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# *THE PERFORMANCE OF RAPID DIAGNOSTIC TEST (RDTs) KITS FOR MALARIA, USED IN THE NEW JUABEN NORTH MUNICIPALITY. A COMPARATIVE STUDY*

***A PROJECT REPORT***

***Submitted by***

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***In partial fulfillment for the award of the degree***

***Of***

**BACHELOR OF TECHNOLOGY**

**IN**

**BIOMEDICAL ENGINEERING**


**FACULTY OF HEALTH AND ALLIED SCIENCES**

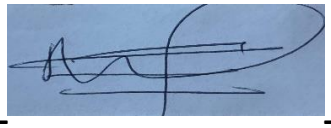
**DEPARTMENT OF BIOMEDICAL ENGINEERING**

**KOFORIDUA, GHANA**

**[NOVEMBER, 2023]**

# BONAFIDE CERTIFICATE

Certified that this project report "***THE PERFORMANCE OF RAPID DIAGNOSTIC TESTS (RDTs) FOR MALARIA, USED IN THE NEW JUABENG NORTH MUNICIPALITY.***" is the bona fide work of **"PRINCE EDUDZI PEWUDIE and OTCHERE EUGENE AGYEI"** that carried out the project work under my supervision.



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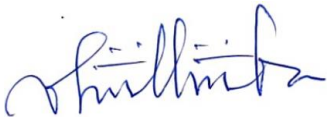

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# ABSTRACT

An acute or chronic illness of the genus Plasmodium that is brought on by obligatory intracellular protozoa is known as malaria. Anemia, splenomegaly, chills, and high fever paroxysms define the clinical course. For millennia, malaria has posed a significant medical challenge throughout the subcontinent.

A tiny protozoon that is a member of the Plasmodium species group and has multiple subspecies is the cause of malaria. Certain Plasmodium species infect humans and cause illness.

An insoluble hemoglobin metabolite known as malaria pigment is accumulated by amoeboid intracellular parasites of the genus Plasmodium. There are 172 Plasmodium species, and only five of these species can cause malaria in humans. They include; P. malariae, P. falciparum, P. vivax, P. ovale, and P. knowlesi.

The main aim of this study is to determine the performance of two of the malaria rdt kits used in the New Juabeng North Municipality.

Data was collected by using three methods; the use of the two malaria rdt kits and the use of microscopy which serves as the control experiment.

For every blood sample collected, the two rdts were used to check for the presence of malaria and the results compared with the results from microscopy examination.

For every test performed, results were recorded for each rdt as well as the microscopy examination. Statistical Package for Social Science (SPSS V22) software was used to conduct the analysis. On the gathered data, a normality test was performed in order to confirm the accuracy of the responses. For the purpose of evaluating the data, descriptive statistics and the Cronbach's Alpha reliability test were applied. The relationship between the two categories that were picked was evaluated using the Pearson’s correlation test.

The Pearson correlation value for the relationship between the moh rdt and the control was 0.500 whereas the Pearson value for the relation between the abbot rdt and the control was 0.988.

Comparing their sensitivities and specificities with the control, abbot rdt has a higher sensitivity of 97.9% compared to 83.3% of the First response rdt and a specificity of 100% compared to 81.6% of the first response rdt.

# CHAPTER ONE

## 1.1 INTRODUCTION

Malaria have killed 435,000 of the world's population in 2017 and sickened an estimated 219 million people. Africa and certain Asian countries have recorded the greatest number of malaria cases because malaria is very common on these continents. Malaria is responsible for 0.3% to 2.2% of deaths globally; in tropical regions, the proportion of severe malaria cases can rise to 30%. Several researches have recorded a massive upsurge of malaria parasite infection since 2015.

Plasmodium species, a tiny protozoon with several subspecies, is the causative agent of malaria. Humans can contract some Plasmodium species infections and become unwell.

Amoeboid intracellular parasites of the genus Plasmodium collect malaria pigment, an insoluble hemoglobin metabolite, on a variety of vertebrates; some of these parasites reside in tissue, while others are found in red blood cells. There are 172 Plasmodium species, of which five of these species are known to cause malaria infection in humans. This group includes P. vivax, P. ovale, P. falciparum, P. malariae, and P. knowlesi. P. knowlesi, a zoonotic malaria, has been discovered in South-East Asia. It is uncommon for other creatures to infect humans. All the Plasmodium species mentioned above can cause malaria, which is derived from the Latin word malus aer, which means "bad air."

