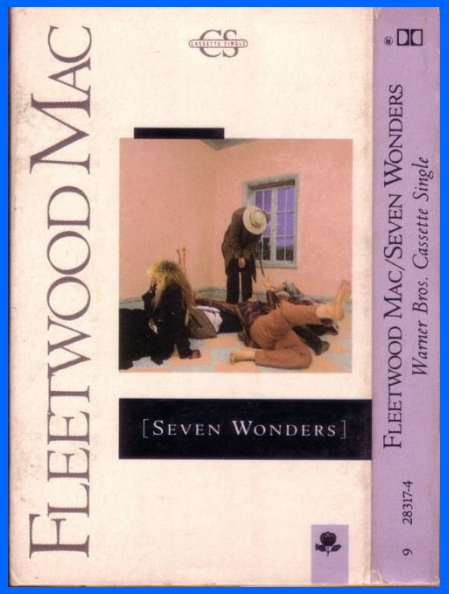
COST/REIMBURSEMENT

Method	Microscopy	Molecular
Reagent co$t	$0.54	$11.81
Direct co$t (labor)	$3.81	$17.84
Reimbur$ement	$5.96	~$40.00

No additional capital

No additional specimen collection

No additional training



I-Clicker Real Question 7

I-CLICKER REAL QUESTION 7

Does your laboratory offer testing for diagnosis of bacterial vaginosis? IF SO, what is your primary offering?

A. Yes, our primary offering is wet mount for clue cells.

B. Yes, our mainstay is Nugent score analysis.

C. Yes, our go-to is BD Affirm VP III.

D. Yes, we are trailblazing nucleic acid amplification testing.

E. No, nothing exists within our testing menu.

Example: WOMEN'S HEALTH PANELS

"Your competitors have molecular tests for women's health; you bring this in and we'll order it."

Example: WOMEN'S HEALTH PANELS

BV Panel

Bacterial vaginosis (several targets)

Example: WOMEN'S HEALTH PANELS

Candida Panel

Yeast

Candida albicans, *Candida krusei*, *Candida glabrata*

Example: WOMEN'S HEALTH PANELS

Vaginitis Panel

Bacterial vaginosis (several targets)

Yeast

Candida albicans, *Candida krusei*, *Candida glabrata*

Trichomonas vaginalis

Example: WOMEN'S HEALTH PANELS

Mycoplasma/Ureaplasma

Mycoplasma / Ureaplasma

M. hominis, *M. genitalium*, *U. urealyticum/parvum*

Example: WOMEN'S HEALTH PANELS

Complete Panel

Bacterial vaginosis (several targets)

Yeast

Candida albicans, *Candida krusei*, *Candida glabrata*

Trichomonas vaginalis

Mycoplasma / Ureaplasma

M. hominis, *M. genitalium*, *U. urealyticum/parvum*

Example: WOMEN'S HEALTH PANELS

MODALITIES

Bacterial vaginosis Commercial assay (1 result)

