Cell. Mol. Biomed. Rep. (ISSN: 2823-2550)
https://doi.org/10.55705/cmbr.2023.376615.1089
2023, 3(3): 152-161

Original Article

Performance and accuracy of SD Bioline malaria Ag P.f (05fk50) in relation to microscopy as the gold standard technique for malaria diagnosis

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Article info
Received: 04 Dec 2022
Revised: 19 Feb 2023
Accepted: 25 Mar 2023

Use your device to scan and read the article online

Keywords:
Isothermal Amplification, Loop-Mediated Isothermal Amplification, Nucleic Acid Amplification Techniques, *P. falciparum*, *P. vivax*, *P. knowlesi*

ABSTRACT

Successful malaria diagnosis is the mainstay of successful treatment, prevention and eradication of malaria infection. Apart from the gold standard technique (Microscopy), numerous diagnostic techniques perform a similar function to microscopy and in most cases tend to have varying sensitivity and specificity, especially when compared with the gold standard technique. Therefore this study aimed to determine the Performance and accuracy of SD Bioline Malaria Ag P.f (05fk50) (Rapid Diagnostic Test kit) to Gold standard (Microscopy). A total of two hundred (200) samples were collected from the consented study subjects and analyzed using RDT and Giemsa staining technique. The result revealed an overall prevalence of 132(66.0%) and 167(83.5%) respectively by RDT and Microscopy, where 115 (57.5%) were true positive, there was no significant difference between the two techniques ($P > 0.05$, $df = 1$, $\chi^2 = 3.695$). The RDT recorded a sensitivity and specificity value of 68.86% and 48.48% respectively with a positive predictive value of 87.78% and a negative predictive value of 23.53%. The RDT recorded an overall accuracy of 0.66. The Rapid Diagnostic test kit used in the present demonstrated a high level of sensitivity and positive predictive value with relatively low specificity and negative predictive value. Regular checks on the Performance and accuracy of all brands of RDT should be conducted as their performance can be easily affected by some intrinsic and extrinsic factors.

1. Introduction

Malaria infection is a deadly parasitic disease that is endemic in sub-Saharan Africa. The disease is caused by five species of genus *Plasmodium*, which include *P. falciparum, P. vivax, P. ovale, P. malariae* and *P. knowlesi* which causes acute, severe illness but mortality rates are low [1]. *P. falciparum* and *P. vivax* are the most prevalent of all the specie [2], but *P. falciparum* is the most deadly and causes most of the malaria episodes in the tropics [3] and *P. knowlesi* causes severe form the disease [4]. This is partly due to favorable conditions for the optimum survival of both the parasite and the vector in the region. The parasites are transmitted to the susceptible host through the bite of a female Anopheles mosquito during a blood meal [5].

In 2019, according to the world malaria report of 2020, globally there were about 229 million clinical cases of malaria with about 409,000 deaths 94% occurring in Sub-Saharan Africa [6], as such the disease ranked second as the infectious disease that causes

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high mortality apart from HIV [7] and Nigeria alone bears about 25% of this burden [8].

Successful prevention and treatment of malaria infection heavenly depends on the successful diagnosis of the causative agent of the disease using reliable and recommended techniques. This is because, in so many regions of the world where the disease is endemic, there are always multiple etiologies of fever, headache, excessive sweating, pain, and shivering, one of the leading symptoms of malaria. These may however lead to misdiagnoses and hence wrong treatment [9]. It is also on this background, that the World Health Organization strongly condemns only treatment without an evidence-based diagnosis that demonstrates the presence of parasites or parasite parts/products in the host and their developmental stages [10] and also requires parasitological confirmation by malaria RDT (mRDT) and/or microscopy. However, some of the advantages of effective diagnosis includes, detecting the presence of the parasite, its specie and its developmental stage for appropriate treatment [11]. In addition, the global malaria policy of universal testing and treatment recommends the detection of malaria cases within the first 24h for effective early treatment [12], this prevents the spread of the disease and also stops its progression into a severe form of the disease [13].

The various diagnostic tools currently available and recommended by the World Health Organization include light and fluorescence microscopy, immune-chromatographic lateral flow assays (commonly known as Rapid Diagnostic Tests (RDTs), flow cytometry, serology and Nucleic Acid Amplification Techniques (NATs) which comprise of Polymerase Chain Reaction and isothermal amplification, Loop-mediated isothermal amplification (LAMP)). Out of these, the most commonly performed diagnosis at primary health care levels and so many other laboratories in Nigeria are either microscopy or RDT [14]. This is partly due to the availability of reagents and the cost-effectiveness of the techniques. Microscopy is regarded as the 'gold standard' for malaria diagnosis [15]. However, the lack of skilled technologists in medical facilities in affected areas often leads to poor interpretation of data. Furthermore, microscopy is time-consuming and labour intensive, cannot detect sequestered *P. falciparum* parasites and is less reliable at low-density parasitaemia [16].

