

Revolutionizing STI Testing for You and Your Patients



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Agenda

Revolutionizing STI Testing for You and Your Patients

1. Review the current STI epidemic and impact on patient health
2. Examine how innovative POC testing can increase efficiency and improved patient care
3. Assess how testing accuracy, deployability, and speed can improve your workflow
4. Evaluate how POC STI testing can provide clinical, operational, and financial benefits to your practice while increasing both the quality of care and satisfaction of your patients

1

Review the current STI epidemic and impact on patient health

Poll Question # 1

What percent of youth under age 25 have had an STI?

25%

50%

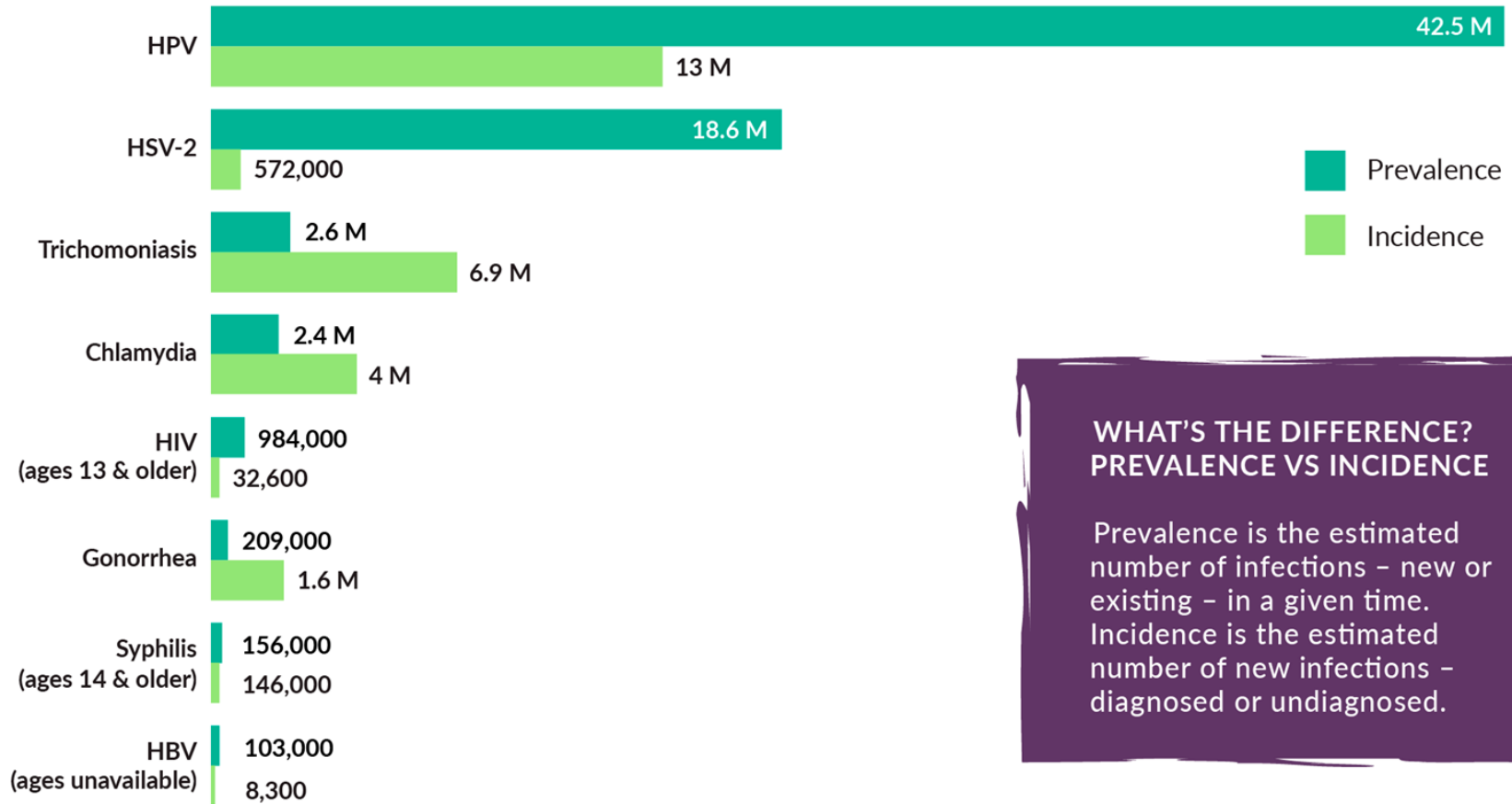
75%

Reported STIs in the US reach all-time high for 6th consecutive year¹

STI rates are at the highest in U.S. History



STI Prevalence and Incidence in the US



WHAT'S THE DIFFERENCE? PREVALENCE VS INCIDENCE

Prevalence is the estimated number of infections – new or existing – in a given time. Incidence is the estimated number of new infections – diagnosed or undiagnosed.

*Bars are for illustration only; not to scale, due to wide range in number of infections. Estimates for adults and adolescents ages 15+ unless otherwise stated. HIV and HBV data only represent sexually acquired infections.

Health & Human Services (HHS)

FIRST- EVER

STI National Strategic Plan

A. Vision

The United States will be a place where sexually transmitted infections are prevented and where every person has high-quality STI prevention, care, and treatment while living free from stigma and discrimination.

This vision includes all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, religion, disability, geographic location, or socioeconomic circumstance.

