

## ORIGINAL ARTICLE

# Diagnostic Accuracy of Rapid Diagnostic Kits Test for Diagnosis of Malaria

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## ABSTRACT

**Objective:** To assess the diagnostic accuracy of rapid diagnostic kits test for diagnosis of malaria taking microscopy as gold standard

**Methodology:** A total of 375 cases with age range 18-65 years of either gender as suspected for malaria were included in the study. We excluded all those cases already taking anti-malarial drugs. The study was conducted at Chughtais Lahore Lab, Lahore. Required blood sample were obtained following aseptic measures. Malaria RDT SD Bioline Malaria Antigen Pf/Pan (Catalogue No. 05FK60, Standard Diagnostics Inc, Hagal-Dong, Korea, from now on referred as "SD RDT") was used. Patients were labeled as positive or negative on the basis of reports from hematology department assessed by microscopy and patients were labeled as positive or negative

**Results:** The mean age of the patients was  $41.84 \pm 13.44$  years, male to female ratio of the patients was 1.01:1. The sensitivity, specificity, and diagnostic accuracy of the RDT for diagnosing malaria was 96.79%, 96.28% and 96.53% respectively taking microscopy as gold standard

**Conclusion:** Rapid diagnostic kits is very useful reliable test with high diagnostic accuracy for diagnosis of malaria taking microscopy as gold standard

**Keywords:** Microscopy, Rapid Diagnostic kits, Malaria,

## INTRODUCTION

Malaria is responsible for higher rate of mortality in tropical countries. Worldwide, more than 500 million population and over one million children are died due to malaria each year. If untreated, malaria parasites *Plasmodium falciparum* is responsible for adverse outcome.<sup>1</sup> Around 38.3% cases dies due to malaria (on smear slides).<sup>2</sup>

Evaluation of malaria infection requires availability of specific, sensitive, rapid and cost effective modality. Over the years, various new diagnostic modalities are developed to improve the malaria diagnosis, however, conventional method i.e. smear microscopy remains the gold standard. However, it requires good quality microscopy in addition to technical expertise.<sup>3</sup>

Diagnosis with staining of thick and thin blood film is considered as gold standard method for malaria. However, well-trained labortorists are it's a time consuming and un-automated protocol.<sup>4</sup> WHO recommends the use of RDTs, especially in absence of microscopy.<sup>5-6</sup> a previous study showed high specificity of RDT i.e. 98.5% whereas sensitivity was 47.5%, NPV was 97.6% and PPV 56.8%.<sup>7</sup> Contrary to this, Abba K and others<sup>8</sup> witnessed 95.0% sensitivity and 95.2% specificity of RDT while detecting malaria.

This study was conducted to assess the diagnostic accuracy of RDT for diagnosis of malaria taking microscopy as gold standard. Microscopy is a gold standard for diagnosis of malaria. But it is time consuming and costly procedure and requires expertise. So an early detection of malaria is needed for early initiation of treatment. But controversial results have also been reported in literature. Also there is no local data available regarding this issue which can help us in implementing the use of RDT instead of microscopy. So we want to conduct this study so that early detection can be done and patients can be prevented from developing hazardous consequences. This will help to

improve our practice and we will be able to recommend the early prediction of malaria through RDT instead of relying microscopy.

## METHODOLOGY

A total of 375 cases with age range 18-65 yearsof either gender as suspected for malaria were included in the study. We excluded all those cases already taking anti-malarial drugs. The study was conducted at Chughtais Lahore Lab, Lahore. Required blood sample were obtained following aseptic measures. Samples were stored in a vial containing ethylene diamine tetra acetate (EDTA) and mixed well to prevent clot formation for microscopy. Meanwhile, malaria RDT SD Bioline Malaria Antigen Pf/Pan (Catalogue No. 05FK60, Standard Diagnostics Inc, Hagal-Dong, Korea, from now on referred as "SD RDT") was used. This was a lateral flow immunochromatographic test that contains a membrane strip encased in a flat plastic cassette. The strip was precoated with two antibodies: one that was specific for *P. falciparum* HRP2 and one that was pan-specific for pLDH for detection of other *Plasmodium* species. Patients were labeled as positive or negative on the basis of reports from hematology department assessed by microscopy and patients were labeled as positive or negative. The data was evaluated/computed with the help of SPSS.

## RESULTS

In this present study a total of 375 cases were included. The mean age of the patients was  $41.84 \pm 13.44$  years with minimum and maximum ages of 18 & 65 years respectively. Table#1

In this study 189(50.40%) patients were male and 186(49.60%) patients were females. Male to female ratio of the patients was 1.01:1. Fig#1

In our study the mean value of duration of fever of the patients was  $4.49 \pm 1.66$  days with minimum and maximum duration of 2 & 7 days respectively.

