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The Evaluation of Diagnostic Accuracy of Rapid Tests for Gonorrhea and Chlamydia

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Abstract: Gonorrhea and Chlamydia are among the most prevalent sexually transmitted infections (STIs) worldwide, presenting significant public health challenges due to their high incidence, potential complications and strain on healthcare systems. This study aims to evaluate the diagnostic performance of rapid tests for these infections. We assessed the Gonorrhea Rapid Test using 169 female cervical swab specimens and 210 male urethral swab specimens, comparing its results to traditional culture methods. Similarly, the diagnostic efficacy of the Chlamydia Rapid Test was evaluated against PCR methods, incorporating 205 female cervical swab specimens and 178 male urethral swab specimens. The results showed good sensitivity, specificity and accuracy for both rapid tests. These findings suggest that rapid testing can provide timely and reliable results, which is crucial for the effective management of these STIs. In resource-limited settings, rapid testing may serve as an effective adjunct to standard diagnostic methods, helping to improve access to care and reduce the transmission of Gonorrhea and Chlamydia in vulnerable populations.

1. Introduction

Gonorrhea and Chlamydia rank among the most common sexually transmitted infections (STIs) globally.[1] These infections pose significant public health challenges due to their high prevalence, risk of severe complications, and impact on healthcare systems. Gonorrhea, caused by the bacterium *Neisseria gonorrhoeae*, and chlamydia, caused by *Chlamydia trachomatis*, share several clinical similarities but also exhibit distinct epidemiological and pathological characteristics.

Gonorrhea is a sexually transmitted infection (STI) caused by bacteria and is mainly spread through sexual activities, such as vaginal, oral and anal intercourse.[2] Gonorrhea is particularly prevalent among sexually active individuals, especially young adults and adolescents. It is estimated that approximately 87 million new cases of gonorrhea occur worldwide each year, with significant regional variations in incidence. The highest infection rates are reported in Southeast Asia and Sub-Saharan Africa. Symptoms of gonorrhea vary depending on the site of infection and may include urethritis, cervicitis, pharyngitis and proctitis. In women, complications such as pelvic inflammatory disease (PID) lead to infertility, chronic pelvic pain and an increased risk of ectopic pregnancy.[3] Complications arising from gonococcal infections in the male urogenital system include orchitis,

epididymitis, lymphangitis of the penis, swelling of the penis and strictures in the urethra due to infection. Additionally, the incidence of rectal and pharyngeal gonococcal infections is rising among men who have sexual contact with other men.[6] The growing resistance of gonorrhea to antibiotics poses a significant threat to public health, highlighting the need for effective diagnostic and treatment approaches. Additionally, gonorrhea elevates the risk of both contracting and spreading HIV.[7]

Chlamydia is the most commonly reported bacterial STI worldwide, with around 131 million new cases each year. This infection often presents without symptoms, particularly in women, contributing to its widespread transmission. *Chlamydia trachomatis* can infect multiple areas, including the cervix, urethra, rectum, throat and conjunctiva. Potential complications may include pelvic inflammatory disease (PID), infertility and adverse outcomes during pregnancy. [4] In men, it may also lead to conditions like urethritis and prostatitis.[5] Transmission from mother to newborn during delivery can lead to conditions such as conjunctivitis and pneumonia in infants. The highest rates of prevalence are found in regions including the Americas, Western Pacific and Southeast Asia.

Timely and precise identification of gonorrhea and chlamydia is crucial for effective patient care and controlling the spread of infections. Currently, the primary clinical techniques for detecting *N. gonorrhoeae* include bacterial cultures, direct microscopy and molecular diagnostics using PCR technology. Bacterial culture is considered the "gold standard" for diagnosing *N. gonorrhoeae*; however, this method can be time-consuming and may lack sensitivity. In contrast, direct microscopy is straightforward, efficient and rapid, but its sensitivity for detecting cervical specimens ranges from only 40% to 60%. [8]

Currently, nucleic acid amplification tests are regarded as the gold standard for screening and diagnosis. These tests include DNA amplification methods, such as polymerase chain reaction (PCR) and strand displacement amplification (SDA), as well as RNA amplification techniques like transcription-mediated amplification (TMA), which are associated with high sensitivity.[10] PCR technology enables swift molecular diagnosis and greatly shortens the time needed to identify pathogens. However, it necessitates costly thermal cycling equipment and skilled operators, making population screening difficult in resource-limited regions.[9]

Recently, rapid diagnostic tests (RDTs) have emerged as valuable tools for the simultaneous detection of gonorrhea and chlamydia. These tests offer several advantages, including a shorter time to results, ease of use in point-of-care settings [11] and the potential to improve patient management by facilitating immediate treatment decisions. The Gonorrhea and Chlamydia Combo Rapid Test Cassette (Swab) is an innovative solution that allows for the qualitative identification of both pathogens from female cervical swabs and male urethral swab specimens. This test exhibits high sensitivity and specificity when compared to culture and PCR methods.