B. Goals

In pursuit of this vision, the STI Plan establishes five goals:



1. Prevent new STIs



2. Improve the health of people by reducing adverse outcomes of STIs



3. Accelerate progress in STI research, technology, and innovation



4. Reduce STI-related health disparities and health inequities



5. Achieve integrated, coordinated efforts that address the STI epidemic

Condom sales went limp during the COVID pandemic



COVID: Big impact on STI testing resources

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The US has a record number of sexually transmitted diseases and COVID-19 is making things worse, experts say

Dr. Catherine Schuster-Bruce Oct 25, 2021, 8:02 AM

[f](#) [✉](#) [↗](#)



SUMMARY

- COVID-19 has made it harder to tackle the rising numbers of US STI, experts warn.¹
- People are now less inclined to use condoms, and testing isn't as readily available.¹
- STD rates in the US were at an all-time-high for the sixth year in a row, the CDC said in April 2021.²

STI Effect on Patients & Healthcare Dollars

Left untreated, STIs can lead to serious health consequences

- pelvic inflammatory disease (PID)
- chronic abdominal pain
- infertility
- ectopic pregnancy
- miscarriage
- neonatal death
- congenital abnormalities.¹
- Chlamydia, gonorrhea, and trichomonas are also associated with increased risk of HIV transmission.³

USPTF STI Screening Recommendations

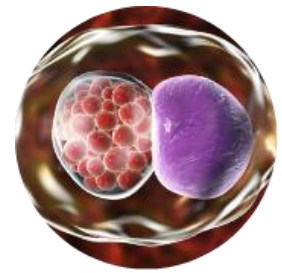
Chlamydia & Gonorrhea

- For sexually active women, including pregnant persons:
 - 24 years or younger
 - 25 years or older and at increased risk for infection

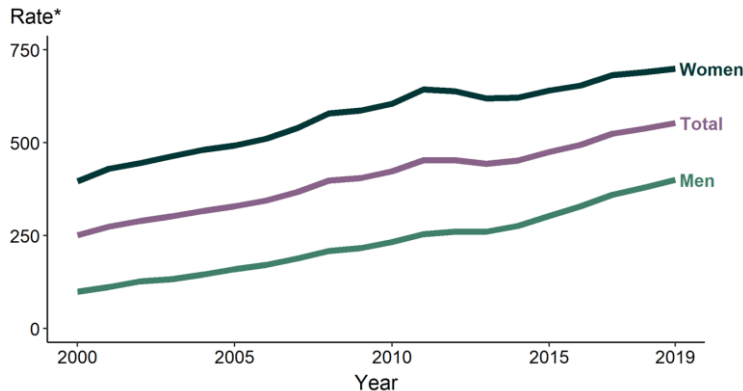
Trichomonas

- Women at risk or with symptoms

Chlamydia Trachomatis (CT)



- **Most common** reportable bacterial STI in the US¹.
- 2 in 3 reported cases were among 15-24 years old¹
- Among females aged 15–24 years, reported cases of **chlamydia increased by 10.0% from 2015¹**
- **Up to 70% of cases are asymptomatic¹**



Recommends Testing

- Sexually active women under 25 years of age
- Sexually active women 25 years of age and older if at increased risk
- Retest approximately 3 months after treatment



If left Untreated:

Chlamydia can cause permanent damage to the female reproductive tract and cause Pelvic inflammatory disease (PID)⁴

PID increases a woman's risk of:⁴

- Infertility
- Chronic pelvic pain
- Tubal or ectopic pregnancy
- Miscarriage

Chlamydia (CT) Treatment

Preferred Regimen: Doxycycline 100 mg orally BID x 7 days

Doxycycline 200 mg delayed release tab orally once
daily x 7 days (\$\$)

Preferred Regimen Pregnancy: Azithromycin 1 g orally in a single dose

Alternative Regimen: Azithromycin 1 g orally single dose (less effective for rectal chlamydia)
Levofloxacin 500 mg orally once daily 7 days

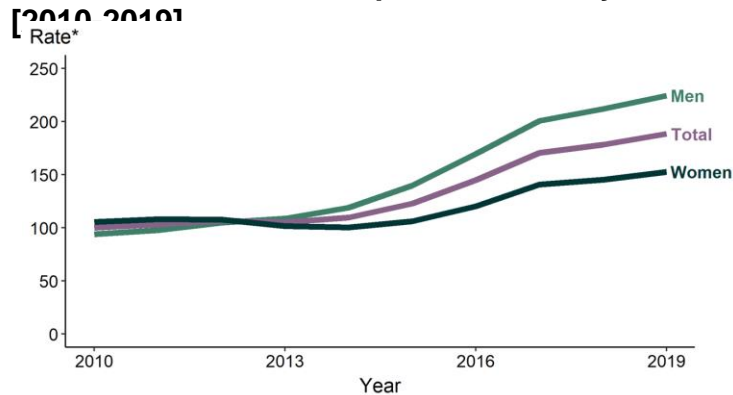
Alternative Regimen Pregnancy: Amoxicillin 500 mg orally 3 times/day for 7 days

Neisseria Gonorrhoea (NG)



- **Second most common** reportable bacterial STI in the US,¹.
- **Rates** of reported gonorrhoea have **increased 92.0% since a historic low in 2009**.
 - During 2018–2019, the overall rate of reported gonorrhoea increased 5.7%.
- **Rates** among women increased **5.1% during 2018–2019** and **43.6% during 2015–2019**.
- In reported Gonorrhoea cases, **50% women are asymptomatic**².

Gonorrhoea – Rates of reported cases by sex



- Sexually active women under 25 years of age
- Sexually active women 25 years of age and older if at increased risk
- Retest approximately 3 months after treatment

➔ **If left Untreated:**

Untreated gonorrhoea can:

- Cause serious and permanent health² problems – In women, can result in PID, complications include ectopic pregnancy, infertility, chronic abdominal pain
- Increases risk of HIV transmission
- Babies of infected mothers can be infected during childbirth
- Disseminated Gonococcal Infection (DGI) occurs in 0.5-3% of untreated NG cases³

1. Platt R, Rice PA, McCormack WM.. JAMA, 250(23), 3205–3209 (1983).
2. Gonorrhoea – CDC fact sheet (detailed version). Centers for Disease Control and Prevention (CDC) website. <https://www.cdc.gov/std/detailed.htm>. Reviewed April 13, 2021. Accessed on July 6, 2021.
3. <https://www.cdc.gov/std/program/outbreakresources/HANtemplate-dgi.htm>

