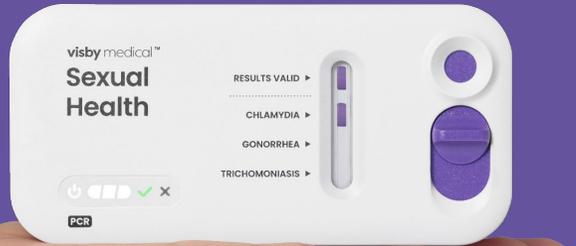


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Advancing STI Diagnosis in Urgent Care: Rapid PCR Point-of-Care Testing

Gary Schoolnik, M.D.

Chief Medical Officer (Visby Medical)

Professor of Medicine (Stanford Medical School)

Attending Physician (Infectious Diseases, Internal Medicine)

Stanford University Hospital

Disclosures

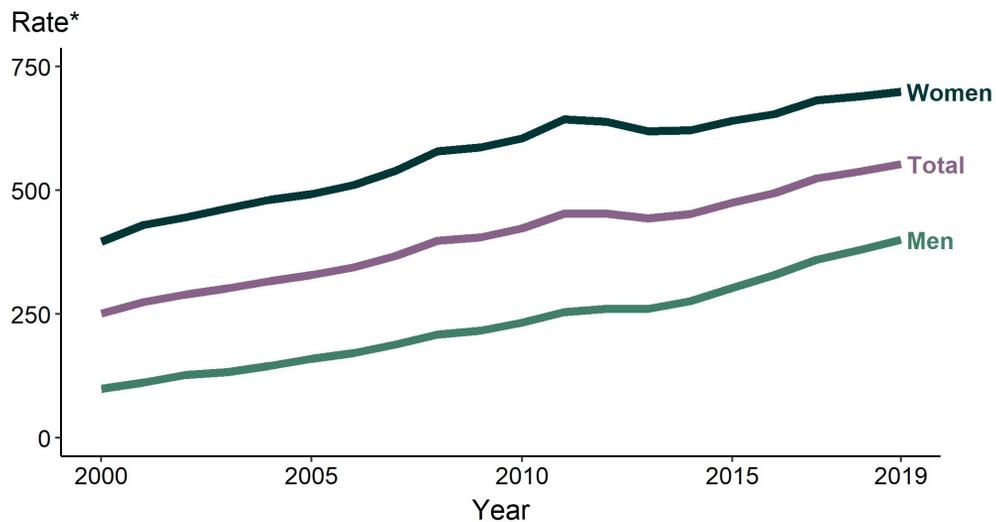
Chief Medical Officer of Visby Medical.

Learning Objectives

- Review the rising rates of Sexually Transmitted Diseases (STD) in the United States and globally
- Review today's STI testing methods
- Discuss the challenges and implications of today's testing methods
- Examine the clinical, operational and economic benefits of STD Point-Of-Care tests for urgent care

Chlamydia is the most common notifiable condition in the US

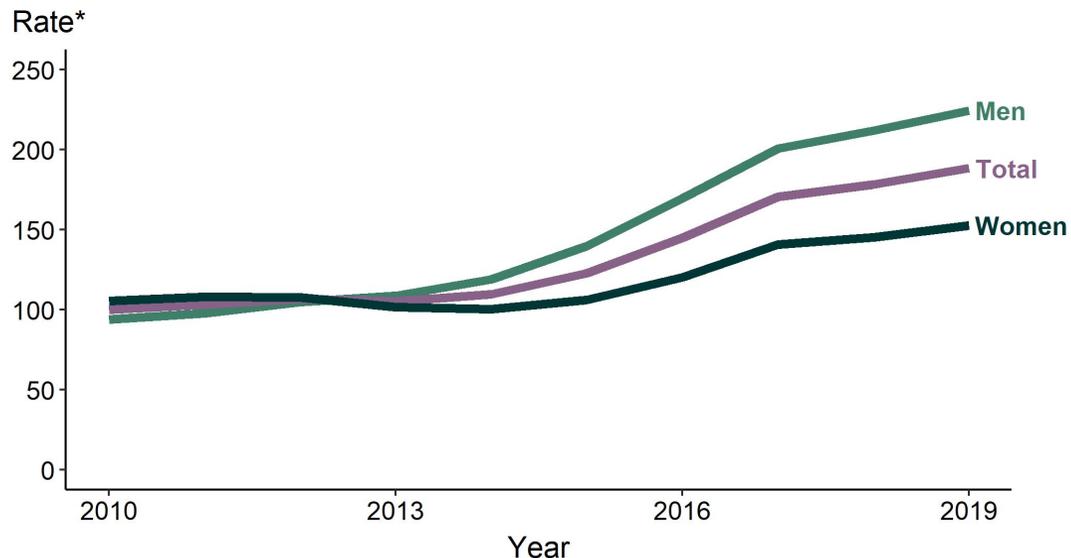
Chlamydia – Rates of reported cases by sex [2000-2019]



