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## Performance of the Atlas rapid test for *Chlamydia trachomatis* and women's attitudes toward point-of-care testing

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### Abstract

**Purpose**—This study compared performance of Atlas io<sup>®</sup> diagnostic platform, a point-of-care (POC) PCR assay for *Chlamydia trachomatis* (CT), to Aptima Combo 2<sup>™</sup>, a standard of care laboratory-based nucleic acid amplification assay (NAAT), and evaluated patient attitudes toward POC testing.

**Methods**—Women 14 years undergoing CT screening/testing were recruited from an urban adolescent primary care practice (Teen Health Center, THC) and a sexually transmitted disease (STD) clinic. Participants provided self-obtained vaginal swabs for testing with the Atlas io<sup>®</sup> platform and Aptima Combo 2<sup>™</sup> testing and completed a questionnaire assessing attitudes toward POC testing.

**Results**—Of 296 women recruited, 284 (192 from the STD clinic, 92 from THC) had Aptima Combo 2<sup>™</sup> and Atlas io<sup>®</sup> results available; 273 completed the questionnaire. Average age was 27.4 years (SD 10.8). Sensitivity and specificity of the Atlas io<sup>®</sup> test were 83.9% (26/31 specimens; 95% CI, 70.9–96.8%) and 98.8% (250/253 specimens; 95% CI, 97.5–100%), respectively. When specimens with discrepant results were included in analyses, adjudicated sensitivity and specificity were 92.9% (26/28 specimens; 95% CI, 83.3 to 100%) and 98.8% (253/256 specimens; 95% CI, 97.5 to 100%), respectively.

A majority (70%) of women preferred to collect vaginal self-swab if a POC test were available. Most (61%) were willing to wait up to 20 minutes and 26% were willing to wait up to 40 minutes for results, if they could be treated before leaving clinic.

**Conclusion**—A POC PCR test detecting CT had high sensitivity and specificity when testing prospective, vaginal swab samples. Availability of CT results during patients' visits may decrease time to treatment.

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**Conflicts of interest:** Dr. Gaydos reports possible conflicts of interest, since her institution is receiving funds for her participation in an ongoing clinical trial of a test cartridge for the detection of both chlamydia and gonorrhea. The remaining authors report no conflicts of interest.

## Keywords

Chlamydia; rapid test; point of care test; acceptability; sexually transmitted infection

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## Introduction

Untreated *Chlamydia trachomatis* (CT) infections have serious sequelae.<sup>1</sup> Early diagnosis and treatment are critical to reduce sequelae. Point-of-care testing for CT has the potential to improve patient outcomes by providing test results to clinicians during the patient's visit, potentially decreasing the time to treatment and increasing the rate of appropriate antibiotic use.<sup>2,3</sup> The Atlas io<sup>®</sup> diagnostic platform (Atlas Genetics, Bath, United Kingdom) is used to detect CT using vaginal samples in Europe, having obtained a CE mark. It is fully automated and does not require sample preparation. The cartridge is processed and analyzed using a reader instrument that provides fluidic and temperature control and electronics and software for user interface. The cartridge contains all reagents needed to test a sample including CT DNA extraction, PCR amplification, and detection using electrochemically-labeled DNA probes. Early studies of the Atlas io for CT demonstrated low limits of detection with very low background interference. Testing of stored samples demonstrated a sensitivity and specificity of 98.1% and 98.0%.<sup>4</sup>

In this study conducted at two clinical sites, we aimed to (1) assess the performance of this rapid, point-of-care PCR assay for CT compared to a laboratory-based nucleic acid amplification assay (NAAT) for CT in clinic populations with high prevalence of CT and (2) evaluate women's attitudes towards sample collection, testing, and partner notification when POC CT testing is available.

## Materials and Methods

### Design

This prospective study was conducted in two clinic locations: a sexually transmitted disease (STD) clinic in Baltimore, Maryland and a Teen Health Center (THC) providing primary care to adolescents, located in an academic medical center in Cincinnati, Ohio. In 2016, we recruited consecutive female patients who were getting CT testing as part of their health care visit and were 14 years or older, sexually active with at least one male partner within the last 3 months, and had not used antibiotics or any vaginal medications within the previous two weeks. Menstruating women were eligible to enroll. The study was approved by the two sites' institutional review boards. Women provided written informed consent, parental permission was waived for minors.