The complex life cycle of Plasmodium consists of two phases: the asexual phase, which involves vertebrate hosts, and the sexual phase, which involves mosquito vectors. In mosquitoes, the parasite's carriers, the sexual phase of its life cycle occurs. In the asexual stage of the disease's life cycle, humans, the intermediate host of malaria, experiences this. Malaria can only be transmitted to humans by female Anopheles mosquitoes. After being bitten by a female mosquito carrying the infection, the parasite enters the human bloodstream as sporozoites and circulates there for 30 minutes before reaching the hepatocytes. Before turning into erythrocytes, hepatocytes go through

the first phase of Plasmodium asexual development. Every type of Plasmodium induces rupture of the erythrocyte.

P. vivax and P. malariae are the two species that are most prevalent in the Americas and Europe. While in Africa it is P. falciparum. (Talakpo et.al 2019)

## 1.2 DISCOVERY OF MALARIA

Epidemics of malaria are thought to have happened ever since human civilization began. It is the most prevalent illness, and a significant number of people have died from it. It's even thought to have played a part in the extinction of entire nations and serious military defeats. Medical records from ancient China date back to 2700 BC, when malaria was first described. 1200 years later, reports of the sickness can be found in the Ebers Papyrus. Alexander the Great, a military commander, died of malaria. The fact that people from all social classes were afflicted by it includes Christopher Columbus, Albrecht Dürer, Cesare Borgia, and George Washington.

Even though malaria and its symptoms were common in ancient times, the fever that would strike patients was ascribed to a variety of supernatural powers and enraged divinities. Thus, it is said that the Assyrian-Babylonian god Nergal was shown as a stylised insect with two wings, just as was the Canaan Zebub, also known as Beelzebub (literally, "the master of the fly"). Around the year 400 BC, Hippocrates gave a description of this illness that totally denied its demonic roots and connected it with evaporation from marshes, which contributed to the illness when breathed. That understanding was sustained until 1880, when Laveran identified the illness's etiology. The French military surgeon Laveran won a Nobel Prize in 1907 for his discovery that malaria patients' blood contained parasites. (Talakpo et.al 2019)