Gonorrhea Treatment

Preferred Regimen: Ceftriaxone 500 mg IM (weight < 150 kg)
Ceftriaxone 1 g IM (weight > 150 kg)

Alternative Regimen:

If cephalosporin allergy: Gentamicin 240 mg IM in a single dose
PLUS

Azithromycin 2 g orally in a single dose

If ceftriaxone administration is not available or not feasible:

Cefixime 800 mg* orally in a single dose

Monotherapy with azithromycin 2 g orally as a single dose no longer recommended

N. gonorrhoeae ease to develop resistance to macrolides

High proportion of isolates with azithromycin decreased susceptibility

Resistance to penicillin, tetracycline, and older macrolides

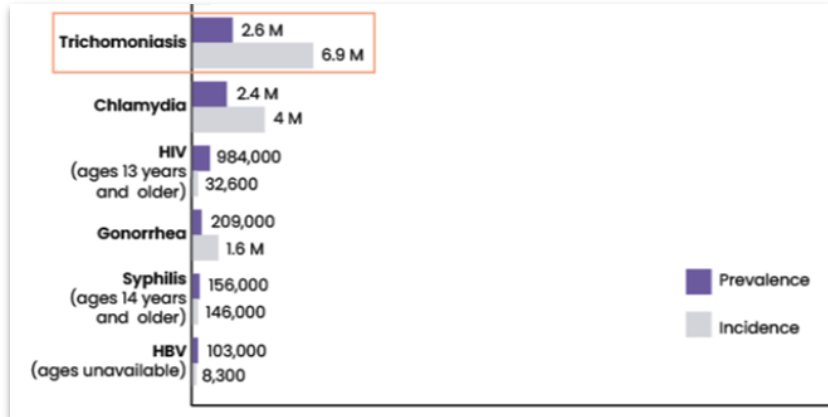
Gonorrhea Treatment -
Expedited Partner Treatment (EPT):

- Cefixime 800 mg, single dose

Trichomonas Vaginalis (TV)



- Caused by a protozoan parasite, Trichomonas is the third most common STI in the US¹.
- The epidemiology of trichomoniasis comes from population-based, not clinic-based surveillance studies (true prevalence is unknown as it is not reportable)
- CDC estimates that there were 2.6 million trichomoniasis infections in 2018²
 - The U.S. population-based prevalence is 2.1% among females with the highest rates among Black females (9.6%)³



1. CDC Trichomonas Fact Sheet <https://www.cdc.gov/std/trichomonas/stdfact-trichomoniasis.htm>
2. CDC STI Prevalence, Incidence, & Estimated Costs in US <https://www.cdc.gov/std/statistics/prevalence-2020-at-a-glance.htm>
3. Flagg EW, Meites E, Phillips C, et al. Sex Transm Dis. 2019;46:e93-e96.
4. STDs during Pregnancy – CDC Fact Sheet (Detailed) <https://www.cdc.gov/std/gonorrhea/stdfact-tr-detailed.htm>
5. Microb Cell. 2016;3:404-418
6. J Infect Dis. 2007;195:698-702

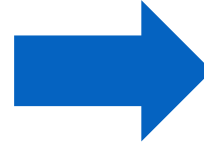
Trichomonas Vaginalis (TV)



Up to
70%
of women are
asymptomatic¹



Recommends
Testing



- Should be performed **for women seeking care for vaginal discharge**⁵
- Women receiving care **in high-prevalence settings** (e.g., STI clinics and correctional facilities) **and for asymptomatic women at high risk for infection** (e.g., women with multiple sex partners, transactional sex, drug misuse, or a history of STI or incarceration)
- Routine annual testing for *T. vaginalis* among **asymptomatic women with HIV** infection is recommended because of these adverse events associated with trichomoniasis and HIV infection

If left Untreated:

T. vaginalis causes reproductive morbidity⁴ – greater likelihood of

- PID⁶
- Female infertility
- Pre-term birth
- Premature rupture of membranes
- Infants who are small for gestational age

Increases risk of contracting other STIs, including 2-3 times greater risk of HIV acquisition

Trichomonas Treatment

Preferred Regimen: Metronidazole 500 mg orally 2 times/day for 7 days

Alternative Regimen: Tinidazole 2 g orally in a single dose

Multidose metronidazole (500 mg orally 2 times/day for 7 days) reduced the proportion of women re-testing positive at a 1-month test of cure visit by half, compared with women who received the 2-g single dose.

2

How can innovative POC testing increase efficiency and improve patient care?


Poll Question #2



What are the average number of days for lab-based STI PCR results to be reported?

- 1 - 2 days
- 3 - 5 days
- More than 5 days

Waiting for STI results usually means presumptive treatment

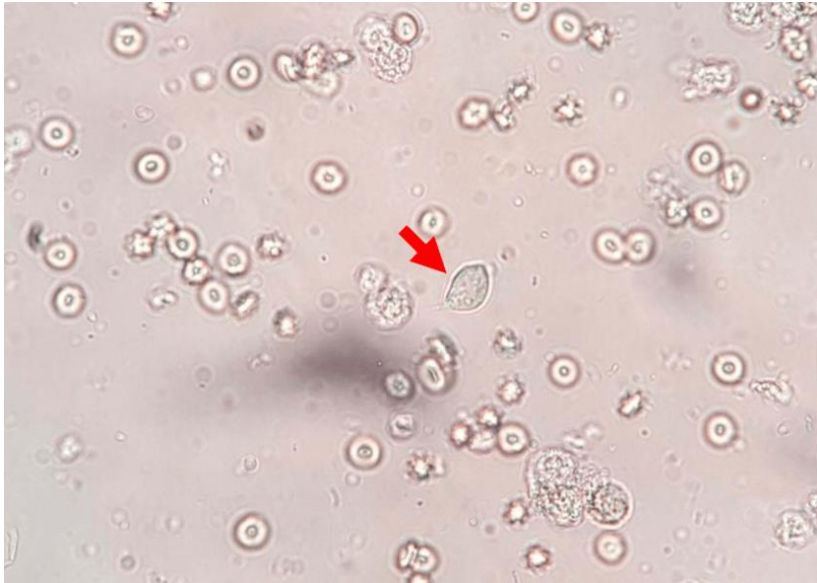
PCR diagnostics for STI require an expensive instrument, specially trained personnel, and *sending samples to a centralized lab, and waiting for test results, so clinicians often treat empirically.*



