Point-of-Care Assays to *Trichomonas vaginalis* Diagnosis: The Road So Far

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Abstract: *Trichomonas vaginalis* infection represents the most prevalent non-viral, curable parasitic sexually transmitted infection (STI) worldwide. The demand for precise and cost-effective point-of-care (POC) tests is paramount in the pursuit of STI epidemic control, ensuring expeditious patient diagnosis and therapeutic interventions. In the present study, we searched academic databases, including PubMed (US National Library of Medicine and the National Institutes of Health), Scopus, and Web of Science, employing the following keywords: “*Trichomonas vaginalis*”, “diagnosis”, “point-of-care tests”, and “rapid diagnosis”, to provide information about the development and effectiveness of POC tests to identify *T. vaginalis*. Present assays for *T. vaginalis* exhibit suboptimal performance, and the integration of advanced technologies, notably nanotechnologies, emerges as a formidable instrumentality for augmenting diagnostic precision while curtailing expenditure. In this review, we provide an encompassing survey of cutting-edge POC tests for *T. vaginalis* diagnosis and offer an outlook on future prospects in this domain.

Keywords: STIs; POC; biosensors; sexually transmitted infections

1. Introduction

Sexually transmitted infections (STIs) that do not involve viruses are among the most widespread communicable diseases globally. They are associated with significant illness and mortality, and their incidence is increasing worldwide. According to the World Health Organization (WHO), there were approximately 376 million cases of four treatable STIs—chlamydia, gonorrhea, trichomoniasis, and syphilis—in 2016 [1]. For trichomoniasis, prevalence estimates were 5.3% (95% UI: 4.0–7.2) in women and 0.6% (95% UI: 0.4–0.9) in men [1].

Trichomoniasis, caused by the motile parasitic protozoan *Trichomonas vaginalis* (*T. vaginalis*), stands as one of the most common non-viral sexually transmitted infections (STIs) worldwide [1–4]. The WHO estimated 156 million cases of *T. vaginalis* globally in 2016, accounting for nearly half of the global incidence of STIs in that year [1]. Its incidence is on the rise worldwide, with researchers reporting a prevalence ranging from 1.3% to 16.5% of *T. vaginalis* in reproductive tract infections [2,3]. This prevalence of *T. vaginalis* likely depends on factors such as sexual behavior, educational level, race, sociocultural status, and economic situation [5]. The preponderance of *T. vaginalis* infections, encompassing 85% of females and 77% of males, manifests asymptotically [3]. However, symptomatic presentations in affected females a variety of symptoms, including vaginal discharge, dysuria, pruritus, vulvar irritation, and abdominal pain [3,4].

*T. vaginalis* infection is associated with serious adverse events. Therefore, diagnostic testing is recommended for individuals who live in environments and acquire risk behav-
iors (such as multiple sexual partners, active substance use, and housing in correctional environments) in addition to asymptomatic HIV-positive women and symptomatic individuals. Furthermore, surveillance of non-symptomatic carriers is of great value in preventing disease transmission [6]. Classical techniques to identify T. vaginalis in clinical samples involve parasite culture and microscopic analysis [4,7,8]. Early and effective diagnosis of trichomoniasis can mitigate the ongoing transmission chain and prevent the consequences of untreated infections. The microscopic examination of a wet mount of vaginal fluid is employed to search for parasites in the sample. This method has been traditionally utilized due to its prompt diagnosis and cost effectiveness, making it suitable for resource-limited settings. However, it exhibits low sensitivity (ranging from 44% to 68%), contingent on the experience of the examiner and the reading time [8,9].

