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Evaluation of the Syphilis Rapid Test in Comparison to TPPA: Assessing Sensitivity, Specificity, and Accuracy for Point-of-Care Diagnosis

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Abstract

Syphilis, a sexually transmitted infection caused by the bacterium *Treponema pallidum*, remains a significant public health concern due to its global prevalence and related complications. Timely screening of syphilis is crucial for its diagnosis and intervention. Rapid and point-of-care tests, requiring just a single blood sample, offer promising prospects for efficient detection. Such innovations can amplify the accessibility and efficacy of syphilis screening.

This study evaluates the performance of the Syphilis Rapid Test, developed by Hangzhou AllTest Biotech Co., Ltd, in comparison to the *Treponema pallidum* Particle Agglutination (TPPA) method. Clinical trials, employing human whole blood, serum, plasma samples, aimed to ascertain the sensitivity, specificity, and accuracy of the Syphilis Rapid Test.

The findings of this study demonstrate that the Syphilis Rapid Test Cassette (Whole Blood/Serum/Plasma) demonstrated ultra-high sensitivity of 99.9% and a specificity of 99.7%, underscoring its accuracy and reliability in identifying syphilis infections. Such performance metrics highlight the viability as a supplementary diagnostic tool in syphilis detection and management.

The comparative analysis conducted in this study provides valuable insights into the concordance between the Syphilis Rapid Test and the TPPA method. These insights are crucial for clinicians to make diagnostic and therapeutic decisions related to the diagnosis and management of syphilis. The adoption of rapid testing methods, like the Syphilis Rapid Test, can expedite the screening process, enable timely diagnosis, and facilitate prompt initiation of appropriate treatment strategies. Ultimately, this contributes to the cumulatively control and prevention of syphilis, furthering global public health objectives.

Keywords: Syphilis; Rapid test; TPPA; Diagnosis; Comparative analysis

Introduction

Syphilis

Syphilis, a sexually transmitted infection, is attributed to the bacterium *Treponema pallidum* subspecies pallidum (*T. pallidum*) [1]. Clinically, syphilis presents variably, segmented into primary, secondary, latent, and tertiary stages. The primary stage is often signaled by a solitary, painless ulcer known as a chancre, predominantly ranging between 1 cm to 2 cm in diameter, although multiple chancres can emerge [2]. The secondary stage manifests as a generalized rash, especially prominent on the palms and soles, accompanied by oral or vaginal sores. The latent phase delineates an asymptomatic period, potentially spanning several years. The tertiary stage, marking the disease's progression, may result in non-cancerous growths termed gummas, neurological complications, or cardiac manifestations [3].

Predominantly, syphilis spreads *via* sexual contact [2]. *T. pallidum* can infiltrate the body through mucous membranes or skin breaches during sexual activity with an affected individual. Furthermore, vertical transmission from an infected mother to fetus, during gestation or delivery, results in congenital syphilis, posing dire implications for neonatal health.

Diagnosis

Despite being sexually transmitted, syphilis frequently remains asymptomatic. Hence, sensitive diagnostic modalities are particularly crucial for prompt detection, guiding therapeutic regimens and further transmission.

Blood tests: Blood tests for the diagnosis of syphilis are categorized into two main types: Nontreponemal tests and treponemal tests [4]. Nontreponemal tests, such as the Venereal Disease Research Laboratory (VDRL) and Rapid Plasma Reagin (RPR) tests, are typically employed as initial screening tests. However, it is important

to note that false positive results can occur with nontreponemal tests in certain viral infections like varicella (chickenpox) and measles, as well as in conditions such as lymphoma, tuberculosis, malaria, endocarditis, connective tissue disease, and pregnancy [5]. Due to the possibility of false positives with nontreponemal tests, confirmation of the diagnosis is necessary using a treponemal test, such as the *Treponema pallidum* Particle Agglutination Assay (TPPA) or the Fluorescent Treponemal Antibody Absorption Test (FTA-Abs) [3]. Treponemal tests typically seroconvert two to five weeks post-infection and can sustain positivity over extended periods [6].