 <p>Lab</p> <p>1-2 day turnaround, expensive, personnel intensive</p>	 <p>Instrument</p> <p>Capital requirements, leading to maintenance & down times</p>
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Wet mount for detection TV is imprecise

Wet mount microscopy is the **most common** method for the detection of *T. vaginalis*.^{1,2}



40%

positive patients were missed when comparing PCR to wet mount³

10-30 mins

delay can drastically reduce sensitivity of wet mount test¹

Multiple Studies: Patients lost to follow-up across health-care settings

STD/Family Planning Clinics

- 26% of patients tested in STD and family planning clinics in VA were lost to follow up²
- 18% of patients presenting to an STD clinic in Washington DC were lost to follow up³.
 - Even though 82% were successfully contacted, only 34% were treated within 14 days, with some individuals receiving treatment 30-60 days after a positive test result

Emergency Departments

- 40% of adolescent females presenting to ED in Grand Rapids, MI were lost to follow up¹
- 40% of young women were lost to care after the initial ED visit in Cincinnati, OH⁴
- ~8% of patients positive for CT or NG were lost to care in an urban ED setting in Philadelphia, PA⁵
 - Even though 92% were successfully contacted, only 13% were treated within 9 days; median time to treatment was 36 days

STD Services in Urban Urgent Care Centers⁶

“Our challenges include... delivering patient results once labs were received after visit. There is no system for follow up the way a primary provider’s office can.”

Symptomatic patients continue to have sex

Among symptomatics,

44.8% of men

58.0% of women

continued to have sex while awaiting treatment

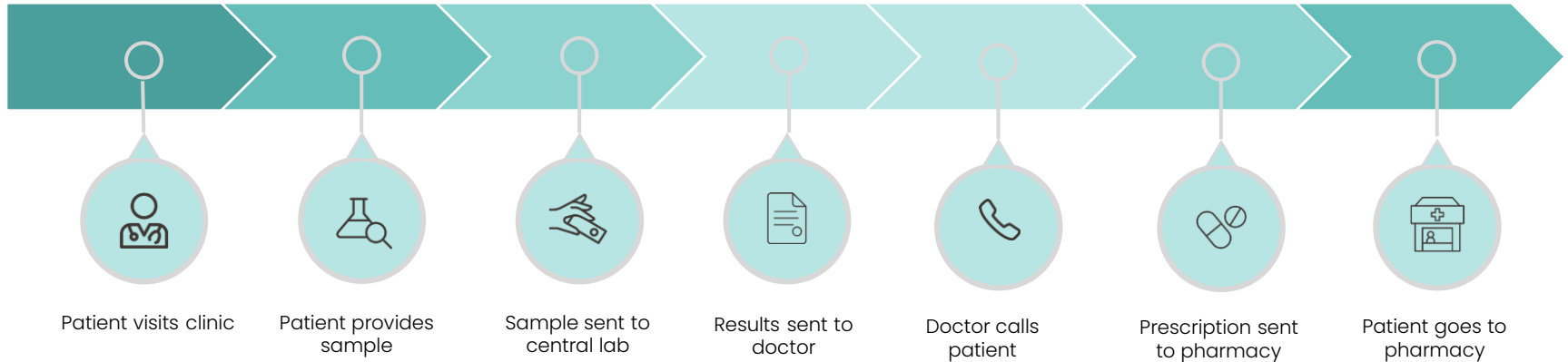
with 7.0% reporting sex with¹ partner;
4.2% of symptomatic patients reported sex without using
condoms with new partner(s) since their symptoms had
begun. ¹



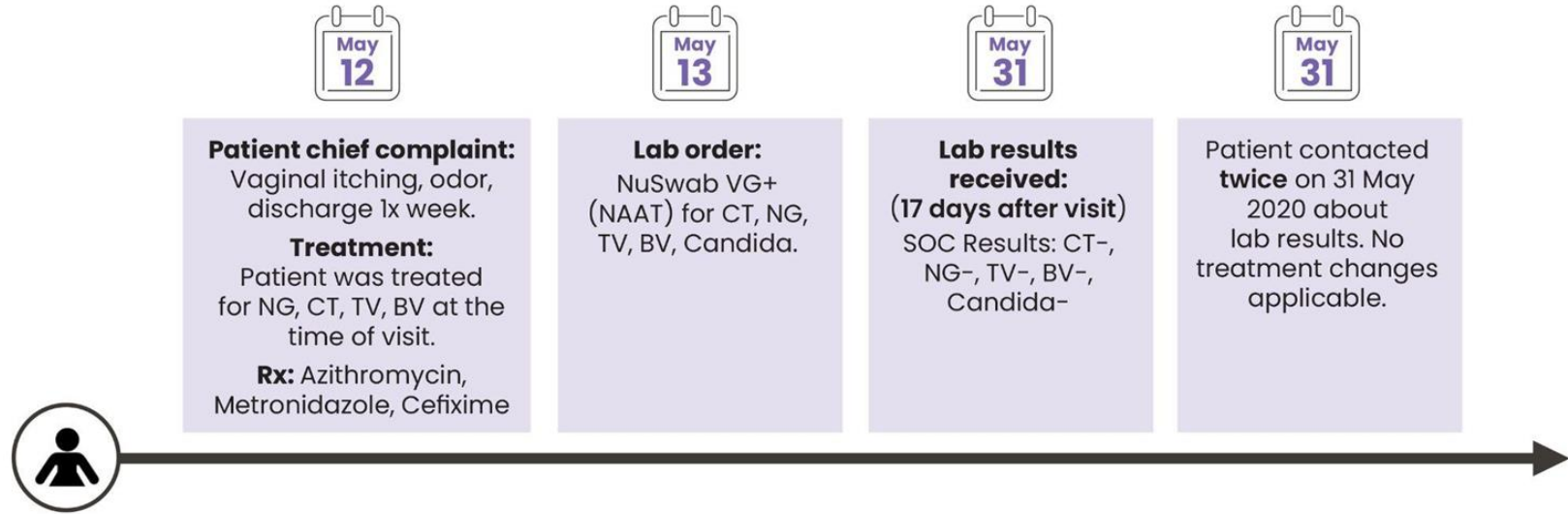
Traditional lab send-out meant no results while the patient was with us