The need for more efficient tests for the diagnosis of T. vaginalis has prompted the emergence of more sensitive tests based on the detection of genetic material through the amplification of the parasite’s DNA or rRNA (NAATs—nucleic acid amplification tests) [7,10]. Despite the elevated sensitivity and specificity achieved by NAATs, their practical utility is contingent upon resource availability, training, laboratory infrastructure, extended turnaround times, and financial considerations, thereby rendering them inaccessible in resource-constrained settings. Furthermore, clinical laboratory analysis may often entail several delays in providing results [11]. In this scenario, point-of-care (POC) tests emerge as an important tool for easy and quick diagnosis. POC tests allow self-collection or collection of samples by untrained staff outside the clinical laboratory [11]. The rapid response and greater sensitivity provide the possibility of rapid decisions regarding treatment strategy, management, and breaking the chain of transmission [12]. The key to a viable POC test is the turnaround time, characterized by the interval between the test being requested by the health care professional and the treatment decision being made. In general, when the POC test is chosen, this time tends to be shorter [11,13].

POC tests allow assessment of a patient’s condition outside of the conventional clinical laboratory setting. These devices can be used in a variety of settings, including a doctor’s office, at a patient’s bedside in a hospital, in the comfort of a patient’s home, or even in the field. The primary purpose of point-of-care testing is to expedite the immediate delivery of treatment and patient care [14]. To merit classification as POC assays, diagnostic devices must align with criteria stipulated by the WHO. The WHO ASSURED criteria, demarcated by attributes such as Affordability, Sensitivity, Specificity, User-friendliness, Rapid/Robust performance, Equipment-free operation, and Deliverability, are pivotal in the delineation of POC tests [15]. POC assays are typically provided with integrated readers, increasing interpretability and the speed of obtaining results. The efficiency of the device enhances surveillance actions and positively interferes in actions to control STIs [16].

POC assays play a pivotal role in broadening access to diagnostic evaluations, expediting and simplifying response times, with the added capacity for diagnosis and subsequent therapeutic initiation during a single clinical encounter. Furthermore, they prove to be fundamental for the rapid monitoring and management of the disease, thus mitigating the prospects of morbidity in affected individuals as well as reducing the potential for transmission from mother to child or transmission to sexual partners [17]. These attributes represent indispensable facets within the realm of trichomoniasis diagnosis and management. In the context of this comprehensive review, we shall deliberate upon a selection of POC assays aimed at T. vaginalis diagnosis.

2. Materials and Methods

This investigation comprises a narrative critical review. The literature search was conducted utilizing comprehensive academic databases including PubMed (U.S. National Library of Medicine and the National Institutes of Health), Scopus, and Web of Science. The search strategy employed the keywords: “Trichomonas vaginalis”, “diagnosis”, “point-of-care tests”, and “rapid diagnosis”. This study leveraged various descriptor algorithms and Boolean logic (AND, NOT) tailored to each database. Specific search strings were as

After excluding duplicates, 3572 articles remained for review. Additionally, we conducted a survey of the devices available on the market and excluded articles that provided redundant information already presented in the selected works. Our review consisted of only those studies that met the following criteria: (1) originally published in the English language; (2) studies containing information on the specificity, sensitivity, functionality, and application of point-of-care (POC) devices for the rapid diagnosis of T. vaginalis; (3) studies that provide relevant information about epidemiology, virulence, comorbidity, and prevention of trichomoniasis. Based on the selection criteria, 63 articles were chosen for this narrative literature review (Figure 1). The scope of the review focused on studies conducted between 2001 and 2023 that specifically investigated POC tests designed for the detection of T. vaginalis, thereby providing a comprehensive overview of the topic (Figure 1).

3. Types of POCs for Trichomoniasis

Prior to the advent of novel diagnostic methodologies, the utilization of Diamond medium culture [18] stood as the gold standard for the identification and isolation of T. vaginalis. This particular technique exhibits variable sensitivity contingent upon the nature of the sample employed, with reduced efficacy observed in male specimens and susceptibility to contamination by vaginal bacterial species, thereby introducing complexities into the procedural framework. It is worth noting that while the cultivation of T. vaginalis demonstrates heightened sensitivity compared to the wet mount examination, it is accompanied by escalated cost implications and protracted procedural durations [8,9,19].