Direct detection methods: Dark field microscopy of serous fluid collected from a chancre is a valuable diagnostic technique that allows for immediate identification of syphilis. In addition to this method, two other tests can be conducted on samples obtained from the chancre to confirm the diagnosis. The first is the Direct Fluorescent Antibody (DFA) test, which utilizes antibodies labelled with fluorescein. These antibodies bind to specific proteins associated with syphilis, enabling their visualization under fluorescent microscopy. The second test is the Polymerase Chain Reaction (PCR), which employs molecular techniques to detect the presence of specific syphilis genes within the sample [4].

It is important to note that, although powerful, dark field microscopy, DFA, and PCR should be synergized with clinical appraisal, patient's anamnesis, and auxiliary laboratory assays to guarantee a comprehensive and accurate diagnosis.

Prevention

By 2022, development of a syphilis-specific vaccine remains elusive, amplifying the urgency of alternative preventive stratagems. Abstinence or sustained monogamy remain effective strategies. Latex condom usage is advocated for its prowess in diminishing syphilis transmissibility. Abstaining from physical intimacy with affected individuals is paramount. Vigilance against recreational drug misuse is pivotal, given its propensity to cloud judgement, thereby augmenting unsafe sexual conduct and syphilis risk.

Congenital syphilis in the newborn can be prevented by screening mothers during early pregnancy and treating those who are infected [7]. Regular screenings for sexually transmitted infections, encompassing syphilis, are paramount for those sexually active or engaging in high-risk behaviors. Early syphilis detection and intervention are instrumental in preventing further transmission and concomitant complications.

Difference between syphilis and HIV

Syphilis and HIV exhibit notable distinctions as Sexually Transmitted Infections (STIs). Syphilis, caused by bacteria, can be effectively treated with antibiotics, ensuring a potential cure upon identification. Although syphilis can lead to severe and potentially fatal consequences without treatment, it is relatively easy to manage once diagnosed. Conversely, HIV is caused by a virus and, while Highly Active Anti-Retroviral Therapy (HAART or cART) can effectively treat it, a complete cure is currently unattainable [8].

Despite their differences, syphilis and HIV share certain characteristics. During the early stages of infection, both STIs can be challenging to detect without medical intervention. Syphilis sores in the initial stage are typically painless and may go unnoticed if they are not easily visible. Similarly, newly acquired HIV infections often present no identifiable symptoms, and individuals infected with HIV can remain asymptomatic for years or even decades. Furthermore, these infections have long been recognized as mutually enhancing susceptibility. Syphilis sores provide an entry point for HIV, while HIV weakens the immune system, making it easier for syphilis to establish itself. These observations underscore the critical importance of early detection of both HIV and syphilis, as well as the significance of accurate differential diagnosis to enhance patient outcomes.

Materials and Methods

Evaluation of the performance of syphilis rapid test compared with TPPA

Objective: The primary intent of this evaluation report centered on assessing the reliability and performance of the Syphilis Rapid Test Cassette (Whole Blood/Serum/Plasma) for the rapid diagnosis of syphilis infections. Syphilis, an ailment resulting from the bacterium *Treponema pallidum*, necessitates accurate and prompt identification to ensure optimal effective patient care and to curtail its spread.

Method: The evaluation process involved a comprehensive analysis of the performance characteristics of the Syphilis Rapid Test Cassette. Clinical studies, involving human-derived samples–whole blood, serum, and plasma–were collected to quantify the test's sensitivity, specificity, and overall accuracy. The performance of the Syphilis Rapid Test was assessed by comparing its results with those obtained from gold-standard reference modalities, notably the TPPA (*Treponema pallidum* Particle Agglutination) assay.

Principle: The Syphilis Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane based immunoassay for the detection of TP antibodies (IgG and IgM) in whole blood, serum or plasma. In this test procedure, recombinant Syphilis antigen is immobilized in the test line region of the test. After specimen is added to the specimen well of the cassette, it reacts with syphilis antigen coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized Syphilis antigen. The double antigen test format can detect both IgG and IgM in specimens. If the specimen contains TP antibodies, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain TP antibodies, a colored line will not appear in this region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Materials and directions for use: The Syphilis Rapid Test kit includes the following components: Test cassettes, droppers, and buffer. Additional materials required to conduct the experiment include specimen collection containers, centrifuge, timer, lancets, heparinized capillary tubes, and a dispensing bulb.