- During 2018–2019, rates of reported chlamydia increased among both males and females, and among Hispanic ethnicity groups
- Among females aged 15–24 years, reported cases of chlamydia increased by 10.0% from 2015
- In women, untreated chlamydia can spread to and damage uterus or fallopian tubes and cause PID
 - Symptomatic PID occurs in 10-15% of women with untreated chlamydia
 - Damage can lead to chronic pelvic pain, tubal factor infertility, and ectopic pregnancy

Gonorrhea is the 2nd most common notifiable condition in the US

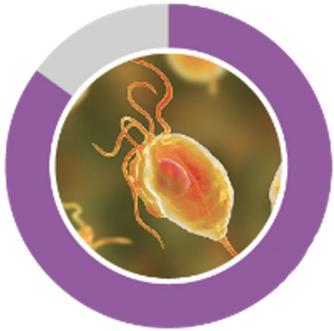
Gonorrhea – Rates of reported cases by sex [2010-2019]



- During 2018–2019, the overall rate of reported gonorrhea increased 5.7%
- Rates among women increased 5.1% during 2018–2019 and 43.6% during 2015–2019
- Untreated gonorrhea can cause serious and permanent health problems – In women this can result in PID, complications include ectopic pregnancy, infertility, chronic abdominal pain
- Untreated gonorrhea increases the risk of HIV transmission

Trichomoniasis – most common curable STD

Trichomoniasis



70-85% of women are asymptomatic

2-3x

Increased risk of contracting HIV⁴

- CDC estimates that there were 2.6 million trichomoniasis infections in 2018
- The epidemiology of trichomoniasis comes from population-based and clinic-based surveillance studies
 - The U.S. population-based prevalence is 2.1% among females with the highest rates among Black females (9.6%)
- Infection is more common in women – 70-85% of women are asymptomatic
- *T. vaginalis* causes reproductive morbidity – 1.4x greater likelihood of pre-term birth, premature rupture of membranes, and infants who are small for gestational age
- Trichomoniasis can increase the risk of getting or spreading HIV

Patient Case Presentation

STD Differential Diagnosis - 3 scenarios

Case Presentation



NG: *Neisseria gonorrhoeae*
CT: *Chlamydia trachomatis*

Ms. Smith presents to an Urgent Care Clinic

Chief complaint: Increase in her vaginal discharge of 10 days duration and, most prominently, concern about having a new sexual partner in a relationship that began two weeks before

Past medical history:

- Positive HPV test one year ago
- 1 episode Bacterial Vaginosis eight months ago
- 3 episodes UTI during the past three years
- On her annual screening tests (last administered 11 months ago), tested negative for NG, CT, syphilis and HIV

Clinic course:

The triage nurse at the clinic, focusing on Ms. Smith's concern about a new sexual partner, initiated:

- Patient collected vaginal swab
- **Swab sent to central lab**
- Complete medical history and pelvic exam performed

Vaginal swab sent to central lab

Sample-To-Result 3 days

Sample-To-Treatment 7 days



SCENARIO A: Under/Delayed-treatment of an STD



Treatment Decision

Clinician elected not to treat due to absence of compelling symptoms or physical exam signs

3 days later: Central lab reported detection of the gonococcus

This is an example of Under-Treatment / Delayed-Treatment.