This study aims to evaluate the performance of the Gonorrhea and Chlamydia Combo Rapid Test Cassette (Swab) developed by Hangzhou AllTest Biotech Co., Ltd. in comparison to other diagnostic methods, including culture and PCR. By assessing the sensitivity, specificity and practical utility of the rapid test, we aim to determine its potential role in enhancing STI diagnostic workflows, particularly in settings with limited laboratory resources or where rapid decision-making is critical.

2. Methods

2.1 Culture

The procedure begins by obtaining a clinical specimen from the suspected infection site, which may include the cervix, urethra, rectum, throat or conjunctiva, using a sterile swab. The specimen is then placed on a selective culture medium, such as Thayer-Martin agar, formulated to promote the growth of *N. gonorrhoeae* while suppressing the proliferation of other microorganisms. The cultured specimen is incubated in a humid environment at a temperature between 35-37 ℃, with 5-10% carbon

dioxide (CO2), for a duration of 24 to 72 hours. Throughout this period, any *N. gonorrhoeae* present in the specimen will develop visible colonies on the medium. These colonies are then evaluated for characteristic morphological features and subjected to confirmatory tests, including oxidase testing and carbohydrate utilization assays, to ensure accurate identification of the bacteria. The culture method is highly specific and allows for antimicrobial susceptibility testing, which is crucial for guiding effective treatment. However, it requires more time (24-72 hours) compared to molecular methods like nucleic acid amplification tests (NAATs), which yield results within a few hours. Although the culture method requires more processing time, it is crucial for identifying antibiotic-resistant strains of *N. gonorrhoeae* and is considered the gold standard for confirming gonorrhea, particularly in cases of suspected treatment failure or concerns about antibiotic resistance.

2.2 PCR

Chlamydia PCR (Polymerase Chain Reaction) is a molecular diagnostic technique renowned for its high sensitivity and specificity in detecting *Chlamydia trachomatis*, a common sexually transmitted bacterial pathogen. This method amplifies and identifies specific DNA sequences associated with the *Chlamydia* organism, allowing for rapid and accurate diagnosis of the infection.

The PCR test for Chlamydia necessitates a small specimen, like a swab taken from the cervix, urethra or another pertinent area, which is subsequently analyzed in a laboratory. The specimen undergoes several stages, including DNA extraction, amplification of specific DNA sequences using specialized enzymes and primers, and detection of the amplified DNA through fluorescent probes or other detection methods. This entire process can be completed within a few hours, offering a quick turnaround for test results, which is a notable advantage over traditional culture-based methods, which may take several days to yield a diagnosis. In comparison to various diagnostic methods like enzyme immunoassay (EIA) and direct fluorescent antibody (DFA) tests, the Chlamydia PCR technique provides enhanced sensitivity and specificity, making it the preferred choice for accurate diagnosis. This PCR method detects low concentrations of the pathogen that might be missed by other techniques and reliably distinguishes Chlamydia from closely related organisms, thereby reducing the likelihood of false-positive results.

2.3 Rapid Test Device

Specimens from female cervical swabs or male urethral swabs were analyzed according to the manufacturer's guidelines. To extract antigens for *Neisseria gonorrhoeae* and *Chlamydia trachomatis*, Specimen Extraction Buffer was added to the extraction tube and the swab was vigorously swirled to create a well-mixed solution. A second dilution was then added to the homogenized solution, which was gently vortexed to ensure thorough mixing. The extracted antigen was then introduced into the specimen window containing antibodies specific to *Neisseria gonorrhoeae* and *Chlamydia trachomatis*. The results were read after 10 minutes and qualitatively analyzed as per the manufacturer's instructions.