Prior to conducting the test, it is important to ensure that the test, specimen, buffer, and/or controls have reached room temperature (15-30˚C). Therefore, it is recommended to allow them to equilibrate at room temperature before proceeding. To ensure accurate testing, place the cassette on a clean and level surface. When dealing with Serum or Plasma specimens, hold the dropper in a vertical position and carefully transfer 1 drop of serum or plasma (approximately 40 µL) to the designated specimen area on the cassette. Subsequently, add 1 drop of buffer (approximately 40 µL) to the same area, and initiate the timer.

For *venipuncture* whole blood specimen: In accordance with the instructions, hold the dropper in a vertical position and carefully transfer 2 drops of whole blood (approximately 80 µL) to the designated specimen area on the test cassette. Subsequently, add 1 drop of buffer (approximately 40 µL) to the same area, and initiate the timer as per the provided guidelines.

For *fingerstick* whole blood specimen: In order to perform the test using a capillary tube, it is necessary to fill the tube with fingerstick whole blood specimen, ensuring an approximate volume of 80 µL. Subsequently, transfer the collected blood to the designated specimen area on the test cassette. Following this, add 1 drop of buffer (approximately 40 µL) to the same area and initiate the timer as instructed.

Alternatively, if the hanging drops method is preferred, allow 2 hanging drops of fingerstick whole blood specimen (approximately 80 µL in total) to descend into the specimen area of the test cassette. Then, add 1 drop of buffer (approximately 40 µL) to the same area and start the timer. It is important to carefully follow these procedures to obtain accurate and reliable results.

Results and Discussion

After conducting the test, it is necessary to wait for the appearance of the colored line(s). The results should be read precisely at the 5 minute mark. It is important to note that interpretation of the results should not be done after 20 minutes since the test was performed.

Performance characteristics

The Syphilis Rapid Test Cassette (Whole Blood/Serum/Plasma) accurately identified the specimens from a performance panel. This was further cross-referenced with outcomes from a leading commercial TPPA Syphilis test, using actual clinical samples. The results underscored the efficacy of the Syphilis Rapid Test Cassette (Whole Blood/Serum/Plasma): It demonstrated a relative sensitivity exceeding 99.9% and a relative specificity is 99.7%. This attests to the test's reliability and its potential as a crucial diagnostic tool for syphilis detection (Table 1).

Method		TPPA		Total results
Syphilis Rapid test Cassette (Whole Blood/ Serum/ Plasma)	Results	Positive	Negative	
	Positive	200	1	201
	Negative	0	319	319
Total results		200	320	520

Table 1: Syphilis rapid test cassette vs. TPPA.

Relative Sensitivity: >99.9% (95%CI*: 99.4%-100%)

Relative Specificity: 99.7% (95%CI*: 98.3%-100%)

Accuracy: 99.8% (95%CI*: 98.9%-100%)

*Confidence Interval

Conclusion

The comparative study presented in this report indicates that the Syphilis rapid test developed by Hangzhou AllTest Biotech Co., Ltd., in comparison to the TPPA results. Demonstrating ultra-high specificity, sensitivity, and accuracy, this test sets a standard in the advancement in diagnostic methodologies for sexually transmitted infections.

One of the notable features of this rapid test is its user-friendliness, which greatly simplifies the diagnostic process for healthcare practitioners. Its design focuses on providing rapid results, a feature that is paramount in conditions like Syphilis where timely diagnosis can significantly influence patient outcomes.

Furthermore, the Syphilis rapid test offers precision in its results, giving healthcare practitioners confidence in providing patient care. In addition to its clinical merits, the test presents an opportunity to bridge the diagnostic gaps in remote and underserved populations, potentially bringing about a notable reduction in global Syphilis prevalence.

However, while these findings hold promise, it is essential to mention that more exhaustive evaluations in diverse real-world settings might provide further insights. Future studies might focus on understanding the utility and reception of this diagnostic tool among different cohorts of healthcare professionals. Also, ongoing research suggest there's still room for improvement, especially in the detection of treponemal antibodies, emphasizing the dynamic nature of medical research and the continuous pursuit of early detection. These results strongly advocate for the integration of the Syphilis rapid test by Hangzhou AllTest Biotech Co., Ltd., into broader screening regimens.

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