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Performance Characteristics of Malaria P.f./P.v./Pan Rapid Test Kits Compared with Traditional Microscopic Analysis Method

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Abstract

Background: In the 21st century, malaria continues to be a serious public health threat. This infectious disease has been responsible for millions of deaths globally, especially in tropical regions. It is difficult to distinguish infection with Plasmodium causes clinical presentation from other fever-causing pathogens. Rapid and accurate diagnosis becomes important for effective malaria case management and surveillance.

Although microscopy was once widely used in parasite-based malaria diagnosis, it was apt to face obstacles when using microscopy in peripheral health care settings. The landscape of malaria diagnostic testing has changed since malaria rapid tests were first commercialized in the early 1990s.

Objective: The main purpose of this evaluation report was to explore the reliability and performance of the All Test Malaria Rapid Test Kits for the qualitative detection of circulating antibodies of P. falciparum (P.f.), P. vivax (P.v.), P.ovale (P.o.). And P. malariae (P.m.) in whole blood to aid in the diagnosis of malaria infection.

Method: Run a rapid in vitro diagnostic test device for detection of Malaria P.f./P.v./Pan in Whole Blood and compare with traditional thick and thin blood films microscopic analysis for validation of the performance.

Results: The results show that the relative sensitivity of the Malaria P.f./P.v./Pan Rapid Test Cassette (Whole Blood) is >98.7% and the relative specificity is >99.0%.

Conclusion: The Malaria P.f./P.v./Pan Rapid Test Cassette (Whole Blood) is a rapid test to qualitatively detect the presence of P. falciparum - specific HRP-II, P. vivax (P.v.) and four kinds of circulating plasmodium falciparum (P.f.), P. vivax (P.v.), P. ovale (P.o.), and P. malariae (P.m.).

The test kit is simple to operate and results are obtained quickly. The use of the test kit will help in the diagnosis of malaria in situations where microscopes are unavailable and professional microscopists are inadequate. Additionally, the test kit has a very high accuracy (99.1%), sensitivity (98.7%), and specificity (99.3%). Patients can obtain accurate test results by using All Test Malaria P.f./P.v./Pan Rapid Test Cassette.

Keywords: Malaria; Rapid Test; RDTs; Infectious Disease

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Introduction

Facts about Malaria

Malaria is a life-threatening disease caused by parasites that are transmitted to people through the bites of infected female Anopheles mosquitoes [1]. For thousands of years, victims of malaria have included Neolithic inhabitants and early Chinese and Greeks. In the 20th century alone, malaria claimed 150 to 300 million lives, accounting for 2% to 5% of all deaths [2]. In the annals of history, malaria occupies a unique place.

At present, malaria is still endemic in many tropical countries. US National Center for Biotechnology Information indicates that the main victims of malaria are the poor in sub-Saharan Africa, Asia, the Amazon Basin, and other tropical regions.

According to the World Malaria Report 2020, there were 241 million cases of malaria globally in 2020 (uncertainty range 218–269 million) and 627,000 malaria deaths (uncertainty range 583–765 thousand). Malaria case incidence reduced from 81 in 2000 to 59 in 2015 and 56 in 2019, before increasing again to 59 in 2020 [3]. Cruel evidence reveals a fact that malaria is destined to become a worldwide threat that needs to provoke global attention and concern.

Symptoms caused by malaria typically include fever, fatigue, vomiting, and headaches. More severely, malaria can cause jaundice, seizures, coma, and even death. Therefore, malaria should be considered a potential medical emergency. According to Makanjuola, R. and Taylor-Robinson, A [4], rapid diagnosis remains the front-line action to initiate a timely and appropriate medical intervention to combat malaria which is one of the major global public health threats. The use of rapid diagnostic tests may effectively decrease the amount of time that it takes to determine that a patient is infected with malaria.

Prevention and Diagnosis for Malaria Control

Over several decades, researchers have struggled to develop vaccines to solve this infectious disease. However, at this time, none are effective and successful yet. Since it is currently impossible to employ vaccines in providing protection against malaria, malaria control by early diagnosis and treatment becomes crucial in global malaria management.

