Cell. Mol. Biomed. Rep. (ISSN: 2823-2550)
https://doi.org/10.55705/cmbr.2022.361911.1066

2022, 2(4): 254-264

Research Article

Performance analysis of polymerase chain reaction in relation to rapid diagnostic test (RDT) kit (SD bioline malaria ag p.f (05fk50)) for malaria diagnosis

Ismail Muhammad[1], *, Pukuma Micah Sale[2]. Tanko Mahmoud Mohammed[3], Saleh Zaliha Miyim[4], Asiya Muhammad Usman[5]

Article info
Received: 13 Apr 2022
Revised: 07 Jun 2022
Accepted: 28 Aug 2022

Use your device to scan and read the article online

Keywords:
Sensitivity, Specificity, Positive Predictive Value, Negative Predictive Value, Accuracy

ABSTRACT

Malaria control and its elimination heavenly depend on successful and reliable diagnosis using recommended diagnostic techniques. These available techniques often have certain peculiarities and mode applications, thus making them have different levels of performance and accuracy. Therefore the aim of this study was to evaluate the performance of PCR in relation to Rapid Diagnostic Test Kit (SD Bio line Malaria Ag P.f (05fk50)) in malaria diagnosis. A total of 200 blood samples were collected from the consented study subjects using the vein puncture technique and analysed using PCR and RDTs. *Plasmodium falcifarum*'s DNA was extracted using Quick-DNA™ Miniprep Plus Kit with catalog number D4069. 18SrRNA gene of *Plasmodium falciparum* from chromosome 13 was amplified using the two primers. For the RDTs technique, the SD Bio line Malaria Ag P.f (05fk50) test kit was used. Malaria prevalence of 106(53.0%) and 132(66.0%) were recorded using PCR and RDTs respectively. The PCR demonstrates an overall accuracy of 0.53 with sensitivity and specificity values of 56.06 and 52.94% respectively. The negative and positive predictive values were 69.81 and 38.30% respectively. PCR demonstrated a good level of performance and is therefore recommended as an effective diagnostic tool for malaria, especially in patients where the parasite density/parasitaemia level is very low.

1. Introduction

One of the factors that have ensured the persistence of malaria has been the lack of analytical sensing tools that allow for early and accurate detection in asymptomatic individuals with low parasitemia levels in peripheral blood [1]. As a result, globally malaria demonstrate some difficulties in the process of diagnosis, thus making the disease a very serious public health concern and in fact, regarded as an important parasitic disease of human[2]. The disease is transmitted to humans through the bite of an infected female Anopheles mosquito during a blood meal [3]. Five *Plasmodia* species, namely *Plasmodium falciparum, Plasmodium vivax, Plasmodium ovale*, *Plasmodium malariae* and *P. knowlesi* [4] are the parasites responsible for the actual disease condition with *P. falciparum* being the most lethal [2, 5] and is the most predominant specie in Nigeria and other sub-Saharan African countries [6]. Over half of the world's population lives in malaria-prone areas[7], and according to

[1]*Department of zoology, Gombe State University, Gombe, Nigeria*
[2]*Zooology Department, Faculty of Science, Modibbo Adama University, Yola, Adamawa Sate, Nigeria*
[3]*Department of Biomedical and Pharmaceutical Technology, Federal Polytechnic, Mubi, Adamawa Sate, Nigeria*
[4]*Department of General Studies, College of Nursing and Midwifery, Gombe state, Nigeria*
[5]*Preliminary and general Studies Department, Federal College of Horticulture Dadin Kowa, Gombe State, Nigeria*
***Corresponding Author**: Ismail Muhammad (muhammadismail5609@gsu.edu.ng)*

World Health Organisation (WHO), in 2017 there were about 219 million clinical cases of malaria and about 435,000 malaria deaths in 87 countries in the world, and Nigeria accounts for 25% of these cases [6]. The disease is a serious public health problem, especially in tropical African countries where transmission of the disease occur more often [8] partly due to favourable climatic condition that favours optimal growth, survival and development of both parasite and vector of the disease.

Malaria control heavenly depends on early diagnosis and effective case management using recommended drugs [9], as these may help in early detection of the disease, halts it development and progression to severe form of the disease and also stops the further spread of the disease in a community [10]. In resource-poor settings, diagnosis of malaria has tended to be made clinically without parasitological confirmation [11]. The disease may present clinical signs and symptoms like in other diseases thus making the diagnosis of malaria difficult in such regions. Signs and symptoms of malaria include intermittent fever, body aches and pains, malaise, and generalized body weakness which may also be presented by typhoid disease [12]. Therefore, the World Health Organization (WHO) in 2010, strongly discourages blind treatment of all fevers suspected to be malaria disease, instead, all treatment should be after a parasite-based diagnosis, either by microscopy or rapid diagnostic test (RDT) [13] or any other reliable and recommended technique as the case may be. This is because specific diagnostic methods differentiate between malaria and other febrile illnesses [14].