Figure 1. Review flow diagram. Details of number of articles screened, exclusion criteria, and selected studies.
The landscape of *T. vaginalis* diagnosis experienced a transformative shift with the emergence of molecular techniques, exemplified by nucleic acid amplification tests (NAATs), which have since superseded the aforementioned standard, establishing a novel gold standard. The Aptima® *T. vaginalis* assay serves as a paradigmatic illustration of a diagnostic test endorsed by regulatory bodies in both developed and developing nations, owing to its molecular detection capabilities. This assay operates through the detection of an rRNA target via transcription-mediated amplification, exhibiting a sensitivity and specificity exceeding 95% [7,10]. It can be executed on a diverse array of specimen types, encompassing vaginal and endocervical swabs, urine samples, and ThinPrep PreservCyt samples, with results attainable within an expedited timeframe of fewer than 8 h. It is imperative to underscore the necessity for internal validation prior to its deployment in male subjects [8,10]. Acknowledging these constraints, point-of-care (POC) diagnostic assays have been conceived, spanning an array of diagnostic categories, including sexually transmitted infections (STIs) like trichomoniasis.

Rapid diagnostic tests hold significant promise and play a crucial role in health care, particularly in ease of use and monitoring and expedited results in disease diagnostics [20,21]. The diagnosis of trichomoniasis offers multiple approaches. In contrast to conventional wet microscopy or culture of parasites and direct observation, the FDA-approved OSOM trichomonas rapid test demonstrates notable specificity and sensitivity (exceeding 85%, for both) [22–24]. This test employs a qualitative analysis through immunochromatographic capillary flow enzyme immunoassay for detecting the vaginal *Trichomonas* antigen, α-actinin protein, in approximately 10 min with high reliability [25]. Research indicates its effectiveness in diagnosing *T. vaginalis* in women, indicating sensitivity and specificity of 97.98% and 99.37%, respectively [22]. However, its effectiveness in detecting *T. vaginalis* in men is less pronounced, with a sensitivity of 37.5% and specificity of 82.9% [26]. Additionally, patients can self-administer this test, contributing to successful disease identification. This seemingly straightforward aspect is linked to patient comfort during self-examination, in contrast to clinical testing, and contributes to successful disease identification (studies involving women reveal that over 90% are willing to self-administer *T. vaginalis* tests). Self-administration results in high success rates for test execution and data interpretation by individuals themselves (99%) [27].

The OSOM test began to be commercialized following the acquisition of the patent for Xenostrip-TV, a test based on immunochromatography for detecting the antigenic protein alpha-actinin in vaginal swabs. The patent also involved tests using saliva; however, this variable was never commercialized. Xenostrip-TV was developed in 2006, which started to market the test under the name OSOM [28,29].

The Visby Medical Sexual Health Test single-use device utilizes DNA amplification to detect *T. vaginalis*, along with other etiological agents of sexually transmitted diseases. All chemical and biological components are lyophilized within the device and are released as needed by the reaction. Heat fluctuations are automatically facilitated by the platform upon device initiation. Collecting biological material is uncomplicated, and sample processing is unnecessary. The device provides a rapid test (30 min) with straightforward interpretation of the colorimetric reaction. The kit includes a self-collection kit (vaginal swab), allowing patients to collect the sample and deliver it to a qualified professional for testing. The material is subsequently transferred to the device and activated in accordance with the manufacturer’s instructions. A positive result is indicated by a color change (indicative of a purplish color), and the reading should be performed within two hours. This test has a sensitivity of 99.2% (95.5–99.9) and specificity of 96.9% [30].