Rapid diagnostic assays detect parasite antigen Histidine-Rich Protein 2 (HRP-2), enzymes parasite lactate dehydrogenase (pLDH) and Aldolase [17] being the targeted antigens for *P. falciparum* and the four common *Plasmodium* species. Due to the technical complications associated with microscopy and it less applicability of the technique in rural areas, coupled with a long time of processing sample and interpreting results, the simple and less technical Rapid Diagnostic Technique have been routinely used in most reference laboratory. Both techniques (Rapid Diagnostic Technique and Microscopy) sometimes produce similar or two parallel results, for instance it has reported [18] that the sensitivity and specificity of microscopy were 42.7% and 99.3%, and RDT showed 49.9% and 90.4%, respectively, from two North-Eastern states of India, while it has reported [19] that, the sensitivity and specificity of studies comparing RDT with microscopy varies from 79%–100% to 80%–100%, respectively

Therefore this study aimed to evaluate the performance Rapid Diagnostic Test in relation to microscopy which is the gold standard for malaria diagnosis.

2. Materials and Methods

2.1. Study Area

The study was conducted in Gombe Local Government Area, Gombe State, Nigeria. The Local Government lies between 11°14′07″E and 11°4′42″E, and Latitudes 10°16′48″N and 10°17′24″N with a total land mass of 52km^2. According to the National Population Commission, Gombe Local government has a projected population figure of 367,500 people (3.3% annual change).

The local government being the capital of the state, both the tertiary (Federal Teaching Hospital) and the secondary (Gombe State Specialist Hospital) health facilities of the state are domiciled in the local government.

This is also in addition to the primary health care centers that are strategically located in each ward of the local government; also there are quite a number of private hospitals providing different services including malaria diagnosis and treatment which provide different services including malaria diagnosis and treatment.

2.2. Ethical consideration and Consent of the Subjects

Before the commencement of the research, the research proposal was submitted to the Gombe State Ministry of Health for approval. After which the approval was communicated via a later MOH/ADM/621/VOL.I/222. Verbal and or written consent of the subject was sought after briefing them on the research and the need for them to participate. In a situation whereby the subjects were not mature enough, consent of his/her parents/guardian was sought. All the subjects were assured that all information collected from the study subjects will be strictly used for the research and will be treated with a high level of confidentiality. In addition, quality control and quality assurance were assured when handling and treating each of the samples.

2.3. Study Subjects and Inclusion Criteria

Human beings of all age groups and gender who willingly and voluntarily agreed to participate were used as the study subjects for the research. Three recruitment centers were selected; Gombe Town Maternity (gidan Magani), Sunnah Clinic and Idi Children and Women Hospital Gombe, with a total of 200 volunteers actively participating in the study.

Only patients who reported themselves to the selected hospitals with (presumed to be malaria positive) symptoms of malaria (fever) or a history of fever in the last 24 hours and were referred by a physician for the screening of malaria infection and in addition they have not used any anti-malarial drugs 60 days prior to the data collection. All subjects having multiple infections were not recruited; only subjects with *Plasmodium falcifarum* mono-infection were recruited.

2.4. Blood sample collection and analysis

The blood samples were collected using the vein puncture technique with the help of medical personnel. Briefly, a Soft tubing tourniquet was fastened onto the upper arm of the respondents to enable the index finger to feel a suitable vein. The puncture site was then be cleaned with 70% alcohol and the venipuncture was made with the aid of a needle attached to a 5ml syringe. When sufficient blood samples had been collected, the tourniquet was removed and the needle removed immediately, after which the blood was transferred into an EDTA container and transferred to the laboratory for analysis.

2.5. Rapid Diagnostic Test

For the rapid diagnostic test, the SD Bioline Malaria Ag P.f (05fk50) kit was used. In this, about 5µl of the collected blood sample from the labeled EDTA container was taken with a pipette provided with the kit. After which it was loaded into the sample well (S) of the RDT. Two drops of provided buffer were loaded into the buffer well of the same RDT. The result was then read within 15-20 minutes as recommended by the manufacturer.

2.6. Microscopy

The collected blood samples were analysed within 1 to 2 hours after collection. Thick and thin films were prepared according to the standard technique. A drop of blood sample was placed on the center of grease-free slides. After which, the reverse side of the slides was cleaned with cotton wool and allowed for air-drying and stained with Giemsa stain for 1 hour. After which the slides were washed off gently with clean water. The slides were left in a rack in order to air-dry for eventual examination of the slides under a microscope, using oil immersion at 100× magnification to observe for *Plasmodium* parasite. The presence of ring forms and or Trophozoites of *Plasmodium* indicated positive results while the absence of either Trophozoites or ring form indicate negative results after a period of 10 minutes of a thorough examination by a qualified microscopist under 100× high power field of the microscope.