Different diagnostic methods have been developed since WHO realised the significance of several novel techniques to malaria diagnosis, which include, rapidness, reliability, accuracy and cost-effectiveness. These and so many other additional benefits help to address the various shortcomings of the conventional diagnostic techniques [15] like microscopy which includes long turnaround time, erratic power supply, and need for technical expertise are some of the major challenges [16], though is still considered as a gold standard technique by World Health Organisation [17]. Other recommended malaria diagnostic techniques include Rapid Diagnostic Tests, Polymerase Chain Reaction (PCR), loop-mediated isothermal amplification (LAMP) [17], Quantitative Buffy Coat etc.

The rapid diagnostic test is a test that usually uses only 5-15µL of blood [18], the technique detects the presence of *P. falciparum* antigens in the blood, either histidine-rich protein 2 (HRP2) or lactate dehydrogenase (pLDH). This tool has greatly improved the ability to provide diagnostic services in rural areas of sub–Saharan Africa, this is because RDTs require minimal training and rely on immune-chromatography, which avoids the need for electricity [19]. Because of the relatively long half-life of HRP2 antigen after clearance of an infection, HRP2-based RDTs cannot necessarily distinguish between active and recently cleared infection [20]. Several research has shown that molecular diagnostic-based techniques like PCR have a high level of accuracy (sensitivity and specificity) for detecting malaria parasites [21]. PCR is a molecular method that uses the 18SrRNA gene of the parasite [22]. This technique is the most sensitive method available that can detect even very low parasite counts and allows accurate species identification [23]. Despite the fact it is more sensitive than the other conventional techniques like microscopy and RDTs but requires well-trained staff, sophisticated laboratory equipment and a good quality assurance system [24].

Several studies from many parts of the globe show contrasting results when it comes to the performance of several malaria diagnostic techniques[2, 5, 12, 14, 17, 22, 23]. Therefore, the aim of this paper was to evaluate the performance and accuracy of PCR in relation RDTs in malaria diagnosis.

2. Materials and Methods

2.1. Study area

The study was carried out in Gombe Local Government Area, (Figure 1) 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. Gombe Local Government has a projected population figure of 367,500 people (3.3% annual change). The vegetation of the local government is typical of that of Gombe state, Sudan savannah, and experiences two distinct seasons, a dry season, which usually commences from November to March, and a rainy season from April to October. Agriculture is the primary occupation in the region (mostly Peasant farmers), while some engage in business and few are civil servants. As the state capital, Gombe local government has tertiary (Federal Teaching Hospital) and secondary (Gombe State Specialist Hospital) health facilities. This is also in addition to the primary health care centers strategically located in each local government ward, with several private hospitals providing different services, including malaria diagnosis and treatment [25].

2. 2. Ethical clearance and Consent of the subjects

The research proposal was submitted to Gombe State Ministry of Health for approval. Afterward, the approval was communicated via a letter with reference number MOH/ADM/621/VOL.I/222. Verbal and or written consent of the 200 subjects from the three recruitment centers (Gombe town maternity (Gidan Magani), Sunnah clinic, and Idi children and Women Hospital Gombe) was sought after briefing them on the research and the need for them to participate. In a situation whereby the subjects were not of legal age (less than 18 years), consent of their parents/guardian was sought. All the subjects were assured that all collected information was strictly used for the research and treated with a high level of confidentiality. In Addition, quality control was assured when handling and treating each sample.

2. 3. Inclusion criteria

Only patients who reported themselves to the selected hospitals with fever or a history of fever in the last 24 hours and were referred by a physician for the screening of malaria infection with the presumption of being malaria positive were included in the study.

2. 4. Blood sample collection

The blood samples were collected with the help of medical personnel and the method employed was the venepuncture technique as described by previous research [26]. The collected blood sample (2-3 ml) was transferred into an EDTA blood-collecting tube and transported to the laboratory.

2.5. Rapid Diagnostic Test (RDT)

SD Bioline Malaria Ag P.f (05fk50) test kit was used for the Rapid diagnostic test. The test was conducted according to the manufacturer's instructions as adopted by previous research [27]. Briefly, about 5µl of the collected blood sample from the labelled 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 15-20minutes as recommended by the manufacturer.

2. 6. Molecular analysis

2. 6. 1. DNA Extraction

The DNA was extracted using Quick-DNA™ Miniprep plus Kit with catalog No D4069 from Zymo research. Techniques and procedures outlined and recommended by the manufacturers and adopted by previous research [28] were strictly adhered to. Briefly, 200µl of biofluid and cell buffer was added on to the pieces of the filter paper containing the dried blood sample in an Eppendorf tube. After which 20µl of proteinase K was added and mixed thoroughly and incubated at 55^{0}c for 10 minutes in order to digest the various component of the sample. After which, 200µl of genomic binding buffer was added. The entire mixture was then transferred in to spin column and centrifuged at 1200rpm for 1 minute. After which the collecting tube was discarded with the follow-through. 400µl of DNA pre-wash buffer was added to the column in a new collection tube and centrifuged for 1 minute. This was followed by the addition of 700µl of genomic DNA wash buffer and centrifuge for 1 minute. After which 200µl of Genomic buffer was then added and centrifuged for 1 minute. Finally in order to elute the DNA 50µl of DNA elution

buffer was added and incubated for 5minute and then centrifuge for 1 minute.