Consequences of STD Under/Delayed-Treatment

- Onward Transmission of an STD pathogen: epidemic propagation
- Delayed treatment resulting in complications of an untreated progressive infection
 - Pelvic inflammatory disease (NG and CT)
 - Infertility
 - Ectopic pregnancy
 - Chronic pelvic pain
- Delayed expedited partner treatment
- Reduced opportunity for result-enabled, face-to-face clinician—patient dialogue
- Inefficient clinic workflow: staff needs to contact patient by phone (often problematic) and schedule return appointment for treatment.
- Reduced patient-satisfaction
- Reduced clinician-satisfaction

SCENARIO B: Over-treatment of an STD



Treatment Decision

Clinician elects to treat before lab results are provided for the vaginitis syndrome because patient complained of a slight change in her normal vaginal discharge.

Prescription provided:

Metronidazole P.O. for 7 days for treatment of possible Bacterial Vaginosis and Trichomoniasis

3 days later: Central lab reported negative for Gonococcus, Chlamydia, Bacterial Vaginosis and Trichomoniasis

This is an example of over-treatment.

Consequences of Over-Treatment of an STD

- Unnecessary exposure of the patient to a medication leading to possible adverse effects
- Selection of antibiotic-resistant microorganisms thus contributing to the further emergence of antibiotic-resistant infections. Reduced opportunity to practice antibiotic stewardship.
- Ineffective or misleading clinician—patient dialogue because discussion will be biased by an incorrect diagnosis
- Inefficient clinic workflow: staff needs to contact patient by phone (often problematic) and schedule return appointment for the correct treatment.
- Reduced patient-satisfaction
- Reduced clinician-satisfaction

Rates of Under- and Over-treatment for Chlamydia (CT) and / Gonococcus (NG)

“... for patients with gonorrhea or chlamydia, women are at a much higher risk of not receiving proper treatment compared to men.” Dretler et al 2020

“Pregnant women may not be receiving appropriate treatment when they present to the ED with chlamydia or gonorrhea.” Bergquist et al, 2020

Empiric treatment;
CT/NG negative lab results

No empiric treatment;
CT/NG positive lab results



Authors	Study Title	% pts OVER-treated	% pts UNDER-treated	Setting
Anaene et al, International Journal of Infectious Diseases, 53 (2016) 34-38	“Factors associated with the over-treatment and under-treatment of gonorrhea and chlamydia in adolescents presenting to a public hospital emergency department”	21%	43%	Emergency department in large safety-net public hospital in Chicago, IL
Holley, et al, Am J Emerg Med, 2015 Sep 33(9):1265-8	“Overtreatment of gonorrhea and chlamydial infections in 2 inner-city emergency departments”	86%	4%	2 inner city emergency departments
Dawkins et al, <u>In Press</u> Sexually Transmitted Diseases (Dec 2021)	“Clinical Integration of a Highly Accurate PCR Point-of-care Test Can Inform Immediate Treatment Decisions for Chlamydia, Gonorrhea and Trichomonas”	87%	12%	Urgent care center in Baton Rouge, LA
Gaydos et al, Ann Emerg Med, 2019 Jul: 74(1):36-44	“Use of a Rapid Diagnostic for Chlamydia trachomatis and Neisseria gonorrhoeae for Women in the Emergency Department Can Improve Clinical Management: Report of a Randomized Clinical Trial”	46%	43%	Urban academic Emergency Department
Bergquist et al, International Journal of STD and AIDS, 2020 Vol 31(2) 166-173	“Undertreatment of chlamydia and gonorrhea among <u>pregnant</u> women in the emergency department”	15.6%	80%	Emergency Department, St. Louis, MO
Dretler et al, Am J Emerg Med 38 (2020) 566–570	“The influence of race and sex in gonorrhea and chlamydia treatment in the emergency department”	67% women	85% women	Emergency department, St. Louis, MO



SCENARIO C: Patient Lost-to-Care (patient does not follow-up)

Treatment Decision:

Clinician elected not to treat due to absence of compelling symptoms or physical exam signs.