2.7. Performance of RDT and accuracy determination

The following formulas were used to determine the performance of the RDT kit used and it accuracy

Sensitivity = True positive/(True positive + false negative)

Specificity = True negative/(True negative + false positive)

Positive predictive value = True positive /(True positive + false positive)

Negative predictive value = True negative/(True negative + false negative)

Accuracy = True positive + false positive/(True positive + false positive + false negative + True negative)

3. Results

3.1. Demographic and clinical characteristics of the subjects

The subjects comprised of 114(57.0%) male and 86(43.0%) female. The age of the subjects ranges from 5-55 years with a mean age of 28.51±10.57 and the ambient body temperature of the subjects at the time of blood sample collection ranges from 33-43^{o}C with a mean of 37.77±1.92.

3.2. Prevalence of malaria

Figure 1 shows the result of malaria prevalence using microscopy and rapid diagnostic technique. The result revealed that, out of the 200 samples examined, a prevalence of 132(66.0%) and 167(83.5%) were respectively recorded using rapid diagnostic tests and microscopy. Statistically, there was no significant difference between the two techniques (P> 0.05, df= 1, χ^2 = 3.695).

3.3. Result of RDTs to Microscopy

Out of the two hundred samples examined by RDT and microscopy, the result revealed that 115(57.5%) were true positive, which is confirmed to be positive by both techniques and on the other hand, 52(26.0%) of the examined sample were negative for *Plasmodium falciparum* with microscopy, thus false negative. 16(8.0%) of the sample were true negative and 17(8.5%) were negative by RDTs as shown in table 1 below

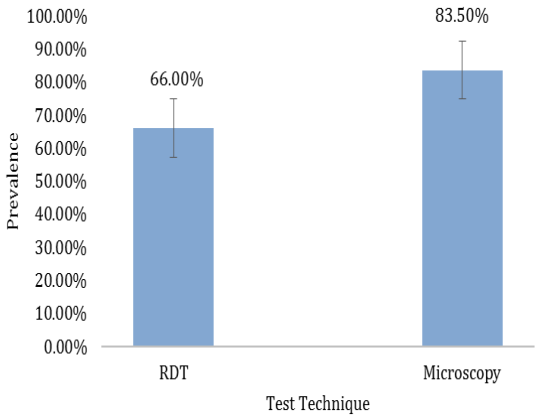

Fig. 1. Malaria prevalence using RDT and Microscopy **(**P> 0.05, df= 1, χ^2 = 3.695**)**

Table 1. Result of RDT to microscopy

Technique	Microscopy		
Positive	Positive	Negative	Total
RDT	115(57.5%)	17(8.5%)	132(66.0%)
Negative	52(26.0%)	16(8.0%)	68(34.0%)
Total	167(83.5%)	33(16.5%)	200(100%)

3.4. Performance and accuracy of RDT

Table 2 below shows the performance and accuracy of the rapid diagnostic test kit (SD Bioline Malaria Ag P.f (05fk50)). The result revealed a sensitivity value of 68.86% and a specificity of 48.48%. A positive predictive and negative predictive value of 87.78% and 23.53% were respectively recorded. The rapid diagnostic technique revealed an overall accuracy level of 0.66

Table 2. Performance and accuracy of RDTs

Parameter	Value
Sensitivity	68.86%
Specificity	48.48%
PPV	87.78%
NPV	23.53%
Accuracy	0.66

Key: PPV= Positive predictive value, **NPV**= Negative predictive value

4. Discussion

In the present study, the performance and accuracy of SD Bioline Malaria Ag P.f (05fk50) (RDT kit) was evaluated to the gold standard technique (Microscopy). Rapid diagnostic tests using different kits have been employed in various laboratories in Nigeria due to so many technicalities and challenges associated

with microscopy which include, compromising standards due to poor infrastructures, and high expertise among others [20] and in some cases the urgent need of providing result due to deteriorating condition of the patient.

In this study, the two techniques (RDT and Microscopy) revealed two different diagnostic results of 132(66.0%) and 167(83.5%) respectively, where 57.8% were found to be truly positive. This disparity could be attributed to some of the inherent and external factors, like the stability of the RDT which include exposure to extreme temperatures, which has been found to the major contributor to poor performance of RDT, especially during transport as well as storage as observed by previous research [21]. In addition, this disparity between the two techniques could be attributed to the false positive and false negative reported in some samples by the RDT. False positive diagnosis in most cases led to about 50-99% unduly treatment of the disease especially in African countries [22], which may lead to the development of resistance by the parasite [23].