2. 6. 2. DNA Confirmation and Purity and Concentration determination

In order to confirm the presence of DNA in the entire sample extracted, a gel electrophoresis was run in 2% agarose stained with 0.5µl of ethidium bromide and was allowed to run for a period of 1 hour at 100mA, after which the gel was visualised using Ultraviolent (UV) Tran's illuminator. Nano-drop Spectrophotometer was used to determine the concentration and purity of the DNA extracted.

2. 6. 3. Primers

The primers; Forward (5'AACAGACGGGTAGTCATGATTGAG3') and Reverse (5'GTATCTGATCGTCTTCACTCCC3') were used and adopted from the work of previous research [28] and validated. All validated Primers were synthesised and supplied by Inqaba biotec™ Africa's genomic company. The primers were reconstituted using the recommended dilution factor (appropriate amount of distilled water) as specified by the manufacturer and stored at -4^{0}c as stock solution. The actual working solution was obtained by diluting 10µl of the stock in 90 µl of Nano pure water making (10%).

2. 6. 4. Amplification of 18SrRNA gene of *Plasmodium falcifarum*

The amplification was carried out using Classic DW-K960 thermal cycler and the reaction was carried in 25µl reaction mixture containing 5µl of the extracted DNA as the template, 1µl of primer (0.5µl each of Forward (5'AACAGACGGGTAGTCATGATTGAG3') and Reverse (5'GTATCTGATCGTCTTCACTCCC3'), 6.5µl distilled water and 12.5µl of the PCR Master mix (Containig dNTPs, $Mgcl_2$ and T*aq* DNA Polymerase). The gene was amplified by setting an initial denaturation at 95^{0}c for 15minutes then followed by forty cycles of denaturation at 94^{0}c for 45 seconds while annealing at 60^{0}c for 90seconds and extension at 72^{0}c for 1minute. The final extension was carried out at 72^{0}c for 5minutes. For this band size of 276bp was used as control for the confirmation of *Plasmodium falciparum* while distilled water was used as negative control for all PCR in the research.

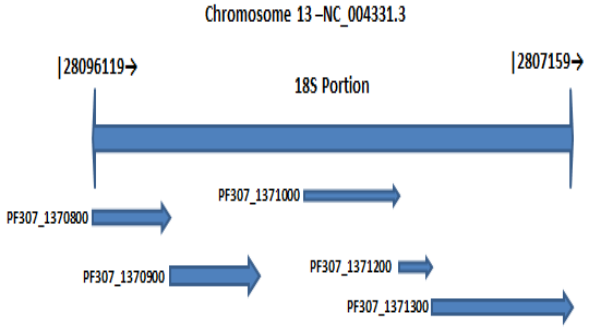

Fig. 1. Chromosome 13 of *Plasmodium falciparum* indicating 18S Portion of Ribosomal RNA gene

2. 6. 5. Gel Electrophoresis

The amplified genes were subjected to electrophoresis in 2% Agarose stained with Ethidium bromide. The gel was allowed to run for a period of 1 hour at 100mA, after which the gel was visualised using an Ultraviolent (UV) Transilluminator.

2. 7. Performance determination of PCR

In order to determine the effectiveness of PCR and Microscopy in malaria diagnosis, it sensitivity, specificity, positive predictive value, negative predictive value and accuracy were calculated using the formula.

Sensitivity = ((True positive / (True positive + False Negative))* 100

Specificity = ((True Negative / (True Negative+ False Positive))* 100

Positive Predictive value = ((True positive / True positive + False Positive))* 100

Negative Predictive value = ((True Negative / True Negative + False Negative))* 100

Overall accuracy = (True positive + False positive) / (True positive + False Positive+ True Negative + False Negative)

3. Results

3. 1. Demographic and clinical characteristics of the subjects

Out of the 200(100%) subjects used in the study, 114(57.0%) and 86(43.0%) were male and female respectively. The age of the

subjects ranges from 5-55years with a mean age of 28.60±10.57, with the modal age being 25years which constitutes 11% of the total subjects. The mean ambient body temperature of the subjects ranges from 33-43°C with a mean of 37.77±1.92. For the molecular analysis, the concentration of the DNA sample extracted ranges from 100.10-600.20ng/µl of the sample, and the mean concentration was 357.55±100.03. For purity, the mean value of A260/280 was 1.7210±0.55 and it ranges from 0.7-5.11, while A260/230 was 1.7215±2.10 and it ranges from 0.4-2.50 as shown in table 1.