3 days later: Central lab reported detection of NG

Despite multiple calls by clinic staff and by a county public health worker, the patient could not be contacted.

This is an example of a patient who is Lost-to-Care.



Consequences of a STD-positive patient who is Lost-to-Care

- Onward Transmission of an STD pathogen: epidemic propagation
- Delayed treatment resulting in complications of an untreated progressive infection
 - Pelvic inflammatory disease (NG and CT)
 - Infertility
 - Ectopic pregnancy
 - Chronic pelvic pain
- No opportunity to proceed with expedited partner treatment
- No opportunity for a result-enabled, face-to-face clinician—patient dialogue
- Inefficient clinic workflow: fruitless attempts by clinic staff to contact patient by phone to schedule a return appointment for treatment.
- Health care provider discontent, stress and apprehension

Patients are lost to follow-up across health-care settings

Emergency Departments

- **40%** of adolescent females presenting to ED in Grand Rapids, MI **were lost to follow up**¹
 - Retrospective study of females presenting with symptoms to the ED in 4 academic medical centers over 36-month period
- **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/Family Planning Clinics

- **26%** of patients tested in STD and family planning clinics in VA **were lost to follow up**²
 - Retrospective analysis of data from clinics in VA in 2016
- **18%** of patients presenting to an STD clinic in Washington DC **were lost to follow up**³.
 - 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

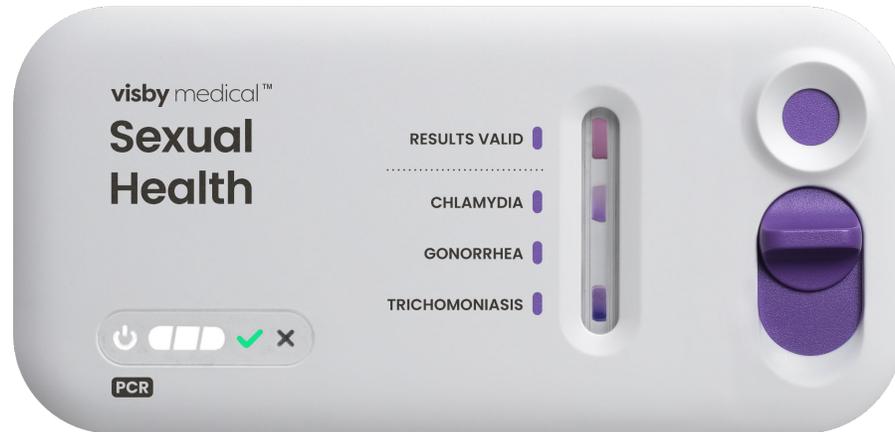
**Rapid, Accurate STD Point-of-Care
Diagnostics can reduce:**