The test is highly accurate (98.5%) and offers faster and less intricate results compared to other tests such as Binx io and GenXpert, which also rely on polymerase chain reaction (PCR) but require separate kit handling and amplification [30]. The GenXpert TV assay (Cepheid, Sunnyvale, California) exhibits specificity of up to 100% compared to wet mounts and up to 99.9% compared to culture-based techniques. Nonetheless, as mentioned earlier, these tests entail greater complexity and consequently higher costs compared to other tests
available on the market [31]. The GenXpert may use patient-collected vaginal swab, urine, or endocervical swabs as the sample to identify the presence of *T. vaginalis*. Moreover, the FDA cleared the use of the technique to also test male urine.

The Solana trichomonas assay (POC QUIDEL) uses molecular techniques with analysis that takes about 40 min. The test is conducted through an in vitro qualitative analysis of *T. vaginalis* DNA. Using vaginal swabs or urine samples, the test identifies by the presence of target-specific fluorescence probe repeat sequences of pathogen DNA. The sample needs to be prepared in advance for subsequent analysis, with detection performed through helicase-dependent isothermal amplification (HDA). It exhibits high sensitivity and specificity, with values for asymptomatic women (100%/98.7%), symptomatic women (98.6%/98.5%), asymptomatic women’s urine (98.0%/98.4%), and symptomatic women’s urine (92.9%/97.9%), compared to the FDA-established reference method. Although the test needs to be performed in clinical laboratories, there is a perspective for use in doctor’s office or clinics. The POC QUIDEL demonstrates suitable performance with sensitivity/specificity of 89.7%/99.0% for smears and 100%/98.9% for urine samples compared to Aptima-TV, a non-point-of-care robotic FDA-cleared NAAT platform [32].

Using the HDA technology, the AmpliVue assay provides a result in approximately 45 min. The test is considered by the FDA as moderately complex and uses vaginal swabs to sample test. The test employs an enzyme (helicase) to separate the DNA before the amplification and targets a conserved sequence of *T. vaginalis*. Based on PCR technique, this test involves three steps: (1) lysis, which involves the sample preparation (dilution/ heating) and exposure to higher temperatures (95 °C—10 min); (2) DNA amplification by isothermal amplification of *T. vaginalis* DNA by HDA in a heat block (64 °C—25 min); and (3) detection based on colorimetric reaction in a disposable device. The sensitivity (100% sensitivity and 98% of specificity) of the test allows the identification of trichomoniasis in symptomatic and asymptomatic women [33].

The BD Affirm VPIII (Becton Dickinson, Sparks, Maryland) exhibits specificity around 95% and sensitivity between 91 and 100%, used to detect *T. vaginalis, Gardnerella*, and *Candida* spp. using vaginal fluids. The test was the first molecular assay to detect the mentioned pathogens, is based on a molecular assay, and comprises a synthetic oligonucleotide DNA probe complementary to the target genetic sequences [9]. It uses a color development detection probe obtained by synthetic acid capture probes according to each target. The sample is treated with lysis solution, heated, and processed to MicroProbe Processor with cassettes and the analysis card [34]. The test is considered to have moderate complexity and requires 10 steps to provide a result. Meanwhile, the BD MAX CTGCTV2 is employed for the detection of *T. vaginalis* in urine samples from both men (urine) and women through vaginal self-collected swabs. Specificity and sensitivity can reach 100% depending on the type of sample [9]. The BD MAX CTGCTV2 is an FDA-cleared second generation of BD Max System molecular triplex to identification of *Clamydia trachomatis, Neisseria gonorrhoeae*, and *T. vaginalis*. The increased volume size of the kit when compared to a first-generation test allows multiple assays with a single sample. In addition, the second-generation test is more stringent than the first-generation test [35,36].

The Cobas TV/MG (Roche) test is an automated qualitative in vitro diagnostic test. It demonstrates high sensitivity/specificity and can be used to detect *T. vaginalis* in urine (100%/99.7%), endocervical specimens (collected by a health care professional) (100%/99.2%), or self-collected vaginal swabs in women (100%/99.2%). This test has a specific target for *T. vaginalis* and is based on molecular techniques (qPCR). Additionally, it offers greater throughput than other tests, with an onboard capacity of up to 4608 TV/MG tests and onboard stability of 90 days when collected in appropriate solution. The stability and the high number of tests allow the kit to be used for testing multiple individuals in communities with limited access, for example [37].