Table 1. Demographic and Clinical characteristic of the study subject and basic characteristics of the DNA sample

	Mean	Range	Gender Male Female
Age	28.51±10.57	5-55	114(57.0%) 86(43.0%)
DNA	357±103	100.10-600.20ng/l	
A260/280	1.7210±0.55	0.7-5.11	
A260/230	1.7215±2.10	0.4-2.50	

3. 2. Malaria prevalence using PCR and RDTs

Out of the 200 samples examined by both PCR and RDTs, 132 (66.0%) were malaria positive with RDTs kit, while 105(52.5%) were positive with PCR as shown in table 2. Statistically, there was no significant difference in the two techniques in diagnosing malaria infection (x^2= 1.460, df= 1, P> 0.05).

Table 2. malaria prevalence using PCR and RDT diagnostic Techniques

Test techniques	Number of Sample examined	Positive Samples	Prevalence
RDT	200	132	66.0%
PCR	200	105	52.5%

x^2= 1.460, df= 1, P> 0.05

In this, 74(37%) samples were found to be malaria positive when diagnosed by both techniques, as such true positive and also 37(18.5%) were found to be true negative. On the other hand, 31(15.5%) were found to be negative with PCR as such false negative while 58(29%) of the samples were found to be false positive as they were only positive with RDT as shown in table 3.

Table 3. Result of PCR in relation to RDT

Techniques		Positive	Negative	Total
PCR	Positive	74(37.0%)	31(15.5%)	105(52.5%)
	Negative	58(29.0%)	37(18.5%)	95(47.5%)
Total		132(66.0%)	68(34.0%)	200(100%)

3. 3. Performance of PCR in relation to RDTs

The performance of the PCR technique in relation to RDTs is shown in table 4 below. The results revealed an overall accuracy of 0.53 with sensitivity and specificity values of 56.06 and 54.41% respectively, while 70.47 and 38.95% were recorded as the positive and negative values respectively as shown in table 4.

Table 4. Performance of PCR in relation RDTsk

Performance of PCR	Value
Sensitivity	56.06
Specificity	54.41
PPV	70.47
NPV	38.94
Accuracy	0.53

4. Discussion

Active malaria case detection is a key component and this requires diagnostic tools capable of detecting low parasitemic infections in low endemicity regions and asymptomatic infections in high transmission settings [29]. several factors can have a direct impact on the diagnosis, (identification and interpretation) of malaria parasitemia, these include different species of the parasite; its different developmental stages; endemicity of different parasite species; the population movements; the interrelation between the levels of transmission, immunity, parasitemia, and the symptoms; the problems of recurrent malaria, drug resistance, persisting viable or non-viable parasitemia, and sequestration of the parasites in the deeper tissues; and the use of chemoprophylaxis or even presumptive treatment based on clinical diagnosis [30]. Therefore WHO recommends that parasite-based diagnosis should be used in all cases of suspected malaria [16]. This serves as one of

the major component elements of global malaria control strategy for effective management and treatment of the disease, prognosis and also monitoring the impact of a given drug during treatment.

In this study performance of PCR in relation to RDTs was evaluated, with a prevalence of 53.0% and 66.0% respectively reported using PCR and RDTs, this confirms the endemicity of the disease in the study area. Malaria prevalence of 66.0% reported (using PCR) is very similar to 65.8% reported by previous research [31] from Dar-es-Salaam, Tanzania and also 63.0% reported by previous research [32] among Pregnant Women and Children under Five years in Ekiti State, Southwest Nigeria. This similarity is mainly attributed to the fact all the study areas are located in core Africa which is regarded as the most endemic region globally in terms of malaria transmission [33]. On the other hand, a lower prevalence of the disease as low of 4.0% was reported from Côte d'Ivoire by previous research [34] and 22.0% by previous research [35] from Northwest Ethiopia, all using RDTs. In addition, a survey conducted by previous research [36] reported a higher prevalence of 97% and 87.9% using the molecular technique (PCR) and RDTs respectively from central Italy

The sensitivity of PCR (56.06) reported in this study is higher than 22.5% reported by previous research [37] and 12.63% reported by previous research [5] among Pregnant Cohorts in Onitsha Southeast Nigeria. The high sensitivity recorded in this study could be attributed to the ability of the PCR to detect more than fifty percent of the samples as positive, this clearly demonstrated the high detection rate of the technique in relation to RDT, as the PCR technique has the ability to detect the presence of *Plasmodium falciparum* with low parasite density and milder malaria symptoms [38]. On the other hand, the sensitivity of PCR reported in this study is lower than 93.3% reported by previous research [39]. The specificity of PCR (54.41%) reported in this study is by far lower than 99.3% reported by previous research [40] during mass surveys conducted in low and high malaria-endemic areas from two North-Eastern states. The specificity value reported in the present study is contrary to the findings of previous research [41] who reported a specificity value of 97.1% from malaria endemic area in Yemen using PCR diagnostic techniques, but higher than 40.7% [42] from Indonesia. The disparity observed in the specificity value could be attributed to the highest number (66.0%) of samples confirmed to be positive by the RDTs, thus affecting true negative samples. Though the sensitivity and specificity value recorded in the present study is lower than 90 and 95% respectively recommended by WHO, the technique still can produce the required necessary result, especially in a situation where the patients or subjects harbour limited number of parasite even as low as 0.5–5 parasites per μL of blood [43] or even 0.01-1 parasite/μL of blood.