**Over-Treatment Rates
Under-Treatment Rates
Patients Lost-to-Follow up**

Seconds of hands on time; Results in under 30 min



Easy to interpret: Informed treatment decisions at the point of care

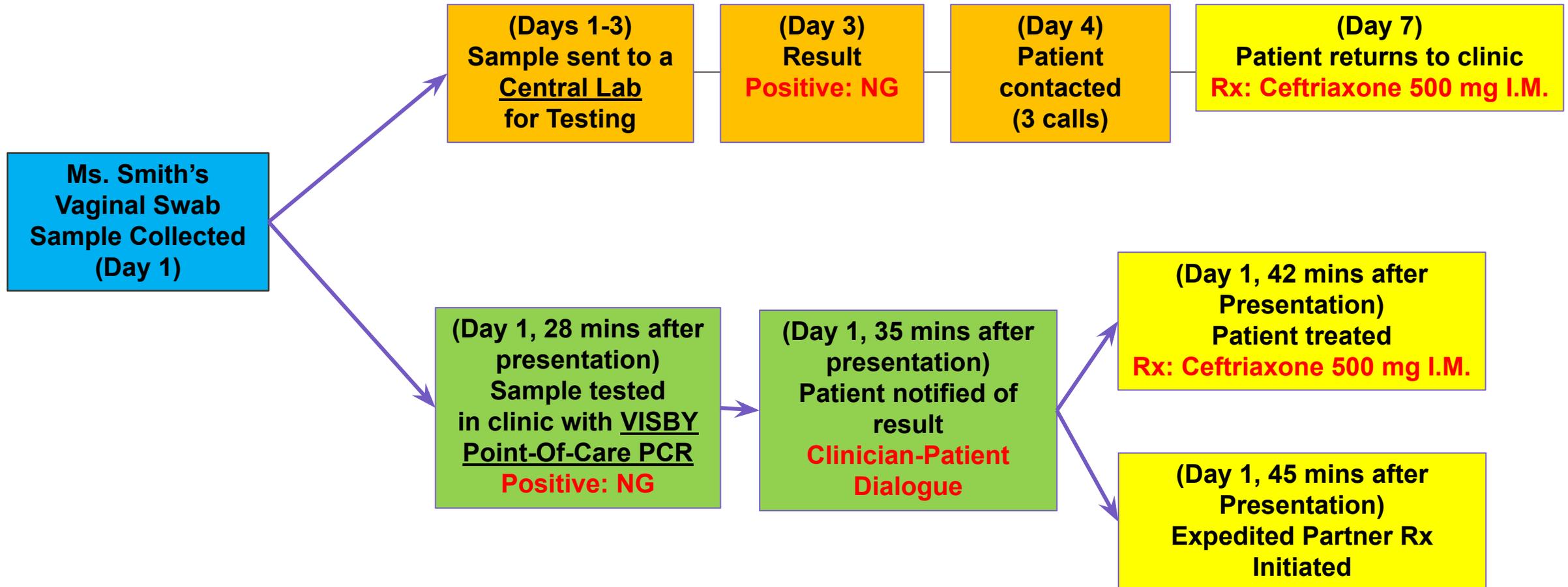


Positive result CT, TV

Test, Talk and Treat - in a single visit

Central Lab vs Visby POC PCR

	Central Lab	Visby POC PCR
Sample to result	3 days	28 minutes
Sample to treatment	7 days	42 minutes



Advantages of STD point-of-care tests

CLINICAL

- Enables result-driven effective treatment within the span of a single clinic visit by eliminating send-outs to a lab for CT/NG/TV
- Reduces probability of untreated STI infection progression
- Reduces probability of onward transmission
- Facilitates patient education by providing an accurate diagnosis before leaving the clinic
- Enables the prompt treatment of the diagnosed patient's sexual partners(s) via the CDC sanctioned EPT program (Expedited Partner Treatment)

OPERATIONAL

Expediting the test and treatment paradigm improves clinic workflow

- Reduces patient call backs
- Increases efficiency of clinical staff, and likely positively impacts the clinic's cost-effectiveness
- Increases patient and physician satisfaction by providing the clinician with an accurate diagnosis during the initial visit

FINANCIAL

- No more follow up calls saves time = Money
- Free up the schedule to see other patients - Patient treated immediately without need for 2nd clinic visit
- Potential for improved patient encounter - increased E/M coding level
- Sexual partner(s) may be referred to the clinic for testing/treatment

Published in The Lancet:

A study on the Performance of the Visby Sexual Health Test

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PlumX Metrics

Summary

Background

Timely detection and treatment are important for the control of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis*. The objective of this study was to measure the performance of the [Visby Medical Sexual Health Test](#), a single-use, point-of-care PCR device.

Methods

Women aged 14 years and older who presented consecutively to ten clinical sites across seven US states were enrolled for a cross-sectional, single-visit study. Patients who consented to participate, and who had not used any exclusionary products in the genital area in the previous 48 h, provided self-collected vaginal swabs for testing with the investigational device. Untrained operators received the specimens and ran the device using the guide provided. Specimens had to be run within 2 h of collection to be considered valid. For comparison, patient-infected status was derived by testing clinician-collected vaginal specimens with the Hologic Aptima Combo 2 Assay and Aptima *Trichomonas vaginalis* Assay, as well as the BD ProbeTec CT/GC Q^x Amplified DNA Assay and BD ProbeTec *Trichomonas vaginalis* Q^x Assay. If the results of those assays did not match, the BD MAX CT/GC/TV was used as a tiebreaker. The primary outcomes were the sensitivity and specificity of the investigational device for the detection of *C trachomatis*, *N gonorrhoeae*, and *T vaginalis* compared with patient-infected status.