Recently, Alderate and Chan (2023) published the validation of a viable POC test for *T. vaginalis*. The technique used the MedMira rapid vertical flow cartridge technology that present a 72.4 kDa α-actinin ACT::SOE3 protein to identify parasite-specific antibodies [38].
This protein is a highly immunogenic-specific target (having no amino acids sequence identity in common with other organisms, not sharing identity with the human homolog or other organisms, and found in serum or whole blood samples, ensuring the test’s specificity) that can be used for serodiagnostic of positive individuals to trichomoniasis. Showing higher sensitivity (99–100%), the advantage of the POC test involves the application to male (5 epitopes detected by sera) and female (13 epitopes detected by sera) individuals and the rapid diagnostic [37]. The protein present on test reacts with specific antibodies of blood or serum of positive individuals and provides a result of the test after 5 min. The test fulfills the assured criteria proposed by WHO, is characterized by low costs, and is user-friendly, transportable, sensitive, and specific. Furthermore, extra equipment is not necessary. The authors conclude in the work of validation of POC test that the test may be an important tool for health care providers and infected individuals [38]. A summary of the methods used for detection of *T. vaginalis* used in the present study can be seen in Figure 2.

**Figure 2.** Methods of POC tests for identification of *Trichomonas vaginalis*. (a) Tests such as OSOM Trichomonas / Xenostrip-Tv employ qualitative analyses through capillary flow immunochromatographic enzyme immunoassays for the detection of the *Trichomonas vaginalis* antigen, α-actinin protein, which binds to antibodies present on the test line of the immunochromatographic membrane. (b) Molecular assay-based tests I) require sample collection and the use of reagents to facilitate II) the amplification and detection of the target genetic material within the device. (c) The MedMira Rapid Vertical Flow test employs qualitative analyses through capillary flow immunochromatographic enzyme immunoassays for the detection of serum antibodies against the *Trichomonas vaginalis* antigen, α-actinin protein, present on the test line of the immunochromatographic membrane.

4. Discussion

In 2006, the WHO introduced the ASSURED criteria for POCT, recognizing the need for rapid development of diagnostic tests aimed at identifying and characterizing STIs [39,40]. These criteria presented requirements stipulating that POC tests should be fast, easy to perform, user-centered, sensitive, capable of mitigating spurious results, showing specificity in relation to the etiological agent, and financially palatable for health infrastructures. Subse-
sequent iterations, incorporated into the REASSURED criteria, have adopted improvements that encompass real-time connectivity and non-invasive modalities for sample acquisition [40,41].

POC tests should yield expeditious results that serve as a predicate for therapeutic stratagem initiation during the first patient encounter (within 60 min of sample acquisition). Furthermore, the possibility of carrying out the test in a non-clinical environment or at least collecting the sample (self-collection) increases patient adherence and consequently effectiveness in test coverage. The challenge of POC tests is to promote results with high sensitivity and effectiveness in the shortest possible time and to promote techniques in which patients feel comfortable performing the collection and are able to perform the complete test in some cases [42,43]. These tests should evince resilience vis-à-vis ambient vicissitudes, including temperature fluctuations, power availability, and accessory equipment requisites [29,44].