So our practice followed SOC of Presumptive Treatment

Patient visit to patient diagnosis: Up to 14 days



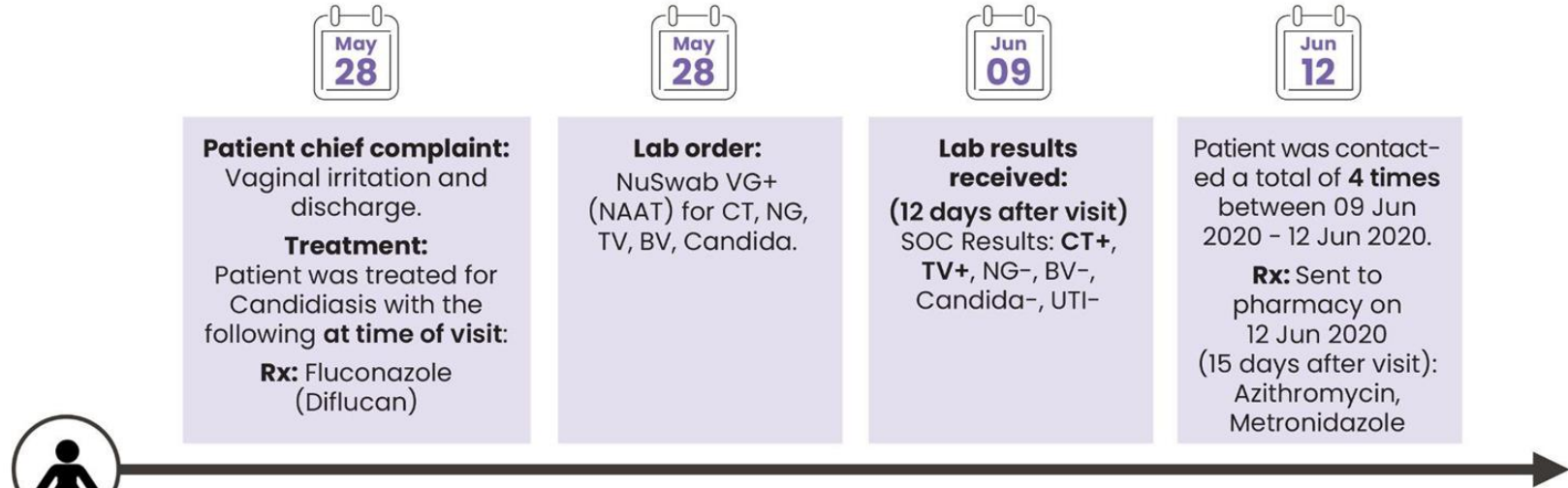
Example of over-treatment¹



NG = Neisseria Gonorrhoea
CT = Chlamydia Trachomatis
BV = Bacterial Vaginosis
NAAT = Nucleic Acid Amplification
Test = Standard of Care
SOC

*NuSwab VG+ is a brand of LabCorp

Example of under-treatment¹



NG = Neisseria Gonorrhoea
CT = Chlamydia Trachomatis
BV = Bacterial Vaginosis
NAAT = Nucleic Acid Amplification
Test = Standard of Care
SOC = Standard of Care

*NuSwab VG+ is a brand of LabCorp

Impact of STI over/under-treatment

Patient

- Inappropriate antibiotic use
- Complications can lead to PID, infertility, ectopic pregnancy
- Imbalance of microbiome
- Disease progression and potential for repeat infections
- Schedule return appointment for NG treatment (ceftriaxone)
- Unnecessary shame, guilt – damage to relationships

Clinic

- Inefficient workflow – staff needs to contact patient
- Staff could be focused on new/other patients
- No opportunity for *specific* face-to-face clinician-patient dialogue
- Reduced clinician satisfaction

Community

- Delayed partner treatment
- Continued transmission – epidemic propagation
- Antibiotic resistant infections

Antibiotics are NOT benign



TABLE 1

Known and potential harms of antibiotic overprescribing¹⁻⁶

Known harms	Potential harms
Antibiotic-associated diarrhea	Increased asthma
<i>Clostridium difficile</i> colitis	Increased obesity
Tendon rupture (quinolones)	Impaired immune system
Long QT syndrome (macrolides and others)	Mental health effects
Renal compromise	
Allergic reactions	

2019 CDC Antibiotic Resistance (AR) Threats Report:

Drug-resistant *Neisseria gonorrhoeae* is one of top 5 Urgent Threats

- Highest level of concern on CDC Antibiotic Resistance Threat list



Patient #1



- 19 year old college female is home for break. She re-connected with her high school boyfriend, but now regrets having sex with him. She wants to test for STIs. She is leaving for school tomorrow morning.