### Participant characteristics and attitudes

Women completed a structured interview to assess sociodemographic characteristics (age, race), risk behaviors (number of sex partners in the past 3 months, condom use at last sex), history of prior CT infection, and clinical symptoms associated with sexually transmitted infections or vaginitis (abnormal discharge, vaginal itching, burning during urination, abdominal pain). Women completed a questionnaire to assess ease of self-sample collection

and, if a point-of-care test was available, attitudes towards sample collection, time willing to wait for results, preferred location to rescreen after positive CT results, cost willing to pay for POC testing, willingness to tell partner about positive results and preferred method to contact partner. Structured interview items have been previously used in other of our studies to examine attitudes toward POC devices.<sup>5,6</sup> Questionnaire items were slightly modified from previously validated items evaluating sexually transmitted infection (STI) testing.<sup>7,8</sup>

### CT testing

All swabs were self-collected at the same visit. During the health care visit in which women collected a vaginal swab for clinical CT testing, participants self-collected study samples, including a flocked nylon Atlas swab and a Dacron swab. Women were provided written and verbal instructions to insert each swab into their vagina and rotate for 10 seconds. After collection, the Atlas io swab was placed in Atlas io liquid transport media.

Samples used for clinical testing were collected, stored, and transported to each site's clinical laboratory according to clinical procedures. Testing of samples collected for clinical testing was conducted according to laboratory procedures using Aptima Combo 2™ (Hologic/GenProbe, San Diego, CA). Results of clinical testing were obtained by study staff from review of participants' electronic medical records.

Atlas io<sup>(R)</sup> samples were tested using Atlas io reader instruments located in the THC clinic and in the laboratory near the STD clinic. THC samples tested within 4 hours of collection. STD clinic samples were refrigerated until tested within 24 hours (72 hours for samples collected Friday). Operators were laboratorian and non-laboratorian research personnel trained by Atlas Genetics representatives. Liquid from the sample collection tube was pipetted using a disposable pipette, which delivered a calibrated amount into the disposable io<sup>®</sup> cartridge. Cartridges were stored at 2–8° C up to four hours before use. Participant information was entered into the reader using the touch screen on the reader. The cartridge was inserted into the reader. Within 30 minutes of cartridge insertion, result readout was displayed on the reader's screen as words (positive, negative, or indeterminate). Results were saved into a downloadable electronic file stored in the reader.

When the Atlas io and Aptima Combo 2™ results from the STD clinic were discordant, the extra specimen collected during the study visit was tested with Cepheid Xpert CT/NG (Sunnyvale, CA). Discrepant results from THC were not retested because specimens were not available at the time of retesting.

### Data analysis

Performance characteristics (sensitivity, specificity and positive and negative predictive values) were calculated by standard methods and are presented with the 95% confidence intervals (CI). The one specimen with indeterminate results by the Atlas io device was conservatively estimated to be negative. Descriptive statistics were generated for interview and questionnaire items and categorized based on response distribution. Analyses were completed using SAS 9.4.

## Results

A total of 296 women were recruited, 284 (192 from the STD clinic, 92 from THC) had both Aptima Combo 2™ and Atlas io testing results available. Characteristics of the participants are shown in Table 1. The average age was 27.4 years (SD 10.8). A majority (92%) self-reported their race as Black or African American; 55% reported a lifetime history of a previous CT infection; nearly three quarters reported no new sex partners in the past three months. A total of 164 (58%) women reported symptoms associated with STI or vaginitis.

### Test Performance

As shown in Table 2, the sensitivity and specificity of the Atlas io test compared with the Aptima Combo 2™ test were 83.9% (26/31 specimens; 95% CI, 70.9 to 96.8%) and 98.8% (250/253 specimens; 95% CI, 97.5 to 100%), respectively. The positive and negative predictive values were 89.7% (26/29 specimens; 95% CI 78.6 to 100%) and 98.0% (250/255 specimens; 95% CI, 96.3 to 99.7%), respectively.