The positive predictive value (PPV) of a test is described as the proportion of people with a positive test result who have the disease condition, while the Negative Predictive Value is the proportion of people with a negative test result who do not have the disease [44]. The positive predictive value (70.47%) recorded in this study is similar to the findings of previous research [2], who also reported 63.1% as the positive predictive value from Tertiary Care Hospital, Chennai, but with a very negative predictive value of 97.1% as compared to 38.95% recorded in the present study. Similarly, it was reported [40] higher values of 87.6% (PPV) and 93.4% (NPV) as compared to 70.47% and 38.95% recorded in the present study. In the present study, an overall accuracy level of 0.53 was observed, this higher than 0.42 reported by previous research [45].

5. Conclusion

The findings of the study reveal the endemicity of malaria infection in the study area. PCR relatively demonstrates a good level of accuracy of more than 50% and high level of performance as revealed by the sensitivity, specificity and predictive values.

Abbreviation

HRP2: Histidine-Rich Protein 2

LAMP: loop-mediated isothermal amplification

PCR: Polymerase Chain Reaction
pLDH: Lactate Dehydrogenase
PPV: Positive Predictive Value
RDTs: Rapid Diagnostic Test
WHO: World Health Organization

Conflict of Interest

The authors hereby declare that they have no conflict of interest.

Author's contributions

All authors equally participated in designing experiment analysis and interpretation of data. All authors read and approved the final manuscript.

Consent for publications

All authors have read and approved the final manuscript for publication.

Availability of data and material

The authors have embedded all data in the manuscript.

Ethics approval and consent to participate

The authors did not use human or animals in the research

Reference

1. Quakyi IA, Adjei GO, Sullivan DJ, Laar A, Stephens JK, Owusu R, Winch P, Sakyi KS, Coleman N, Krampa FD (2018) Diagnostic capacity, and predictive values of rapid diagnostic tests for accurate diagnosis of *Plasmodium falciparum* in febrile children in Asante-Akim, Ghana. Malaria journal 17 (1): 1-9. doi:https://doi.org/10.1186/s12936-018-2613-x
2. Santhy B, Ravichandran T, Ramani C, Sumathy P, Heber A (2015) Rapid Laboratory Techniques in Diagnosis of Malaria in a Tertiary Care Hospital, Chennai. International journal of scientific study 2 (11): 94-99. doi:https:///doi.org/10.17354/ijss/2016/64
3. Jayasingh A, Rompicherla V, Radha RKN, Shanmugam P (2019) Comparative Study of Peripheral Blood Smear, Rapid Antigen Detection, ELISA and PCR Methods for Diagnosis of Malaria in a Tertiary Care Centre. Journal of Clinical & Diagnostic Research 13 (1): 8-13. doi:https://doi.org/10.7860/JCDR/2019/38213.12483
4. Aschar M, Sanchez MCA, de Jesus Costa-Nascimento M, Maria de Lourdes R, Hristov AD, Lima GF, Inoue J, Levi JE, Di Santi SM (2022) Ultrasensitive molecular tests for Plasmodium detection: applicability in control and elimination programs and reference laboratories. Revista Panamericana de Salud Pública 46 (e11): 1-10. doi:https://doi.org/https://doi.org/10.26633/RPSP.2022.11
5. Mouatcho JC, Goldring JD (2013) Malaria rapid diagnostic tests: challenges and prospects. Journal of medical microbiology 62 (10): 1491-1505. doi:https://doi.org/10.1099/jmm.0.052506-0
6. Uba CC, Ikegbunam MN, Anagor IS, Eleanya LC, Ezeumeh EN, Ezekwueche SN, Okechukwu EC, Esimone CO (2021) Comparative Performance of Different Malaria Diagnostic Tools among Pregnant Cohorts in Onitsha Southeast Nigeria. Advances in Infectious Diseases 11 (4): 384-394. doi:https://doi.org/10.4236/aid.2021.114035
7. Uzochukwu BS, Obikeze EN, Onwujekwe OE, Onoka CA, Griffiths UK (2009) Cost-effectiveness analysis of rapid diagnostic test, microscopy and syndromic approach in the diagnosis of malaria in Nigeria: implications for scaling-up deployment of ACT. Malaria journal 8 (1): 1-15. doi:https://doi.org/10.1186/1475-2875-8-265
8. Ojurongbe O, Adegbosin OO, Taiwo SS, Alli OAT, Olowe OA, Ojurongbe TA, Bolaji OS, Adeyeba OA (2013) Assessment of clinical diagnosis, microscopy, rapid diagnostic tests, and polymerase chain reaction in the diagnosis of Plasmodium falciparum in Nigeria. Malaria research and treatment 2013): Article ID: 308069. doi:http://dx.doi.org/10.1155/2013/308069
9. Berzosa P, de Lucio A, Romay-Barja M, Herrador Z, González V, García L, Fernández-Martínez A, Santana-Morales M, Ncogo P, Valladares B (2018) Comparison