in



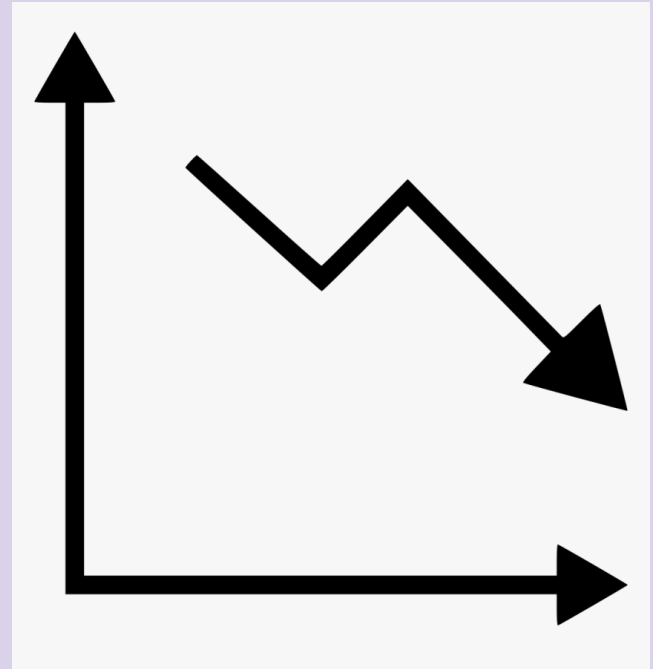
SEXUALLY ACTIVE PEOPLE

GET AN STD BY AGE 25

Counseling

A study on the relationship between sexual health education and recurrent rates of STI's in sexually active women aged 15-19, showed that **women who received health educator counseling after testing positive for Gonorrhea, Chlamydia, or Trichomonas showed significantly lower rates of reinfection after 1 year versus the control group which received usual care (p=0.002).**¹

In-iw, Supinya, et al. The Impact of Health Education Counseling on Rate of Recurrent Sexually Transmitted Infections in Adolescents. Journal of Pediatric and Adolescent Gynecology, vol. 28, no. 6, 2015, pp. 481–485.



Poll Question #3

What are the average number of contact attempts made to reach a patient about test results?

- 1 – 2 attempts
- 3 – 4 attempts
- 5 + attempts

Patient #2



31 year old pregnant female presents for routine OB visit. She recently broke up with her boyfriend, and is not sure if he was cheating.

Patient #3

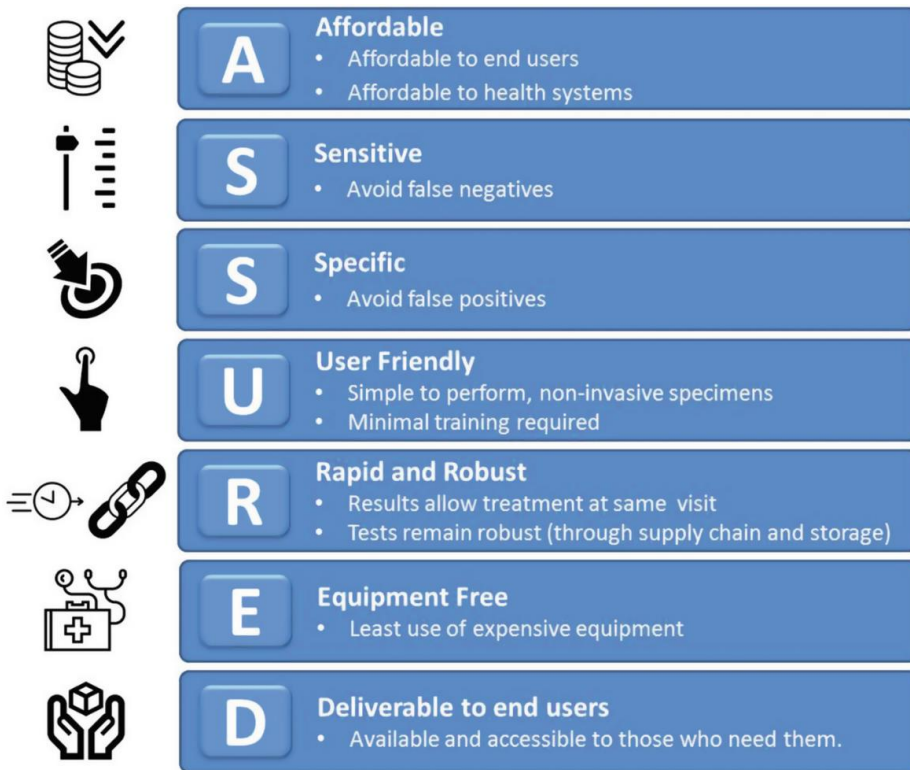


51 year old married female presents with complaints of vaginal discharge and discomfort. She recently found out that her husband of 25 years is having an affair. She is worried that she may have an infection. She wants to know the results as soon as possible, and it is going to be very difficult at home until she knows.

3

Assess how testing accuracy, deployability, and speed can improve your workflow

The WHO 'ASSURED' criteria for POC test



2004
WHO Special Program for Research and
Training in Tropical Diseases:
Urgent Need for New Point-of-Care
Diagnostic Tests for Bacterial STDs

**POC tests should return results in
less than 30 minutes**

After Adamson, Loeffelholz and Klausner. *Arch Pathol Lab Med.* 144: 1344-1351, 2020

POC Testing Goals



Test

Test first, for a PCR result while the patient is present



Talk

Educate patients during the visit (show them their result!)



Treat

Prescribe with confidence, knowing the result before treatment (*no presumptive Tx!*)

Why is it better?

- Accurate, accessible PCR
- Easy to use, and interpret
- Scalable (not limited by an instrument)
- Enables appropriate and actionable healthcare decisions at the point of care - for treatment and counselling *while with the patient*



Clinical Performance

	PPA	NPA
CT	97.4%	97.8%
NG	97.8%	99.1%

	Sensitivity	Specificity
TV	99.3%	96.7%

Table 3. Clinical Performance of the Visby Test for CT vs. Composite Comparator Results, by Symptom Status

Symptom Status	N	TP	FP	TN	FN	Prevalence %	PPA (95 CI)	NPA (95 CI)
Symptomatic	918	95	26	795	2	10.6%	97.9% (92.8%-99.4%)	96.8% (95.4%-97.8%)
Asymptomatic	856	54	10	790	2	6.5%	96.4% (87.9%-99.0%)	98.8% (97.7%-99.3%)
Overall	1774	149	36	1585	4	8.6%	97.4% (93.5%-99.0%)	97.8% (96.9%-98.4%)

PPA=Positive Percent agreement with CCR; NPA=Negative Percent Agreement with CCR;
TP=true positive; FP=false positive; TN=true negative; FN=false negative