3. Results

3.1 Gonorrhea Rapid Test

The performance characteristics of the gonorrhea rapid test were evaluated using female cervical swab and male urethral swab specimens, with culture as the reference method. Table 1 shows that for female cervical swab specimens, the gonorrhea rapid test demonstrated a relative sensitivity of 94.4% (95% CI: 86.2%-98.4%), a relative specificity of 96.9% (95% CI: 91.3%-99.4%) and an overall

accuracy of 95.9% (95% CI: 91.7%-98.3%). These results indicate that the gonorrhea rapid test has a high ability to correctly identify positive cases (sensitivity) and correctly rule out negative cases (specificity) in female patients.

Similarly, as seen in Table 2, for male urethral swab specimens, the gonorrhea rapid test showed a relative sensitivity of 91.6% (95% CI: 84.6%-96.1%), a relative specificity of 97.1% (95% CI: 91.7%-99.4%), and an overall accuracy of 94.3% (95% CI: 90.2%-97.0%). These findings suggest that the gonorrhea rapid test also performs well in male patients, with a high accuracy in detecting and excluding the infection.

Table 1: Performance Characteristics of Gonorrhea Rapid Test. (For Female Cervical Swab Specimens)

Method		Culture		Total Results
Gonorrhea Rapid Test Cassette (Swab)	Results	Positive	Negative	
	Positive	67	3	70
	Negative	4	95	99
Total Results		71	98	169

Relative Sensitivity: 94.4% (95%CI*: 86.2%-98.4%)
Relative Specificity: 96.9% (95%CI*: 91.3%-99.4%)
Overall Accuracy: 95.9% (95%CI*: 91.7%-98.3%)
*: Confidence Intervals

Table 2: Performance Characteristics of Gonorrhea Rapid Test. (For Male Urethral Swab Specimens)

Method		Culture		Total Results
Gonorrhea Rapid Test Cassette (Swab)	Results	Positive	Negative	
	Positive	98	3	101
	Negative	9	100	109
Total Results		107	103	210

Relative Sensitivity: 91.6% (95%CI*: 84.6%-96.1%)
Relative Specificity: 97.1% (95%CI*: 91.7%-99.4%)
Overall Accuracy: 94.3% (95%CI*: 90.2%-97.0%)
*: Confidence Intervals

3.2 Chlamydia Rapid Test

The performance of the chlamydia rapid test was evaluated using female cervical swab and male urethral swab specimens, with PCR as the reference method. Table 3 shows that for female cervical swab specimens, the chlamydia rapid test showed a relative sensitivity of 93.3% (95% CI: 81.7%-98.6%), a relative specificity of 97.5% (95% CI: 93.7%-99.3%) and an overall accuracy of 96.6% (95% CI: 93.1%-98.6%). Table 4 shows that for male urethral swab specimens, the chlamydia rapid test demonstrated a relative sensitivity of 86.2% (95% CI: 74.6%-93.9%), a relative specificity of 95.8% (95% CI: 90.5%-98.6%), and an overall accuracy of 92.7% (95% CI: 87.8%-96.1%).

Table 3: Performance Characteristics of Chlamydia Rapid Test. (For Female Cervical Swab Specimens)

Method		PCR		Total Results
Chlamydia Rapid Test Cassette (Swab)	Results	Positive	Negative	
	Positive	42	4	46

	Negative	3	156	159
Total Results		45	160	205

Relative Sensitivity: 93.3% (95%CI*: 81.7%-98.6%)
Relative Specificity: 97.5% (95%CI*: 93.7%-99.3%)
Overall Accuracy: 96.6% (95%CI*: 93.1%-98.6%)
*: Confidence Intervals

Table 4: Performance Characteristics of Chlamydia Rapid Test. (For Male Urethral Swab Specimens)

Method		PCR		Total Results
Chlamydia Rapid Test Cassette (Swab)	Results	Positive	Negative	
	Positive	50	5	55
	Negative	8	115	123
Total Results		58	120	178

Relative Sensitivity: 86.2% (95%CI*: 74.6%-93.9%)
Relative Specificity: 95.8% (95%CI*: 90.5%-98.6%)
Overall Accuracy: 92.7% (95%CI*: 87.8%-96.1%)
*: Confidence Intervals