of three diagnostic methods (microscopy, RDT, and PCR) for the detection of malaria parasites in representative samples from Equatorial Guinea. Malaria journal 17 (1): 1-12. doi:https://doi.org/10.1186/s12936-018-2481-4

10. Kitutu FE, Wamani H, Selling KE, Katabazi FA, Kuteesa RB, Peterson S, Kalyango JN, Mårtensson A (2018) Can malaria rapid diagnostic tests by drug sellers under field conditions classify children 5 years old or less with or without Plasmodium falciparum malaria? Comparison with nested PCR analysis. Malaria journal 17 (1): 1-12. doi:https://doi.org/10.1186/s12936-018-2508-x
11. Poti KE, Sullivan DJ, Dondorp AM, Woodrow CJ (2020) HRP2: transforming malaria diagnosis, but with caveats. Trends in parasitology 36 (2): 112-126. doi:https://doi.org/10.1016/j.pt.2019.12.004
12. Adedoja A, Babatunde SK, Tijani BD, Akanbi AA, II OO (2019) Usefulness of Polymerase Chain Reaction in the diagnosis of asymptomatic malaria among school age children in Ilorin, Nigeria. Pan African Journal of Life Sciences 1): 39-45. doi:https://doi.org/10.36108/pajols/8102/10(0170
13. Murungi M, Fulton T, Reyes R, Matte M, Ntaro M, Mulogo E, Nyehangane D, Juliano JJ, Siedner MJ, Boum Y (2017) Improving the specificity of *Plasmodium falciparum* malaria diagnosis in high-transmission settings with a two-step rapid diagnostic test and microscopy algorithm. Journal of clinical microbiology 55 (5): 1540-1549
14. Calderaro A, Montecchini S, Buttrini M, Piccolo G, Rossi S, Arcangeletti MC, Farina B, De Conto F, Chezzi C (2021) Malaria Diagnosis in Non-Endemic Settings: The European Experience in the Last 22 Years. Microorganisms 9 (11): 2265. doi:https://doi.org/10.3390/microorganisms9112265
15. Wardhani P, Butarbutar TV, Adiatmaja CO, Betaubun AM, Hamidah N (2020) Performance comparison of two malaria rapid diagnostic test with real time polymerase chain reaction and gold standard of microscopy detection method. Infectious disease reports 12 (s1): 8731. doi:https://doi.org/10.4081/idr.2020.8731
16. Garba BI, Muhammad AS, Musa A, Edem B, Yusuf I, Bello NK, Adeniji AO, Kolawole T (2016) Diagnosis of malaria: A comparison between microscopy and rapid diagnostic test among under-five children at Gusau, Nigeria. Sub-Saharan African Journal of Medicine 3 (2): 96. doi:https://doi.org/10.4103/2384-5147.184371
17. Roth JM, de Bes L, Sawa P, Omweri G, Osoti V, Oberheitmann B, Schallig HDFH, Mens PF (2018) *Plasmodium* Detection and Differentiation by Direct-on-Blood PCR Nucleic Acid Lateral Flow Immunoassay: Development, Validation, and Evaluation. The Journal of Molecular Diagnostics 20 (1): 78-86. doi:https://doi.org/10.1016/j.jmoldx.2017.09.004
18. Oyeyemi OT, Ogunlade AF, Oyewole IO (2015) Comparative assessment of microscopy and rapid diagnostic test (RDT) as malaria diagnostic tools. Res J Parasitol 10 (3): 120-126. doi:https://doi.org/10.3923/jp.2015.120.126
19. Mogeni P, Williams TN, Omedo I, Kimani D, Ngoi JM, Mwacharo J, Morter R, Nyundo C, Wambua J, Nyangweso G (2017) Detecting malaria hotspots: a comparison between RDT, microscopy and polymerase chain reaction. The J Infec Dis 2016): 1091-1098. doi:https://doi.org/10.1093/infdis/jix321
20. Badiane A, Thwing J, Williamson J, Rogier E, Diallo MA, Ndiaye D (2022) Sensitivity and specificity for malaria classification of febrile persons by rapid diagnostic test, microscopy, parasite DNA, histidine-rich protein 2, and IgG: Dakar, Senegal 2015. International Journal of Infectious Diseases 121): 92-97. doi:https://doi.org/10.1016/j.ijid.2022.04.060
21. Charpentier E, Benichou E, Pagès A, Chauvin P, Fillaux J, Valentin A, Guegan H, Guemas E, Salabert AS, Armengol C, Menard S, Cassaing S, Berry A, Iriart X (2020) Performance evaluation of different strategies based on microscopy techniques, rapid diagnostic test and molecular loop-mediated isothermal amplification assay for the diagnosis of imported malaria.