In the present study, we addressed, in general lines, aspects of POC tests for the diagnosis of *T. vaginalis* in human samples. Many tests available use molecular techniques for the direct diagnosis of *T. vaginalis* (Visby Medical Sexual Device; GenXpert Tv assay; Solana trichomonas assay; AmpliVue assay; BD Affirm and MAX CTGTC2; Cobas Tv/Mg). Some of these tests are PCR-based and involve multiple steps, which can increase the price, complexity, and waiting time to obtain results, like the Solana trichomonas assay, which needs sample preparation and laboratory environment for sample collection, or GeneXpert, which is more expensive and time-consuming that other PCR-based tests [30–32]. However, DNA identification can be highly sensitive, allowing diagnosis before symptoms appear and preventing transmission. In addition to DNA, direct identification based on antigens can be found in the OSOM trichomonas rapid test and Xenostrip-Tv [25], while tests that involve indirect identification by the presence of specific antibodies against *T. vaginalis* can be found in the MedMira rapid vertical flow. Although the presence of immune response depends on the time of the response development, the specific targets provide highly sensitive and specific tests. However, the test presents challenges due to the temporal nature and duration of anti-*T. vaginalis* antibody responses in individuals post infection, post diagnosis, and cure (immediate and long-term response immunoglobulins). There is a possibility of both long- and short-lived serum antibodies, which may not indicate an ongoing infection [38].

The temporal aspect of testing may loom salient in the adjudication of POC tests, as empirical data asseverate that upwards of 98% of patients are amenable to a 30 min wait for test outcomes, with a notable 26% willingness to extend their wait up to 1 h. Expeditious diagnosis can concretely influence the clinical determination to inaugurate therapeutic interventions [17]. All the tests detailed in the present study show an adequate time to perform and provide results; however, there is fluctuation in the time to obtain the result in the tests addressed (5–45 min). It is notable that the incorporation of molecular tools into the use of POC tests has helped to optimize the time, complexity, and effectiveness of rapid tests as well as the constant search for new strategies to identify pathogens for STIs such as *T. vaginalis* [43]. In the point of view of the patient, the speed of diagnosis may be related to less treatment delay, which is related to the reduction of mortality and morbidity [11]. These characteristics are advantageous in the point of view of health systems and the government, as they reduce costs [11]. Furthermore, the study performed by Alderate and Chan (2023) [38] demonstrated that the search for new strategies in the rapid and sensitive diagnosis of trichomoniasis, like serodiagnosis, is still a path to be explored and can provide new products for human health.

The WHO has promulgated a compendium of target product profiles intended to furnish guidance in the formulation of rapid tests. In the context of trichomoniasis, these diagnostic modalities ought to evince a sensitivity surpassing the 80% threshold [45]. Mathematical modeling has illuminated that POC tests endowed with a sensitivity hovering around 60% can engender superior therapeutic success rates compared to high-sensitivity tests plagued by a dearth of patient compliance [7].
In resource-constrained milieus, expeditious diagnosis may assume decisive importance in the efficacy of therapeutic interventions [17]. Infection induced by *T. vaginalis* is endemic, with a well-documented association with grave morbidity. Diagnostic assays to detect the parasitic agent are recommended for symptomatic individuals (manifesting vaginal discharge). For asymptomatic cohorts, testing is warranted for HIV-positive women and encouraged for individuals at heightened risk (e.g., attendees of sexually transmitted disease clinics and those with a history of multiple sexual liaisons) [6]. Conversely, the prevalence of *T. vaginalis* in men is comparatively low: 0.6% in men compared to 5.3% in women [1]. The test may be recommended for men who have urethritis, and it is important to screen populations with risky sexual behavior. [46,47]. Testing of male individuals is also important to prevent sexual transmission of the pathogen to women.

It is important to highlight that some considerations must be considered when applying POC tests. POC does not replace complete and in-depth laboratory diagnosis; however, it expands the diagnostic potential for greater agility and acceptance. Furthermore, the lack of need for specialized training, equipment maintenance, acquisition costs, and development of complex laboratory systems allow for greater dissemination in communities with limited resources [11]. The advantages of POC tests for identifying *T. vaginalis* can be seen in Figure 3.