Five of 8 specimens with discrepant results between Atlas io test and Aptima Combo 2™ test were retested (Table 2). One Atlas positive/NAAT negative sample retested negative by both Cepheid® Xpert CT/NG and Aptima Combo2. Two Atlas negative/NAAT positive samples retested negative by Cepheid Xpert CT/NG, one Atlas negative/NAAT positive samples retested negative by Aptima Combo2; and one Atlas negative/NAAT positive retested positive by Cepheid Xpert CT/NG. The adjudicated sensitivity and specificity of the Atlas test were 92.9% (26/28 specimens; 95% CI, 83.3 to 100%) and 98.8% (253/256 specimens; 95% CI, 97.5 to 100%), respectively. The positive and negative predictive values were 89.7% (26/29 specimens; 95% CI 78.6 to 100%) and 99.2% (253/255 specimens; 95% CI, 98.1 to 100%), respectively.

### Women's Attitudes Toward POC Testing for CT

A total of 273 (96%) women completed the questionnaire to assess attitudes toward POC testing. As shown in Table 3, a majority of the 273 women (70%) preferred vaginal self-sample specimen collection if a POC test were available and a majority of women (86%) reported that collecting the vaginal self-sample during the study was easy or very easy. Most women (61%) were willing to wait up to 20 minutes for results if they could be treated before leaving clinic. A quarter of women (26%) were willing to wait up to 40 minutes for results if they could be treated before leaving clinic. Most women were willing to pay \$20 or less for CT testing if they could mail a specimen collected at home to a laboratory for testing or get a CT test done at a pharmacy. Women (96%) would tell a partner about a positive CT test result from a POC test and a majority (97%) prefer to notify their partner in person.

If rescreening after a positive result was necessary, 45% of women preferred to collect the specimen for rescreening at home. We examined these results by participant characteristics (Table 4) and found that among women 25 years old, a higher proportion (68%) preferred to rescreen at home compared to an STD clinic or private doctor ( $p < 0.05$ ). Among women 14–18 years old, a higher proportion (87.5%) preferred to rescreen at an STD clinic or

private doctor ( $p < 0.05$ ). Among women with no STI symptoms, a higher proportion (66%) preferred to rescreen at an STD clinic or private doctor ( $p < 0.05$ ).

## Discussion

Among 284 women seeking care at an STD clinic and a Teen Health Center who were tested for CT as part of their medical care, the sensitivity and specificity of a novel, rapid, easy to use, diagnostic test to detect CT had a sensitivity of 84% and specificity of 99%. After discordant testing and sensitivity analysis, sensitivity was 92.9 and specificity was 98.8. Women reported vaginal self-sampling was acceptable and easy and reported a willingness to wait for results if they could receive treatment for a positive infection.

Most current NAAT CT tests have a prolonged turnaround time leading to results reported hours or days after the patient has left the health care visit. These delays can impact clinical outcomes due to treatment delays or missed treatment when patients cannot be located.<sup>9</sup> Shorter assays, such as the Atlas io system, which requires 30 minutes, and the GeneXpert assay, which currently requires 90 minutes,<sup>10</sup> have the potential to be exceptions to this. Reporting STI test results to patients during the clinical encounter in which testing was initiated may decrease the amount of time spent by clinical staff for following up on STI testing results, assessing for sequelae that may have developed since the clinical encounter, arranging for the patient to get treatment, and discussing and arranging for partner treatment. An additional benefit of patients learning STI test results during the same visit in which testing was ordered is higher understanding among patients of a positive diagnosis.<sup>2</sup> Therefore, CT diagnostic tests that provide results quickly at the point of care have the potential to improve patient outcomes,<sup>11,12</sup> and improve antibiotic stewardship.<sup>3,13–15</sup>