Findings

Between Feb 25, 2019, and Jan 6, 2020, 1585 participants aged between 14 years and 80 years (mean 34·8 [SD 14·2]) were enrolled. 1555 participants had tests run with the investigational device, of whom 1532 (98·5%) had a valid result on either the first or repeat test. Among the patients with evaluable results (including a determinate patient-infected status), the device had a sensitivity of 97·6% (95% CI 93·2–99·2) and specificity of 98·3% (97·5–98·9) for *C trachomatis* (n=1457), sensitivity of 97·4% (86·5–99·5) and specificity of 99·4% (98·9–99·7) for *N gonorrhoeae* (n=1468), and sensitivity of 99·2% (95·5–99·9) and specificity of 96·9%

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C trachomatis (n=1457),
sensitivity of 97·6% (95% CI 93·2–99·2)
specificity of 98·3% (97·5–98·9)

N gonorrhoeae (n=1468)
sensitivity of 97·4% (86·5–99·5)
specificity of 99·4% (98·9–99·7)

T vaginalis (n=1449)
sensitivity of 99·2% (95·5–99·9)
specificity of 96·9% (95·8–97·7)

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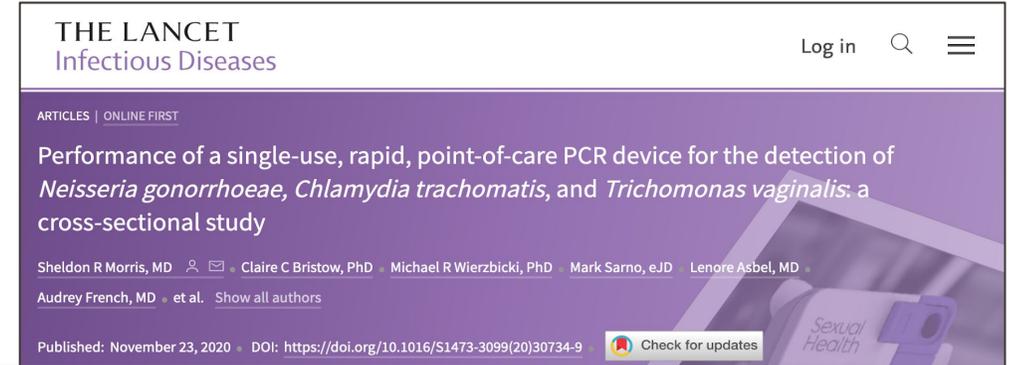
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C trachomatis
sensitivity
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THE LANCET

“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](#)

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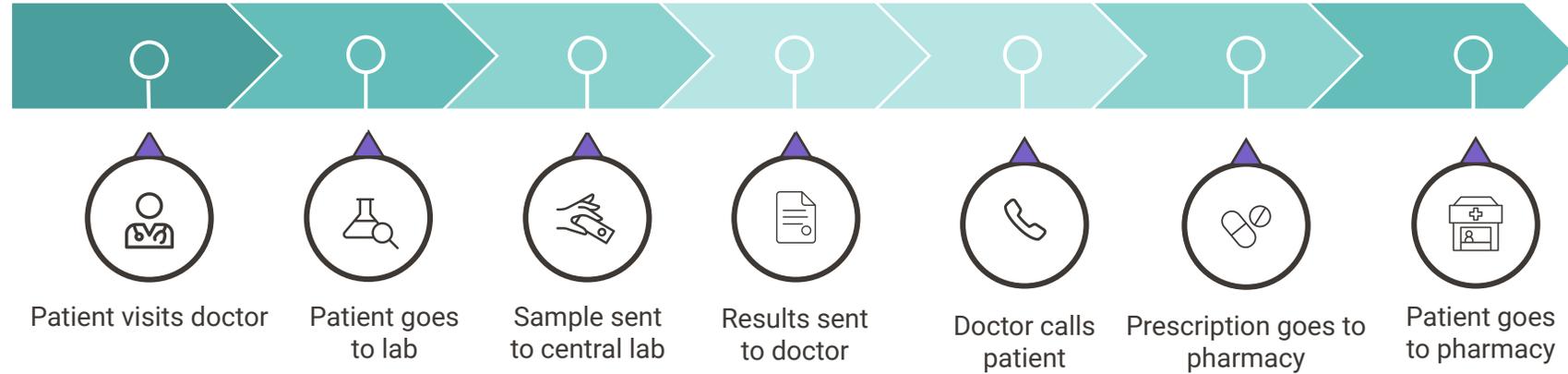