Clinical Microbiology and Infection 26 (1): 115-121. doi:https://doi.org/10.1016/j.cmi.2019.05.010

22. Adams M, Joshi SN, Mbambo G, Mu AZ, Roemmich SM, Shrestha B, Strauss KA, Johnson NE, Oo KZ, Hlaing TM (2015) An ultrasensitive reverse transcription polymerase chain reaction assay to detect asymptomatic low-density *Plasmodium falciparum* and *Plasmodium vivax* infections in small volume blood samples. Malaria journal 14 (1): 1-5. doi:https://doi.org/10.1186/s12936-015-1038-z
23. Ahmad A, Soni P, Kumar L, Singh MP, Verma AK, Sharma A, Das A, Bharti PK (2021) Comparison of polymerase chain reaction, microscopy, and rapid diagnostic test in malaria detection in a high burden state (Odisha) of India. Pathogens and global health 115 (4): 267-272. doi:https://doi.org/10.1080/20477724.2021.1893484
24. Feleke DG, Alemu Y, Yemanebirhane N (2021) Performance of rapid diagnostic tests, microscopy, loop-mediated isothermal amplification (LAMP) and PCR for malaria diagnosis in Ethiopia: a systematic review and meta-analysis. Malaria journal 20 (1): 1-11. doi:https://doi.org/10.1186/s12936-021-03923-8
25. Vandi KD, Ntekim EE, Ahmed HA Science Forum (Journal of Pure and Applied Sciences). In: Science forum (journal of pure and applied sciences), 2019. pp 18-42
26. Alemu G, Mama M (2016) Assessing ABO/Rh blood group frequency and association with asymptomatic malaria among blood donors attending Arba Minch blood bank, South Ethiopia. Malaria research and treatment 2016): Article ID: 8043768,. doi:http://dx.doi.org/10.1155/2016/8043768
27. Wanja EW, Kuya N, Moranga C, Hickman M, Johnson JD, Moseti C, Anova L, Ogutu B, Ohrt C (2016) Field evaluation of diagnostic performance of malaria rapid diagnostic tests in western Kenya. Malaria journal 15 (1): 456. doi:https://doi.org/10.1186/s12936-016-1508-y
28. Londono BL, Eisele TP, Keating J, Bennett A, Chattopadhyay C, Heyliger G, Mack B, Rawson I, Vely J-F, Désinor O (2009) Chloroquine-resistant haplotype Plasmodium falciparum parasites, Haiti. Emerging infectious diseases 15 (5): 735. doi:https://dx.doi.org/10.3201%2Feid1505.081063
29. Yimam Y, Mohebali M, Abbaszadeh Afshar MJ (2022) Comparison of diagnostic performance between conventional and ultrasensitive rapid diagnostic tests for diagnosis of malaria: A systematic review and meta-analysis. PloS one 17 (2): e0263770. doi:https://doi.org/10.1371/journal.pone.0263770
30. Kakkilaya BS (2003) Rapid diagnosis of malaria. Lab medicine 8 (34): 602-608. doi:https://doi.org/10.1309/J4ANKCCJ147JB2FR
31. Nwangwu J, Roland I, Mbelwa D, Magori C, Evans M, Price C (2017) Prevalence of Malaria Infection and ABO Human Blood Group in Dar-es-Salaam, Tanzania. Advances in Infectious Diseases 7 (04): 153. doi:https://doi.org/10.4236/aid.2017.74016
32. SIMON-OKE IA, Ogunseem M, Afolabi O, Awosolu O (2019) Prevalence of Malaria Parasites among Pregnant Women and Children under Five years in Ekiti State, Southwest Nigeria. Journal of Biomedicine and Translational Research 5 (1): 5-10. doi:https://doi.org/10.14710/jbtr.v5i1.3711
33. Gomerep SS, Terver AM, Oye IH (2017) Prevalence of malaria parasitaemia and its association with ABO blood group in Jos, Nigeria. International Journal of Infectious Diseases and Therapy 2 (3): 59-65. doi:https://doi.org/10.11648/j.ijidt.20170203.13
34. Benié E, Silué KD, Ding XC, Yeo I, Assamoi J, Tuo K, Gnagne AP, Esso LJ, Coulibaly JT, Assi S-B (2022) Accuracy of a rapid diagnosis test, microscopy and loop-mediated isothermal amplification in the detection of asymptomatic Plasmodium infections in Korhogo, Northern Côte d'Ivoire. Malaria journal 21 (1): 1-10. doi:https://doi.org/10.1186/s12936-022-04133-6