According to our study results 188(50.1%) patients were diagnosed positive for malaria by RDT and 187(49.9%) patients were diagnosed with negative malaria by RDT. Table#2

According to our study results 187(49.87%) patients were diagnosed with positive malaria by microscopy and 188(50.13%) patients were diagnosed with negative malaria by microscopy. Fig#2

The study results showed that the sensitivity, specificity, PPV, NPV and diagnostic accuracy of the RDT for diagnosing malaria was 96.79%, 96.28%, 96.28%, 96.79% & 96.53% respectively taking microscopy as gold standard. Table#3

Table 1: Descriptive statistics of age (years)

Age (years)	n	375
	Mean	41.84
	SD	13.44
	Minimum	18
	Maximum	65

Fig 1: Frequency distribution of gender

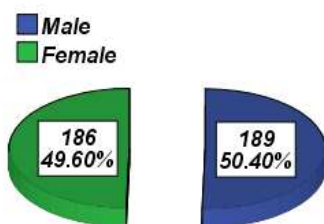


Table 2: Frequency distribution of malaria on RDT

Malaria on RDT	Frequency		Percent
	Positive	188	
	Negative	187	
	Total	375	

Fig 2: Frequency distribution of malaria on microscopy

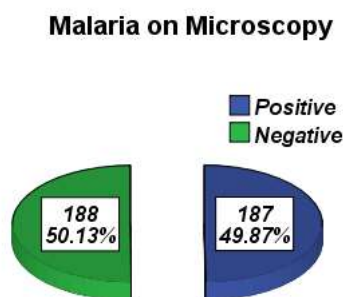


Table 3: Comparison of malaria on RDT with malaria on microscopy

		Malaria on microscopy		Total
		Positive	Negative	
Malaria on RDT	Positive	181	7	188
	Negative	6	181	187
Total		187	188	375

## DISCUSSION

This present cross sectional study was carried out at the department of Hematology, Chughtai's Lahore Lab, to assess the diagnostic accuracy of rapid diagnostic kits test for diagnosis of malaria taking microscopy as gold standard

Annually, malaria affect >300 million and at least 1 million people do not survive. Early detection and appropriate treatment may reduce the risk of morbidity and mortality. However, early and accurate diagnosis remains a challenge and also creates hindrance for adequate management of malaria.

Detecting evidence of malarial parasites i.e. antigens with RDTs may assist in early diagnosis. RDTs are shown to be reliable particularly in healthcare centers in absence of microscopy.<sup>9-10</sup>

In our study high sensitivity, specificity and diagnostic accuracy of RDT for diagnosing malaria was noted. The sensitivity, specificity and diagnostic accuracy of RDT was 96.79%, 96.28% & 96.53% respectively taking microscopy as gold standard. Some of the studies are discussed below showing their results as.

Studies, especially in remote areasevidenced RDTs to be easy and useful due to their easy use without any supervision and also require no training or instruments.<sup>11-13</sup>

It is documented that the use of RDTs may be useful in peripheral areas where laboratory facilities or even microscopy are not available and when the urgent diagnosis is required without any delay relating to laboratory results.<sup>14</sup>

Another study showed that the sensitivity and specificity of RDT were 95.0% and 95.2% for detection of malaria.<sup>8</sup> According to the USAID/WHO consensus report, RDTs usually achieve higher sensitivity rate for the diagnosis of *P. falciparum* malaria.<sup>9</sup>

A study by CCA Azikiwe et al<sup>15</sup> showed that the samples tested positive to RDTs based on malaria antibodies (serum) method (100%). 128 out of 200 tested positive to RDTs based on malaria antigen (whole blood) method (64%), while 118 out of 200 patients under present study tested positive to visual microscopy of Lieshman and diluted Giemsa (59%) stains.

Maltha et al<sup>16</sup>also showed that *P. falciparum*, *Plasmodium vivax* and *Plasmodium malariae* 94.6%, 92.9% and 94.7% degree of sensitivity using RDTs in malaria parasites concentration of  $\geq 1000/\mu\text{L}$ , respectively.

Vincent Batwala et al<sup>17</sup>concluded that the HRP2-based RDT has shown superior sensitivity compared to microscopy in diagnosis of malaria and may be more suitable for screening of malaria infection. Some studies have however reported on the accuracy of RDTs using expert microscopy as gold standard.<sup>18-20</sup>

One study by Catherine O. Falade et al<sup>21</sup>demonstrated that the RDTs are useful while dealing with malarial management successfully used for detection by trained health care workers. Whereas, false-negative RDT results were identified and can undermine confidence in results and control efforts.

One more study showed high specificity i.e 98.5%whereas low sensitivity i.e. 47.5% with a PPV 56.8% and NPV 97.6% by using RDTs under field conditions.<sup>7</sup>

## CONCLUSION

According to our study results the rapid diagnostic kits are very useful, efficient and reliable technique with for diagnosis of malaria taking microscopy as gold standard

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