![Figure 3. The advantages of point-of-care tests to identification of *Trichomonas vaginalis*. When comparing (a) classic laboratory diagnostic tests with (b) innovative POC tests, it becomes evident that POC tests have greater diagnostic potential due to their higher sensitivity and specificity, affordability, deliverability, user-friendliness, equipment-free operation, and rapidity /robust performance.](image)

In this comprehensive review, we have presented a panoramic survey of several POC tests (as detailed in Table 1) suitable for clinical diagnosis of *T. vaginalis*. Collectively, these assays epitomize stringent specificity and unwavering reliability, all while obviating the need for specialized training among end-users. Moreover, the integration of such diagnostic modalities, even those characterized by reduced specificity, holds the potential to precipitate heightened engagement with therapeutic regimens, thereby contributing...
substantively to the curtailment of trichomoniasis transmission [48–50]. Many POC tests for *T. vaginalis* diagnoses use DNA-based identification, which culminates in high sensitivity. The disadvantages of POC tests involve higher costs and development complexity, which demonstrates that new technologies that aim to make devices cheaper can help in their popularization. The amalgamated data corpus underscores the imperative of investing in the development of cost-effective and accessible POC testing technologies, thereby affording a potent arsenal in the battle against *T. vaginalis*.

### Table 1. Point-of-care (POC) tests for *T. vaginalis* detection.

<table>
<thead>
<tr>
<th>POC Test</th>
<th>Sample</th>
<th>Time to Diagnosis</th>
<th>Sensitivity</th>
<th>Mechanism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mount microscopy</td>
<td>Vaginal and urethral</td>
<td>10 min</td>
<td>44–68%</td>
<td>Direct observation of parasites</td>
</tr>
<tr>
<td>Culture</td>
<td>secretions</td>
<td></td>
<td></td>
<td>Culture Qualitative</td>
</tr>
<tr>
<td>OSOM trichomonas rapid test</td>
<td>Vaginal swab and urine</td>
<td>-</td>
<td>Variable</td>
<td>immuno-chromatography (antigen detection)</td>
</tr>
<tr>
<td>Xenostrip-TV</td>
<td>Vaginal swab</td>
<td>10 min</td>
<td>85–100%</td>
<td>Immunochromatography</td>
</tr>
<tr>
<td>Visby Medical Sexual Health Test</td>
<td>Vaginal swab</td>
<td>10 min</td>
<td>98–100%</td>
<td>PCR</td>
</tr>
<tr>
<td>GenXpert TV assay</td>
<td>Vaginal swab</td>
<td>30 min</td>
<td>98.50%</td>
<td>PCR</td>
</tr>
<tr>
<td>SolanA trichomonas assay</td>
<td>Vaginal swab</td>
<td>30 min</td>
<td>99.9–100%</td>
<td>PCR</td>
</tr>
<tr>
<td>AmpliVue</td>
<td>Vaginal swab</td>
<td>&lt;40 min</td>
<td>92–100%</td>
<td>DNA presence</td>
</tr>
<tr>
<td>BD Affirm VP III</td>
<td>Vaginal fluids</td>
<td>45 min</td>
<td>98–100%</td>
<td>PCR</td>
</tr>
<tr>
<td>BD MAX CTG CTV2</td>
<td>Vaginal swab and urine</td>
<td>-</td>
<td>100%</td>
<td>Molecular probe—acid nucleic identification</td>
</tr>
<tr>
<td>BD MAX CTV2</td>
<td>Blood or serum</td>
<td>5 min</td>
<td>99–100%</td>
<td>Specific antibodies</td>
</tr>
</tbody>
</table>

5. Conclusions

Point-of-care (POC) tests are a valuable tool for the rapid diagnosis of sexually transmitted diseases such as trichomoniasis. These tests utilize various methodologies, including molecular targets (PCR or molecular probes), immunochromatographic, and serological tools to identify genetic material, specific antigens, and antibodies of *T. vaginalis*. Samples can be self-collected and read by the patient in some cases (vaginal swab or urine), while some tests use blood or serum samples. The time to obtain the result is less than 1 h in all tests evaluated, indicating greater acceptability by the patient. Most tests are easy to use and do not require complex equipment to produce results. In general, the tests show high specificity and effectiveness in detecting the pathogen, especially in women, who are the primary targets of treatment for the disease. However, new methods are required for the development of more rapid, specific, and transposable devices to improve the health of the human community.