4. Discussion

Infections caused by Chlamydia trachomatis (CT) and Gonorrhea are significant global concerns, leading to considerable health expenses and severe outcomes if not treated properly. Despite years of efforts to control sexually transmitted infections, these challenges persist. To effectively reduce the prevalence of these infections and their associated personal and economic burdens, innovative tools and strategies are essential. The most effective approach currently available involves managing and interrupting the transmission cycle through comprehensive screening and surveillance programs. These initiatives are crucial for ensuring timely and appropriate diagnosis and treatment for those infected.[12] The Combo Rapid Test Cassette (Swab) for Gonorrhea and Chlamydia, developed by Hangzhou AllTest Biotech Co., Ltd., marks a notable progression in sexually transmitted infection (STI) diagnostics. This rapid point-of-care (POC) test has the capability to enhance and simplify the identification of two widespread bacterial STIs—gonorrhea and chlamydia—when contrasted with conventional diagnostic techniques.

One of the primary advantages of the rapid test is its ability to deliver timely results, often within 30 minutes, allowing healthcare providers to make prompt clinical decisions and initiate appropriate treatment without delay. This is particularly valuable in settings where access to laboratory resources is limited or where rapid decision-making is crucial, such as in resource-constrained regions or emergency healthcare settings. By facilitating immediate diagnosis, the rapid test helps reduce the risk of disease transmission, as patients can be informed and treated more efficiently.

In addition, the results of the study showed that the rapid test has high sensitivity and specificity compared to the two gold-standard diagnostic methods, culture and PCR. This suggests that rapid tests reliably detect *Neisseria gonorrhoeae* and *Chlamydia trachomatis*, the causative agents of gonorrhea and chlamydia, respectively. The high accuracy of rapid tests can provide confidence to healthcare providers and patients, thereby reducing the need for repeat testing or confirmation procedures. Moreover, rapid tests require only a simple swab specimen and feature user-friendly designs that enhance patient engagement and improve accessibility to STI screening. This is particularly beneficial for patients who are reluctant to undergo more invasive or time-consuming diagnostic procedures. The simplicity of rapid testing helps overcome barriers to detection, leading

to higher screening rates and earlier detection of infections. By streamlining the testing and treatment process, clinics can improve efficiency by reducing the need for follow-up appointments for results and treatment initiation, resulting in cost savings. Additionally, this approach supports better antimicrobial stewardship.[13]

However, it is important to acknowledge the potential limitations of the rapid test. While the study demonstrates its overall accuracy, there may be specific scenarios or populations where its performance may not be as robust. For example, the rapid test may exhibit lower sensitivity in detecting asymptomatic or low-level infections, which are common in both gonorrhea and chlamydia. In such cases, healthcare providers should be aware of the test's limitations and consider supplementing it with additional diagnostic methods or maintaining a high index of suspicion when the rapid test results do not align with clinical presentation. We need to highlight the necessity for continual evaluation and validation of rapid diagnostic technologies. With the introduction of new products, it is essential to assess their effectiveness across various clinical environments and populations to confirm their reliability and applicability. Ongoing assessment and comparison with established gold-standard methods are critical to maintaining trust in the rapid test's effectiveness and identifying any potential areas for improvement.

Another consideration is the potential impact of the rapid test on healthcare workflows and resource allocation. While the rapid test streamlines diagnosis and treatment, it may also introduce new challenges related to specimen collection, storage and transportation, particularly in resource-limited settings. Healthcare systems should carefully evaluate the logistical and operational requirements for implementing the rapid test to ensure its seamless integration into existing diagnostic pathways. Moreover, the integration of the rapid test could have significant implications for public health strategies and surveillance initiatives. By facilitating more accessible and timely STI screening, the rapid test may enhance case detection and provide more accurate epidemiological data. This improved information could guide targeted interventions, resource distribution and the creation of effective prevention and control programs. Challenges include accurately reflecting the true incidence of chlamydia to expand screening efforts, reducing testing costs and increasing investment and awareness of sexually transmitted infections, particularly in developing nations. These approaches aim to educate individuals about the risks, promote early treatment and effectively manage infections.

5. Conclusion

In conclusion, the Gonorrhea and Chlamydia Combo Rapid Test Cassette (Swab) developed by Hangzhou AllTest Biotech Co., Ltd. represents a promising advancement in STI diagnostics. Its ability to provide rapid, accurate and accessible results significantly enhance the detection and management of gonorrhea and chlamydia, especially in settings with limited laboratory resources or where timely decision-making is critical. However, it is essential to recognize the test's limitations, maintain ongoing evaluation and carefully consider its integration into existing healthcare systems to maximize its potential impact on public health outcomes.

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