Accurate test performance is critical for new STI POC tests, both in order to gain Food and Drug Administration clearance and because clinicians identify test performance as an important attribute for STI POC tests.<sup>16,17</sup> The sensitivity and specificity reported in package inserts for current laboratory-based NAATs for CT using self-collected vaginal specimens range from 96.1% to 98.7% and 95.6% to 99.2%, respectively.<sup>18–20</sup> Published evaluations of NAATs report sensitivities ranging from 96.1% to 98.7 and specificities ranging from 96.5% to 99.4%.<sup>21–23</sup> A recent report of a multisite study of the Atlas test reported a sensitivity of 96.1% (95%CI 86.5–99.5) and a specificity of 97.7 (95%CI 96.3–98.7).<sup>24</sup> In our population, the Atlas io test had similar performance. We could not evaluate test performance in symptomatic and asymptomatic patients due to the sample size. The sensitivity and specificity in this study compared Atlas to BD ProbeTec Qx on BD Viper (BD Diagnostics, Becton, Dickinson and Company, Franklin Lakes, NJ). The BD ProbeTec Qx Assays can be less sensitive than Aptima Combo 2™.

The diagnostic accuracy combined with the rapid turn-around time of the Atlas io test may lead to improved antibiotic stewardship and patient outcomes, but this remains to be studied. Because commonly available platforms for CT testing also include detection of gonococcal infections, future studies of the clinical impact of POC STI tests for CT should consider the impact of POC testing on both CT and gonococcal infections.

Understanding patient attitudes toward POC tests for CT is important to identify potential barriers and facilitators in the acceptance and uptake of new diagnostic tests. The low price point preferred by women in this study could be a barrier to adoption of POC tests by consumers, if and when POC tests become available over-the-counter. It may also be a barrier for adoption of STI POC tests within health care systems; cost of test has been identified as important to clinicians and others offering STI POC tests.<sup>25</sup> Patient's preference for vaginal swabs was similar to clinicians and health educators reported preferences during focus groups examining end-users preferences for STI POC tests.<sup>17</sup> Additionally, nearly two thirds of participants reported a willingness to wait 20 minutes and a quarter reported a willingness to wait 40 minutes for results, if they received treatment before leaving clinic. These findings are similar to the consensus of clinician and health educator focus group participants that indicated an acceptable turnaround time for STI POC test results was 20 minutes or less.<sup>17</sup> Tests that take longer than 60 minutes may be limited in their clinical impact without careful implementation into the clinical work flow, but this remains to be studied. Optimal strategies for implementing STI POC testing in clinical settings that maximize the benefits of rapidly available results have yet to be demonstrated.<sup>26,27</sup>

Collection of specimens for rescreening at home may improve rescreening rates. A preference for home collection among older women may reflect greater access to privacy at home among older women compared to younger women. A preference for collection in a medical setting among asymptomatic women with a positive test, might suggests a greater trust in specimen collection in the health care setting among women whose only indication of infection was a test result. However, this remains to be studied.

In this preliminary study in two clinical populations, the performance of the Atlas io test suggests it is adequate for adoption as a CT diagnostic test in clinical settings. The potential of this diagnostic test to impact patient outcomes warrants further study.

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The device manufacturer supplied all testing supplies and trainings on the operation of the device and the final manuscript was reviewed by the manufacturer.

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**Table 1**

## Characteristics of Participants

Characteristic	n (%)
Site	
STD Clinic, Baltimore	192 (68)
Teen Health Center, Cincinnati	92 (32)
Race, Black/African American	262 (92)
Age, years	
14–21	128 (45)
22	154 (54)
History of Chlamydia <sup>1</sup> , yes	156 (55)
Number of new partners in past 3 months	
0	210 (74)
1–2	70 (25)
3 or more	3 (1.1)
missing	1 (0.4)
Reported STI symptoms, yes <sup>2</sup>	164 (58)

Abbreviations. STD, sexually transmitted diseases; STI, sexually transmitted infection

<sup>1</sup>History of chlamydia assessed by participant's report

<sup>2</sup>Abnormal discharge, vaginal itching, burning with urination, abdominal pain

**Table 2**  
Performance Characteristics of Atlas io® CT Assay Compared to Laboratory-Based NAAT Testing (Aptima Combo 2™)