35. Endeshaw T, Graves PM, Ayele B, Mosher AW, Gebre T, Ayalew F, Genet A, Mesfin A, Shargie EB, Tadesse Z (2012) Performance of local light microscopy and the ParaScreen Pan/Pf rapid diagnostic test to detect malaria in health centers in Northwest Ethiopia. PloS one 7 (4): e33014. doi:https://doi.org/10.1371/journal.pone.0033014
36. Alessia C, Claudia D, ValzanoMatteo MMV, Paolo R, Irene R Molecular Diagnosis of Malaria Infection: A Survey in a Hospital in Central Italy. Adv Biotechnol Microbiol 5 (4): 11-14. doi:http://dx.doi.org/10.19080/AIBM.2017.05.555670
37. Andrade BB, Reis-Filho A, Barros AM, Souza-Neto SM, Nogueira LL, Fukutani KF, Camargo EP, Camargo L, Barral A, Duarte Â (2010) Towards a precise test for malaria diagnosis in the Brazilian Amazon: comparison among field microscopy, a rapid diagnostic test, nested PCR, and a computational expert system based on artificial neural networks. Malaria journal 9 (1): 1-11. doi:https://doi.org/10.1186/1475-2875-9-117
38. Leski TA, Taitt CR, Swaray AG, Bangura U, Reynolds ND, Holtz A, Yasuda C, Lahai J, Lamin JM, Baio V (2020) Use of real-time multiplex PCR, malaria rapid diagnostic test and microscopy to investigate the prevalence of Plasmodium species among febrile hospital patients in Sierra Leone. Malaria journal 19 (1): 1-8. doi:https://doi.org/10.1186/s12936-020-03163-2
39. Johnston SP, Pieniazek NJ, Xayavong MV, Slemenda SB, Wilkins PP, da Silva AJ (2006) PCR as a confirmatory technique for laboratory diagnosis of malaria. Journal of Clinical Microbiology 44 (3): 1087-1089. doi:https://doi.org/10.1128/JCM.44.3.1087
40. Shankar H, Singh MP, Phookan S, Singh K, Mishra N (2021) Diagnostic performance of rapid diagnostic test, light microscopy and polymerase chain reaction during mass survey conducted in low and high malaria-endemic areas from two North-Eastern states of India. Parasitology Research 120 (6): 2251-2261. doi:https://doi.org/10.1007/s00436-021-07125-8
41. Othman R, Eldeek H, Almatary A, Sayed A, Alsakaf A (2015) Detection of malaria in healthy blood donors using PCR in an endemic area in Yemen. J Adv Parasitol 2): 40-47. doi:http://dx.doi.org/10.14737/journal.jap/2015/2.2.40.47
42. Arifin S, Fitri LE, Sujuti H, Hermansyah B, Endharti AT, Sulistyaningsih E, Burhan N, Candradikusuma D, Tuda JSB, Zein U (2018) Sensitivity and specificity of nested PCR for diagnosing malaria: Cases in several areas of Indonesia. J Trop Life Sci 8 (2): 172-176. doi:https://doi.org/10.11594/jtls.08.02.11
43. Mbanefo A, Kumar N (2020) Evaluation of malaria diagnostic methods as a key for successful control and elimination programs. Tropical Medicine and Infectious Disease 5 (2): 102. doi:https://doi.org/10.3390/tropicalmed5020102
44. Akobeng AK (2007) Understanding diagnostic tests 1: sensitivity, specificity and predictive values. Acta paediatrica 96 (3): 338-341. doi:https://doi.org/10.1111/j.1651-2227.2006.00180.x
45. Ali IM, Nji AM, Bonkum JC, Moyeh MN, Carole GK, Efon A, Dabou S, Tchuenkam VPK, Tah C, Kengne J-PC (2021) Diagnostic Accuracy of CareStart™ Malaria HRP2 and SD Bioline Pf/PAN for Malaria in Febrile Outpatients in Varying Malaria Transmission Settings in Cameroon. Diagnostics 11 (9): 1556. doi:https://doi.org/10.3390/diagnostics11091556

How to Cite This Article:

Muhammad I, Micah Sale P, Mohammed TM, Miyim SZ, Usman AM (2022) Performance analysis of polymerase chain reaction in relation to rapid diagnostic test (RDT) kit (SD bio line malaria ag p.f (05fk50)) for malaria diagnosis. Cellular, Molecular and Biomedical Reports 2 (4): 254-264. doi:10.55705/cmbr.2022.361911.1066

Download citation:

RIS; EndNote; Mendeley; BibTeX; APA; MLA; HARVARD; VANCOUVER