6. Future Directions

The rapid advancement of scientific knowledge also holds implications for the future of point-of-care (POC) testing. Recent studies have shown that tests for identifying *T. vaginalis* are becoming increasingly faster and more efficient. The integration of molecular and immunological tools with straightforward, rapid, and safe engineering can enhance community acceptability and extend diagnostic capabilities to endemic regions lacking access to appropriate treatment decisions. However, achieving ideal devices still necessitates a significant developmental journey.

One promising avenue for enhancing POC testing for sexually transmitted infections (STIs) is nanotechnology. Nanotechnology involves the manipulation of particles ranging from 1 to 100 nm in size. These particles can contain conductive metals and various compounds, enabling the fabrication of biosensors for detecting cancer cells [51], chemical
contaminants, and pathogens in food [52,53]. Biosensors have also been utilized for identifying zoonotic bacterial pathogens [54] in biological samples and viral nucleic acids [55], suggesting their potential application in human health for rapid testing.

The biosensor device consists of two essential components engaged in biorecognition: the bioreceptor, which comprises biological elements like antibodies, proteins, nucleic acids, or cells that identify targets, and a transducer that converts the captured signal (chemical, physical, or biological) into a visible or measurable message, often an electrical signal. In certain cases, an amplifier may be necessary to boost the signal and enhance the sensor’s sensitivity [56]. This promising branch could soon be employed to identify etiological agents of sexually transmitted infections (STIs) such as T. vaginalis. Nanotechnology facilitates signal amplification through nanochords or nanoparticles (such as silver, gold, quantum dots, and titanium oxide nanoparticles), which are also utilized in characterized biosensors based on nanomaterials. When applied in diagnostic tests, these nanomaterial-based biosensors can offer point-of-care (POC) devices with improved responsiveness, faster and more accurate results, and easier handling [14,57]. The advantages of using nanomaterials in diagnostic devices include rapid, simple, and toxicity-free synthesis; a high surface-to-volume ratio enhancing particle action; low cost; and enzymatic activity in some metallic nanoparticles. These characteristics collectively underscore biotechnology as a promising field for the development of electrochemical devices for pathogen identification [58].

Another promising strategy for rapid detection of T. vaginalis in human samples is the use of aptamers. Aptamers were selected by a systematic linker evolution by exponential enrichment (SELEX) process that involves the construction of genome libraries using primers linked to constant regions flanking random DNA sequences [59–61]. Aptamer selection involves five steps: (1) incubation of the genomic library with the target; (2) separation of binding molecules and non-binding oligonucleotides; (3–4) elution; and (5) amplification of selected regions and formation of amplified single-stranded DNA [62]. The SELEX process involves repeating these steps to build genomic libraries. After construction, the product of the SELEX rounds is sequenced, and aptamers are selected according to their binding capabilities to specific targets. A final refinement step can then be applied, where non-essential sequences are removed from the molecule, which can increase its efficiency. This is a crucial step, while sequences that functionally alter the binding site to the target molecule cannot be removed [63].

Using SELEX technology, Espiritu et al. (2018), reported for the first time the selection of aptamers against the T. vaginalis adhesion protein (AP65). Tests carried out by the authors demonstrated that the aptamer developed did not show cross-reactivity with other organisms and meets the sensitivity and specificity requirements. The low cost of the product and the binding time with the target demonstrated a good strategy for the development of POC immunochromatographic tests involving aptamers [63].

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References


8. Van Gerwen, O.T.; Muzny, C.A. Recent advances in the epidemiology, diagnosis, and management of Trichomonas vaginalis infection. F1000Research 2019, 8, 1666. [CrossRef]


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