False positive is mainly due to the persistence of the antigens of the parasite (HRP2, HRP3, pLDH and aldolase antigens) [24] in the blood for up to 28 days even after clearance of the asexual stage of the parasite with chemotherapy [25], as a such passive form of the infection cannot be distinguished from active infection [26]. On the other hand, a false negative diagnosis always increases the number of carriers (reservoir hosts) of the parasite (*Plasmodium falciparum*) in a community, especially when clinical symptoms have not been developed (asymptomatic patients). The presence of false negatives in a population is a major public health problem as such subjects can still harbour the parasite but are not treated due to misdiagnosis. This could have serious implications as it will aid new transmission and possibly mortality. One major factor that is usually attributed to false negative diagnosis is mainly due to either mutation or complete deletion of antigen (HRP2 HRP3, pLDH and aldolase antigens) of the parasite [27-29], in addition, parasite density could also lead to false negative diagnosis [30], though it was not considered in the present study. The false negative recorded in the present study (8.5%) is by far lower than 26.7 and 22.2% but similar to the 11.11% reported by previous research [31] when comparing the effectiveness and accuracy of three different Raid Diagnostic kits.

The Prevalence (66.0% and 83.5%) recorded by the two techniques clearly reflects the pattern of high transmission and also demonstrates the endemicity of the disease in the study area. These findings are in agreement with the findings of [32] who reported a malaria prevalence of 60.6% from Hausa communities in Kano, Nigeria and [33] who also a prevalence of 80.5% from Ogun state, Southwestern Nigeria. Only one specie (*Plasmodium falciparum*) was reported in the present study, this is not surprising, as the specie is the most prevalent species that cause about 99% of all malaria cases in subtropical African countries, Nigerian inclusive [34]. This finding is in agreement with the finding of [35] who similarly reported *Plasmodium falciparum* as the only prevalent specie from two Tertiary Care Hospitals in Rivers State, Nigeria.

The sensitivity (68.86%) and specificity (48.48%) of RDT recorded in the present study contradict the findings of [36] who reported a sensitivity and specificity of 17.8% and 100% respectively from asymptomatic subjects in Korhogo, Northern Côte d'Ivoire. This also differs from the result of [37] who reported high RDT sensitivity and specificity values of 95.8 and 97.3% respectively in Uganda. This disparity in the sensitivity and specificity values recorded in the present study could be ascribed to the false positive and false negative diagnosis which affected the sensitivity and specificity of the RDT. It has reported [38] a high sensitivity value of 97.5% from the PCR diagnostic technique, but with a similar specificity value of 40.7% as recorded in the present study. Differences in sensitivity values of the two techniques might be attributed to the fact that PCR has a very sensitivity as it detects the presence of *Plasmodium falciparum* below the threshold of other diagnostic techniques like microscopy

and RDT, as it can detect as low as 0.01-1parasite/μL of blood [39].

The positive predictive value (PPV) of a test is described as the proportion of the actual people with a positive test result who have a disease condition, while the Negative Predictive Value is the proportion of people with a negative test result who really do not have the disease [40]. Positive (87.78%) and Negative predictive values (23.53%) recorded in the present study is lower than 100% and 91.2% positive and negative predictive values reported by previous research [41-44]. The accuracy (0.66) of the RDT recorded in the present study is lower than the 0.98 reported by previous research [45-48] among Non-Severe Febrile Patients in two Tanzanian Hospitals. The differences observed in the accuracy values could be ascribed to the .sensitivity of the two diagnostic techniques.

5. Conclusion

SD Bioline Malaria Ag P.f (05fk50) used in the present demonstrated a high level of sensitivity and positive predictive value with relatively low specificity and negative predictive value. Though the sensitivity demonstrated by the RDT in the study is lower than the world health organization's recommended value, it can still be used as an alternative to the microscopic diagnostic technique for malaria, especially in rural areas as it demonstrated an appreciable level of high accuracy.

Abbreviations

LAMP: Loop-mediated isothermal amplification
mRDT: malaria RDT
NATs: Nucleic Acid Amplification Techniques
PPV: Positive Predictive Value
RDTs: Rapid Diagnostic Tests

Conflict of interest

The authors declare that there is no conflict of interest to publish this manuscript.

Consent for publications

All authors have read and approved the final manuscript for publication

Data Availability Statement

All data generated or analyzed in this study are available from the corresponding author upon reasonable request.

Author contributions

All authors read and approved the final manuscript.

Ethics approval and consent to participate

This study was approved by the ethics committee of the Gombe State Ministry of Health, with the ethical code in research: MOH/ADM/621/VOL.I/222

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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How to Cite This Article:

Muhammad I, Sale PM, Muhammad TM, Rufai A, Midala AL, Abubakar B (2023) Performance and accuracy of SD Bioline malaria Ag P.f (05fk50) in relation to microscopy as the gold standard technique for malaria diagnosis. Cellular, Molecular and Biomedical Reports 3 (3): 152-161. doi: 10.55705/cmbr.2023.376615.1089

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