	Number	True Positive	False Positive	True Negative	False Negative	Prevalence, %	Sensitivity, % (CI)	Specificity, % (CI)	Positive Predictive Value, % (CI)	Negative Predictive Value, % (CI)
<b>Initial Results</b>	284	26	3	250	5	10.2	83.9 (70.9, 96.8)	98.8 (97.5, 100)	89.7 (78.6, 100)	98.0 (96.3, 99.7)
<b>After Discrepant Testing<sup>1</sup></b>	284	26	3	253	2	9.9	92.9 (83.3, 100)	98.8 (97.5, 100)	89.7 (78.6, 100)	99.2 (98.1, 100)

Abbreviations: NAAT, nucleic acid amplification test; CI, 95% confidence interval

<sup>1</sup> Five samples with discordant results were retested: one Atlas(+)/NAAT(-) sample retested (-), three Atlas (-)/NAAT(+) samples retested (-), one Atlas(-)/NAAT(+) sample retested (+). Three samples with discordant results were not retested due to availability of samples: two Atlas (+)/NAAT(-) and one Atlas(-)/NAAT(+)

**Table 3**

## Attitudes Towards Specimen Collection, Testing, and Partner Notification for Point of Care Testing for CT

	n (%)
Preferred specimen for CT testing, if POC test were available today	
Vaginal	199 (70.1)
Cervical	14 (4.9)
Urine	60 (21.1)
Missing	11 (3.9)
Ease of self-sample vaginal collection today	
Very easy, Easy	245 (86.3)
O.K., Hard	28 (9.9)
Missing	11 (3.9)
Time willing to wait for results, if treated before leaving clinic	
20 minutes	173 (60.9)
40 minutes	73 (25.7)
60 minutes	16 (5.6)
90 minutes	11 (3.9)
Missing	11 (3.9)
Preferred location to rescreen for positive CT	
Home specimen collection	127 (44.7)
STD clinic/private doctor	137 (48.2)
Missing	20 (7.0)
How much willing to pay, if you could buy test and mail specimen to a laboratory	
US\$10	153 (53.9)
US\$20	76 (26.8)
US\$30	20 (7.0)
US\$40	6 (2.1)
US\$50	18 (6.3)
Missing	11 (3.9)
Get a CT test done at a pharmacy	
US\$10	155 (54.6)
US\$20	72 (25.4)
US\$30	24 (8.5)
US\$40	9 (3.2)
US\$50	13 (4.6)
Missing	11 (3.9)
If a point of care test indicated you had CT infection, would you tell your partner?, yes	272 (95.8)
If a point of care test indicated you had a CT infection and you would tell your partner, how would you prefer to notify them? (n=272)	
Health department call	9 (3.3)
Health department letter	3 (1.1)
Send my partner a text message or email	3 (1.1)

	n (%)
Tell my partner in person	264 (97.1)
Missing	1 (0.4)

Abbreviations: CT, *Chlamydia trachomatis*; US, United States, STD, sexually transmitted disease

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Association Between Participant's Characteristics and Their Preferred Rescreening Site among 284 Female Participants

**Table 4**

Characteristics	Categories	Number	Preferred Rescreening Site	
			Home, n (%)	STD Clinic/Private Doctor, n (%)
Age, years*	14 – 18	48	6 (13)	42 (88)
	19 – 24	103	31 (30)	72 (70)
	25	133	90 (68)	43 (32)
Race	African-American	262	115 (44)	147 (56)
	Other	22	12 (55)	10 (46)
Site*	STD Clinic	192	120 (63)	72 (38)
	Teen Health Center	92	7 (7.6)	85 (92)
Reported STI symptoms <sup>1</sup> *	Yes	164	86 (52)	78 (48)
	No	120	41 (34)	79 (66)
New partner in past 3 months <sup>2</sup>	Yes	73	36 (49)	37 (51)
	No	210	91 (43)	119 (57)
History of Chlamydia <sup>2</sup>	Yes	156	73 (47)	83 (53)
	No	123	53 (43)	70 (57)

\* p<0.05

<sup>1</sup> Abnormal discharge, vaginal itching, burning with urination, abdominal pain

<sup>2</sup> 1 participant did not respond to new partner question; 5 participants did not respond to previous chlamydia diagnosis question