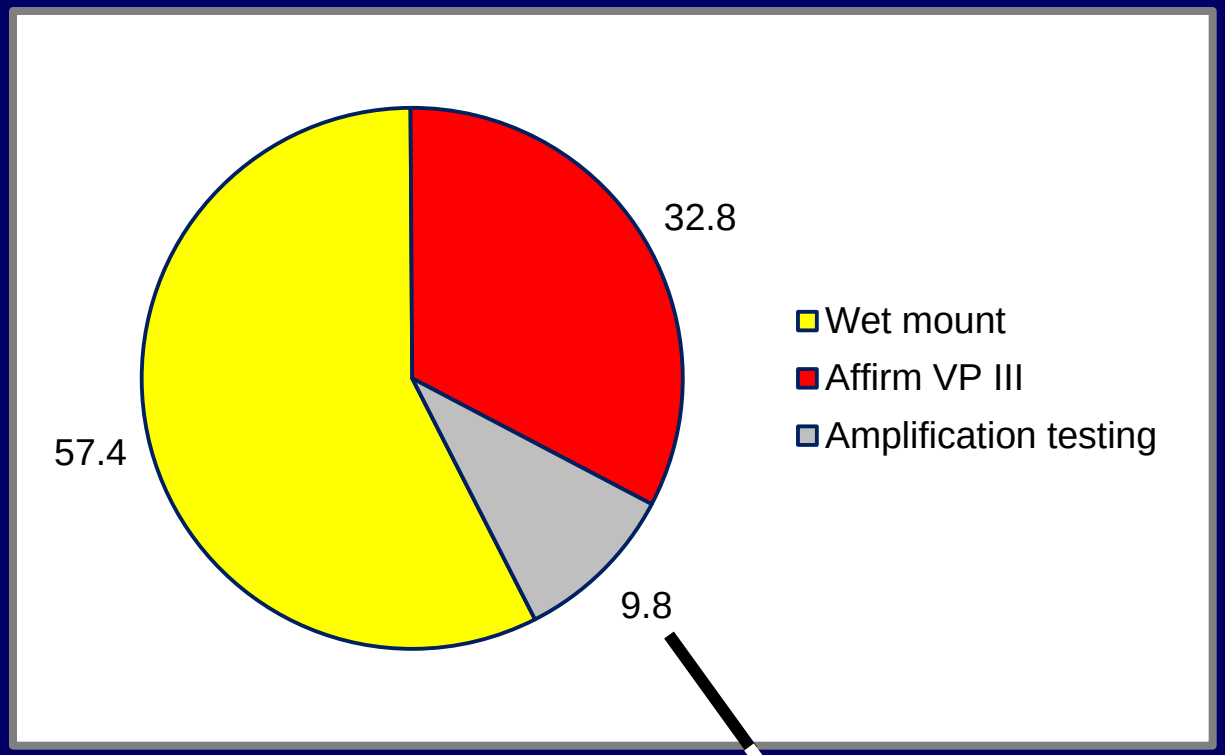
Yeast Commercial assay (same; 3 results)

Trichomonas vaginalis Commercial assay (same)

Mycoplasma / Ureaplasma LDT (3 results)

PERCENTAGE MONTHLY UTILIZATION

n ~ 6100 tests



BV panel 15/month
Candida panel 5/month
Vaginitis panel 300/month
Mycoplasma / *Ureaplasma* 75/month
Complete panel 200/month

SOME AUTOMATED PLATFORMS

BD MAX™

Candida albicans
Candida glabrata
Candida krusei
Chlamydia trachomatis
Neisseria gonorrhoeae
Trichomonas vaginalis
Streptococcus agalactiae

Healthcare infections

Gastrointestinal

Cepheid

C. trachomatis
N. gonorrhoeae
T. vaginalis
S. agalactiae

Healthcare infections

Genetic markers

Critical infectious diseases

Cobas 4800

Chlamydia trachomatis
Neisseria gonorrhoeae
HSV 1/2
HPV

Healthcare infections

Oncology markers

BD Viper XTR™

C. trachomatis
N. gonorrhoeae
T. vaginalis
HSV 1/2

SOME AUTOMATED PLATFORMS

Luminex

ARIES® GBS assay
ARIES® HSV 1&2 assay
MultiCode®-RTx HSV 1&2

Respiratory

Gastrointestinal

Blood culture

*m*2000 RealTi*me*

C. trachomatis
N. gonorrhoeae
HIV-1
HCV
HCV genotype II

Others (Zika EUA)

Cobas 6800/8800

Chlamydia trachomatis
Neisseria gonorrhoeae
HIV-1
HCV

Blood screening

Panther system

C. trachomatis
N. gonorrhoeae
T. vaginalis
M. genitalium
HSV 1/2
S. agalactiae
HPV; 16, 18/45
HIV-1
HCV

Others (Zika EUA)

TAKE HOME

- Can be a $ generator
  Accurate detection of emerging STI
  Automation may assist
- Many options available; laboratory-modified and -developed testing may be considered
- Review literature with a critical eye
- Don’t develop a test “just because you can”…
  Ask first if you should