Table 4. Clinical Performance of the Visby Test for NG vs. Composite Comparator Results, by Symptom Status

Symptom Status	N	TP	FP	TN	FN	Prevalence %	PPA (95 CI)	NPA (95 CI)
Symptomatic	929	25	8	896	0	2.7%	100.0% (86.7%-100.0%)	99.1% (98.3%-99.6%)
Asymptomatic	857	19	8	829	1	2.3%	95.0% (76.4%-99.1%)	99.0% (98.1%-99.5%)
Overall	1786	44	16	1725	1	2.5%	97.8% (88.4%-99.6%)	99.1% (98.5%-99.4%)

PPA=Positive Percent agreement with CCR; NPA=Negative Percent Agreement with CCR;
TP=true positive; FP=false positive; TN=true negative; FN=false negative

Table 5. Clinical Performance of the Visby Test for TV vs. Patient Infected Status, by Symptom Status

Symptom Status	N	TP	FP	TN	FN	Prevalence %	Sensitivity % (95 CI)	Specificity % (95 CI)
Symptomatic	916	83	35	797	1	9.2%	98.8% (93.6%-99.8%)	95.8% (94.2%-97.0%)
Asymptomatic	849	53	18	778	0	6.2%	100.0% (93.2%-100.0%)	97.7% (96.5%-98.6%)
Overall	1765	136	53	1575	1	7.8%	99.3% (96.0%-99.9%)	96.7% (95.8%-97.5%)

TP=true positive; FP=false positive; TN=true negative; FN=false negative

Easy to Use

Step 1: Sample



Input sample

Step 2: Run Test



Close button 1



Press buttons 1, 2, 3

Step 3: Plug in



Results in < 30 minutes
(positive for Gonorrhoeae)



Negative Result

& easy to interpret the results

POC testing enables result-driven, effective treatment during a single clinic visit

Improve patient care

- Improved clinician-patient engagement
- Reduced probability of infection progression into the fallopian tubes
- A better patient experience
- Advancements in Trichomonas testing

Enhanced practice

- Bring the lab to you
- Simplified clinic workflow
- Easy integration
- Informed treatment every time
- Increased clinician satisfaction

Impact the community

- Impact STI epidemic
- Minimize antibiotic resistance
- Prompt treatment of sexual partner(s)
- Reach unserved populations
- Educate and de-stigmatize

CDC Position of POC Testing for Chlamydia STI Treatment Guidelines 2021

POC tests for *C. trachomatis* among asymptomatic persons can expedite treatment of infected persons and their sex partners. Among symptomatic patients, POC tests for *C. trachomatis* can optimize treatment by limiting unnecessary presumptive treatment at the time of clinical decision-making and improve antimicrobial stewardship. Thus, using a POC test will likely be a cost-effective diagnostic strategy for *C. trachomatis* infection (807). Newer NAAT-based POC tests have promising performance and are becoming commercially available (807–809).

Poll Question #4

Are you currently using POC for STIs such as CT, NG, TV?

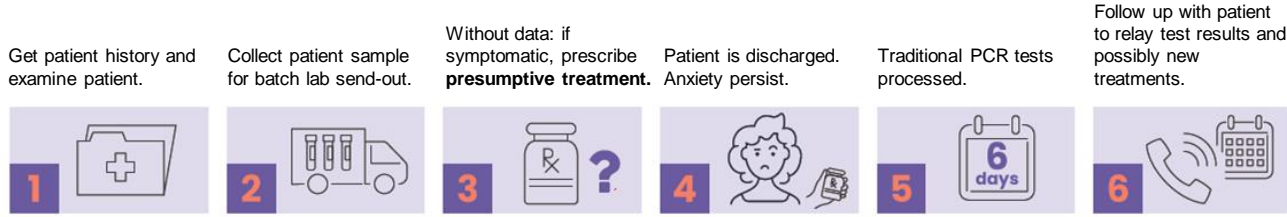
Yes

No

Not sure

STI testing

Traditional send out vs. Point of care



Traditional PCR

~50% of patients are lost to follow-up

Time: ~6 days
Touchpoints: 4

Traditional PCR STI testing
vs.
POC PCR <30 min.



Test, talk, treat in a single visit

Time: Under one hour
Touchpoints: 1

0% patients lost to follow-up.

If patient input triggers concern, then prescribe a provided Vaginal Self Collection Kit and send patient to private room/restroom.



Run POC PCR test immediately

Get patient history and examine patient

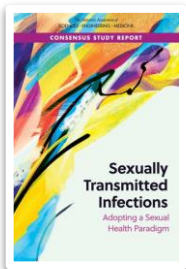
Provide POC PCR test results, patient education and provide data-driven patient management in same visit. Partner treatment can be expedited.

ARTICLES | VOLUME 21, ISSUE 5, P668-676, MAY 01, 2021

Performance of a single-use, rapid, point-of-care PCR device for the detection of *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, and *Trichomonas vaginalis*: a cross-sectional study

Sheldon R Morris, MD   Claire C Bristow, PhD · Michael R Wierzbicki, PhD · Mark Sarno, eJD · Lenore Asbel, MD · Audrey French, MD · et al. [Show all authors](#)

Published: November 23, 2020 · DOI: [https://doi.org/10.1016/S1473-3099\(20\)30734-9](https://doi.org/10.1016/S1473-3099(20)30734-9)  Check for updates



*The National
Academies of*

SCIENCES
ENGINEERING
MEDICINE

THE LANCET

“The device is potentially the new gold standard for point-of-care tests for infectious diseases such as sexually transmitted infections (STIs) and influenza and coronavirus infections, in which rapid turnaround is key.” [read more](#)

Conclusions

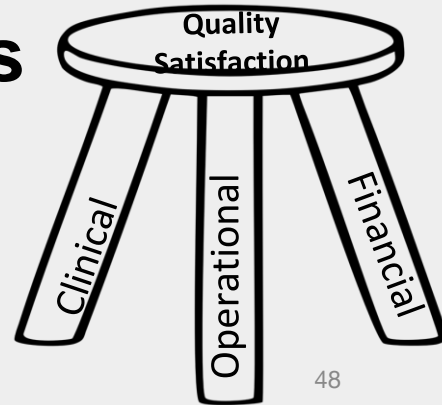
Clinical adoption of the Visby STI Panel into primary care clinics and doctors' offices could reduce overtreatment and undertreatment of STIs. If integrated efficiently into the clinical workflow, the test would have minimal impact on staff time and visit duration for patients.