The World Health Organization (WHO) point out that malaria is both preventable and curable. Site-based diagnostic testing can minimize sickness and mortality by enabling healthcare providers to quickly differentiate between malarial and non-malarial fevers and select the most effective therapy. It contributes to the overall care of patients with febrile diseases and may also help prevent medication resistance from developing and spreading [5].

Meanwhile, for people who live in or travel to areas where malaria is common, some preventive actions are indispensable to lower the probability of getting malaria.

The WHO also recommends that all patients with suspected malaria receive prompt malaria diagnosis using microscopy or rapid diagnostic tests (RDTs) before receiving therapy. Early and precise diagnosis is critical for both good illness care and efficient malaria monitoring [5]. If a person develops symptoms of malaria, it is necessary to look for healthcare providers immediately, to seek treatment and medication to cure malaria effectively.

Malaria Diagnostic Methods

Malaria diagnostic methods generally include clinical diagnosis, microscopic diagnosis, rapid tests for antigen detection, molecular diagnosis (such as PCR), serology, and drug resistance tests. Among them, microscopic examination and rapid tests are the most widely used in malaria diagnosis [5].

Microscopy and Rapid Test

The commonly used method of malaria diagnosis is using microscopy to observe the plasmodium parasite within the erythrocyte. It is a diagnostic method that is highly available even in a remote laboratory setting, easily used, and yet needs an experienced and professional microscopist [6]. However, this method is unlikely to detect infections with low density by conventional microscopy.

Rapid tests, however, require no technical equipment and expertise for operating. Unlike microscopy examination, the accuracy is rarely affected by operational limitations or technical problems. Additionally, it can be performed directly at the point-of-care and yield results in 10 minutes, allowing the patient to obtain results quickly.

Evaluation of All Test Malaria P.f./P.v./Pan Rapid Test Cassette

Materials in All Test Malaria P.f./P.v./Pan Rapid Test Cassette

In this test kit, materials provided included a test cassette, disposable specimen droppers, buffer, and a package insert.

Evaluation Method

The following data were collected after obtaining the participants' consent. Blood samples were collected from each patient and subjected to malaria diagnosis using All Test Malaria P.f./P.v./Pan Rapid Test Kits and microscopy by experienced staff.

All test Malaria P.f./P.v./Pan Rapid Test Cassette (Whole Blood) is a qualitative, membrane-based immunoassay for the detection of P.f., P.v., P.o. and P.m. antigens in whole blood to aid in the diagnosis of infection. In this study, All Test Malaria P.f./P.v./Pan Rapid Test Kit has been compared with traditional thick and thin blood film microscopic analysis.

Direction for Using All test Malaria P.f./P.v./Pan Rapid Test Cassette

The Malaria P.f./P.v./Pan Rapid Test Cassette can be performed using whole blood. Both finger stick whole blood and venipuncture whole blood can be used.

The first step involves the use of a pipette which is not provided in the materials of the test kit. The operator used a pipette to transfer 5µL of whole blood to the Specimen well (S), and added 3 drops of buffer (approximately 180 µL) to the Buffer well (B), and began a timer.

The next step requires a disposable specimen dropper to be held vertically. Then, draw the specimen up to the upper end of the nozzle (approximately 5 µL).

After that, transfer the specimen to the Specimen well (S). Three drops of buffer (approximately 180 µL) should be added to the Buffer well (B), and then the timer can be started.

The test results can be obtained in 10 minutes or less once a colored line appears. Results should not be interpreted after 20 minutes.

Interpreting Results Instructions

Instructions for interpreting the results are illustrated as follows:

Positive:* Two or Three or Four distinct colored lines appear.

P. falciparum Infection (Either of the results)

One line appears in the control region, one line appears in the P.f. line region.

One line appears in the control region, one line appears in the P.f. line region and one line appears in Pan line region.

P. vivax Infection (Either of the results)

One line appears in the control region, one line appears in the P.v. line region.

One line appears in the control region, one line appears in the P.v. line region and one line appears in Pan line region.

Non-P. falciparum/ Non-P. Vivax Infection

One line appears in the control region, one line appears in the Pan Line region.

Mixed malaria infection

One line appears in the control region, one line appears in the P.f. line region, and one line appears in the P.v. line region.