Changing standard of care in clinics



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1-14 days



<1 hour



Test, Talk and Treat - in a single visit

Data-driven result during the visit enables effective clinician-patient dialogue, called **The Teachable Moment**

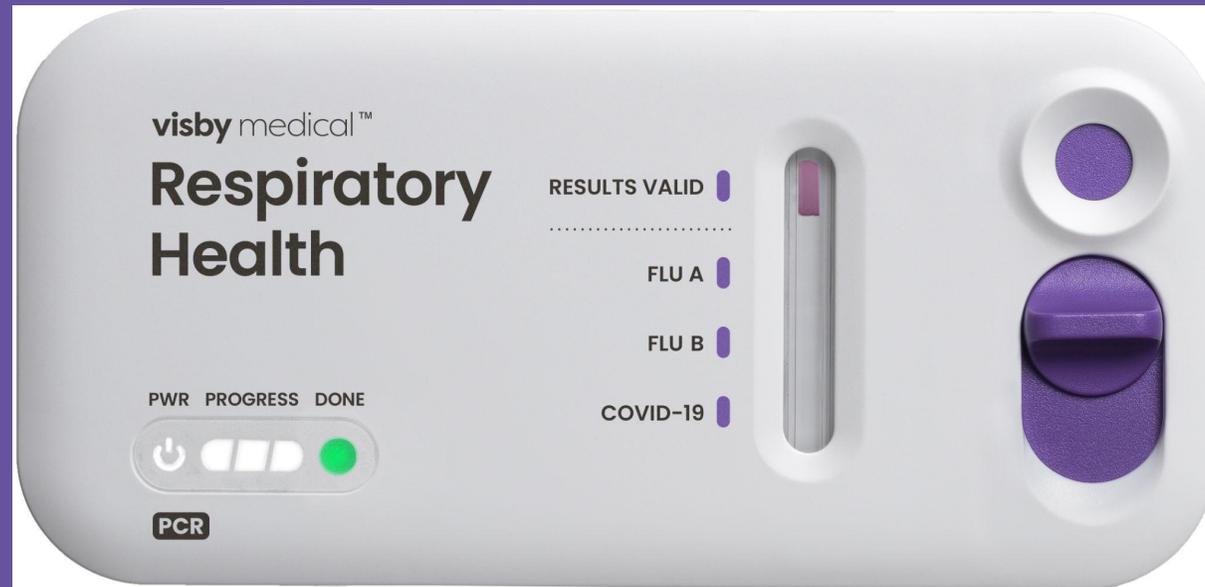
Includes

- ❑ Cause of the STI
- ❑ Treatment and the effectiveness of treatment
- ❑ Potential complications of the diagnosed STI
- ❑ The practice of safe sex to avoid future STIs
- ❑ Treatment to the patient's sexual partner(s)



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Also available now
Respiratory Health Test (Covid, FluA, FluB)



Key takeaways

- Rates of STD are at all time high in the U.S. and globally
- Sendouts for STD often lead to over/under-treatment and patients lost to care
- In urgent care setting, rapid, POC PCR STD test can
 - Help mitigate challenges with sendouts
 - Improve clinic workflow
 - Improve patient experience