“The development and implementation of accessible, effective, and affordable POC tests promise to enhance rapid STI diagnosis and treatment.”

- NASEM, Chapter 12, p. 350

4

Evaluate how POC STI testing can provide clinical, operational, and financial benefits to your practice while increasing both the quality of care and satisfaction of your patients



Goals



Additional Goals: Decrease Provider Burnout



Advantages for our office: POC PCR Testing

CLINICAL advantages

- Accurately and promptly treating the right infection with the right treatment
- Patient has reduced anxiety waiting for results
- Reduced liability by decreasing probability of untreated STI infection
- Reduced probability of onward transmission
- Facilitates patient education by providing an accurate diagnosis before leaving the clinic
- Confidently treat or refer partners
- Patient satisfaction increased with a value added service

OPERATIONAL advantages

- Streamlined clinical workflow.
- Portable device can be deployed around the office
- Visual easy to read result that can be shown to the patient, increasing confidence and adherence to treatment
- Ease of use by all staff
- Decreased time documenting in the EMR
- Decreased time spent by staff contacting the patient and pharmacy preferences
- Decreased in-basket results (happy doctors!)

Economic advantages

- (Save) Time = Money
- Patients value immediate results and this drives business
- No more follow up calls :
Follow up on patient results with traditional labs *is uncompensated*
- Free up time to see more patients
- Happy staff



Implementing POC Testing in Your Office

1

Patient calls for STI concerns, appointment scheduled.

- Instructed to arrive 30 minutes prior to appointment to collect specimen

2

Patient checks-in & is given a collection kit with instructions and ask her to leave kit in silver lab door in patient restroom. She then returns to the front desk to check in.

3

MA is informed of patient arrival, retrieves and starts the test

4

- Places order in computer (PR 87491, PR 87591 and PR 87661)
- Rooms the patient and updates EMR, pharmacy

Physician/NP/PA sees patient with result available, discussed, treats

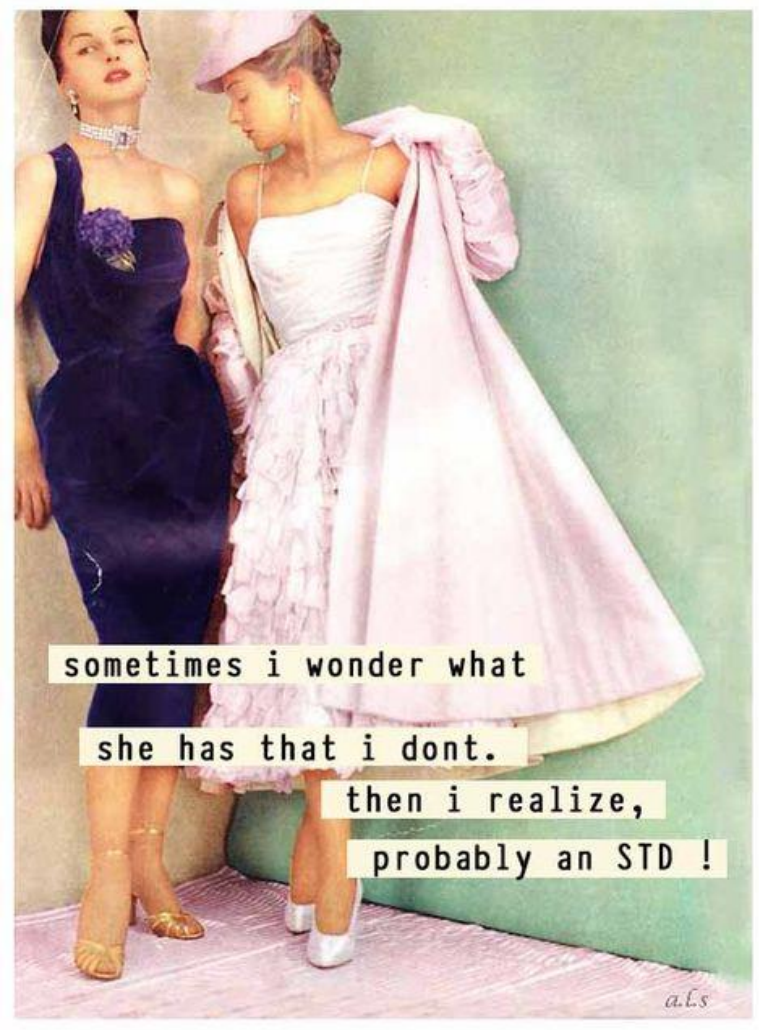
Why I like PCR at my POC

1. True PCR results in under 30 minutes
2. Portable, deployable, and scalable
3. Greater than 97% accuracy
4. No instrument, no maintenance
5. No capital investment, no service contracts
6. Decreased In Basket time in the EMR
7. Patients value immediate accurate results
8. Providers value immediate accurate results

Summary

Revolutionizing STI Testing for You and Your Patients

1. Review the current STI epidemic and impact on patient health
2. Examine how innovative POC testing can increase efficiency and improved patient care
3. Assess how testing accuracy, deployability, and speed can improve your workflow
4. Evaluate how POC STI testing can provide clinical, operational, and financial benefits to your practice while increasing both the quality of care and satisfaction of your patients



sometimes i wonder what

she has that i dont.

then i realize,

probably an STD !

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ASSOCIATES IN WOMEN'S HEALTH CARE
OBSTETRICS & GYNECOLOGY

Wednesday June 29, 2022