One line appears in the control region, one line appears in the P.f. line region, one line appears in P.v. line region and one line appears in Pan Line region.

***Note:** The color intensity of P.f., P.v. or Pan Test lines may vary depending on the concentration of antigens, viz., HRP-II, P.v. LDH or Plasmodium-specific LDH present in the specimen.

Negative: Only one colored line appears in the control region.

Invalid: Control line fails to appear.

Results Analysis

The correlation between the two systems is over 99.0%. The results show that the sensitivity of All Test Malaria P.f./P.v./ Pan Rapid Test Cassette is >98.7% and the relative specificity is >99.0% when compared to results obtained from microscopy. (See Table: All Test Malaria P.f./P.v./ Pan Rapid Test Kits Compared to Microscopy Analysis)

Within-run precision has been determined by using 3 replicates of ten specimens: negative, P.f. low positive, P.f. middle positive, P.f. high positive, P.v. low positive, P.v. middle positive, P.v. high positive, Pan Low positive, Pan middle positive, Pan high positive. The specimens were correctly identified >99% of the time.

Between-run precision has been determined by 3 independent assays on the same ten specimens: negative, P.f. low positive, P.f. middle positive, P.f. high positive, P.v. low positive, P.v. middle positive, P.v. high positive, Pan Low positive, Pan middle positive, Pan high positive. Three different lots of All Test Malaria P.f./P.v./ Pan Rapid Test Cassette have been tested using these specimens. The specimens were correctly identified >99% of the time. (**Table 1**)

Table 1. All Test Malaria P.f./P.v./ Pan Rapid Test Kits Compared to Microscopy Analysis.

Method		Microscopy		Total Results
Malaria P.f./P.v./Pan Rapid Test Cassette (Whole Blood)	Results	Positive	Negative	
	Positive	77	1	78
	Negative	1	148	149
Total Results		78	149	227

Relative Sensitivity: 98.7% (95%CI*: 93.1%~100%)
Relative Specificity: 99.3% (95%CI*: 96.3%~100%)
Accuracy: 99.1% (95%CI*: 96.8%~99.9%)

All Test Malaria P.f./P.v./Pan Rapid Test Cassette has been tested for positive specimens of HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-Syphilis, anti-HIV, anti-HCV, and anti-H. Pylori, anti-MONO, anti-CMV IgM, anti-Rubella IgM and anti-TOXO IgM. The results showed no cross-reactivity.

Summary

Based on the detection of parasite antigens in patient blood, RDTs effectively offer qualitative diagnosis to determine whether an individual has been infected with malaria using immunochromatographic lateral flow devices [7]. The All Test Malaria P.f./P.v./Pan Rapid Test Cassette in this evaluation performed satisfactorily in standard experimental conditions. The tests showed both excellent sensitivity and specificity. The results of tested samples demonstrate that the Malaria P.f./P.v./ Pan Rapid Test Cassette developed by Hangzhou All Test Biotech Co., Ltd meets the requirements of in vitro diagnostic intended use.

Thus, a conclusion can be drawn that All Test Malaria P.f./P.v./ Pan Rapid Test Cassette is capable to be employed in malaria diagnosis.

References

1 WHO (2022) Fact sheet about malaria [online] Available at: <https://www.who.int/news-room/fact-sheets/detail/malaria>

2 Carter R, Mendis KN (2002) Evolutionary and historical aspects of the burden of malaria. Clin Microbiol Rev 15:564-594.

3 WHO int (2022) Malaria <https://www.who.int/data/gho/data/themes/malaria>

4 Makanjuola R, Taylor-Robinson A (2020) Improving Accuracy of Malaria Diagnosis in Underserved Rural and Remote Endemic Areas of Sub-Saharan Africa: A Call to Develop Multiplexing Rapid Diagnostic Tests. Scientific 1-7.

5 WHO int (2022) diagnostic testing for malaria.

6 LE Fitri (2016) WHO Malaria Microscopy Quality Assurance Manual-Ver 2 WHO. WHO Press 1-2.

7 Cunningham J (2019) A reviews of the WHO malaria rapid diagnostic test product testing programme (2008–2018): performance, procurement and policy. Malar J 18.