## 1.3 TRANSMISSION

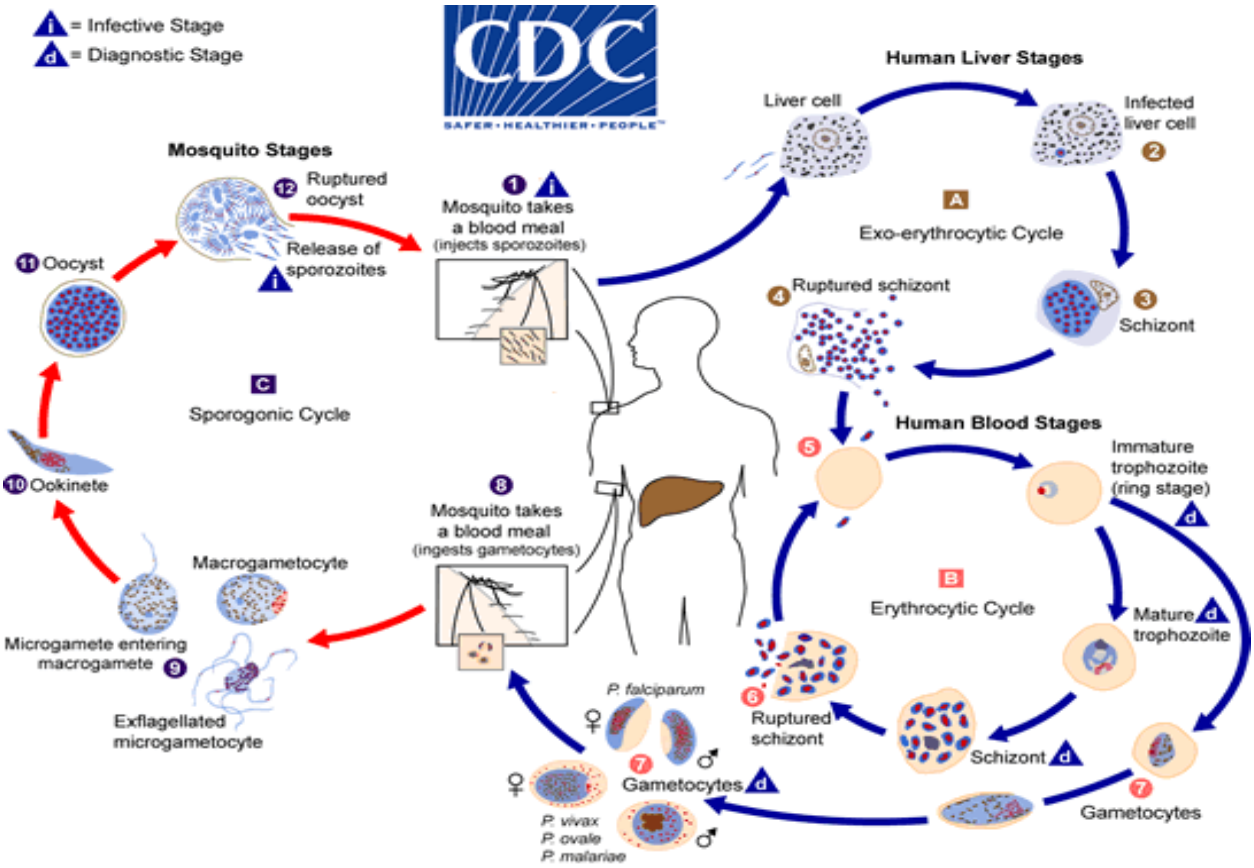


*Figure 1.1 showing malaria transmission*

## 1.4 SYMPTOMS OF MALARIA


*Figure 1.2 showing some malaria symptoms*

## 1.5 MALARIA DETECTION AND DIAGNOSIS

There are now only a few different approaches available for diagnosing malaria.

Among these techniques are;

- Clinical diagnosis using physical examination and history.
- The examination of stained peripheral blood smears using light microscopy.
- The application of kits for rapid diagnostic tests (RDTs).

## 1.6 CLINICAL DIAGNOSIS USING PHYSICAL EXAMINATION AND HISTORY

Clinicians may diagnose patients based on the symptoms of malaria which includes;

- Fever
- Nausea
- Headaches
- Sweating profusely

- Chills

This method can however lead to wrong diagnosis since other infections like typhoid fever may manifest similar symptoms.

## THE EXAMINATION OF STAINED PERIPHERAL BLOOD SMEARS USING LIGHT MICROSCOPY

In most endemic countries, microscopic slide analysis of peripheral blood is the gold standard for diagnosing malaria parasitemia.

To give the parasites a distinct appearance, the specimen is dyed before viewing (most commonly using the Giemsa stain).

This procedure depends on the caliber of the chemicals, the experience of the laboratory operator, and the microscope.

Not much has changed since the blood film technique was created in the early 1900s. The staining process is labor-intensive and can last about 60 minutes before generating a stained film, despite the fact that there are now more stable stains available. Significant experience is needed for interpretation, especially at low parasitemia levels. For instance, a P. falciparum infection could be undetected in blood films due to insufficient parasite presence. (Moody, 2002)

## 1.7 THE APPLICATION OF KITS FOR RAPID DIAGNOSTIC TESTS (RDTS).

Given its significance in diagnosing malaria in the absence of trustworthy microscopy, Fast diagnostic tests (RDT) for malaria are increasingly being used.

Fast diagnostic tests (RDTs for malaria) search for parasite antigens in human blood in order to make a diagnosis. A drop of peripheral blood must be collected for these tests, usually by pricking the fingertip. Visual readouts can usually be accessed in 20 minutes or less.

RTDs come in a variety of configurations, including hybrids, cassettes, and dipsticks. Whichever format they are in, they are usually quite easy to use and require little in the way of training or specialized skills. They can be utilized at the point-of-care and in extremely remote locations, and they don't require any equipment or infrastructure. (WHO, 2022b)

It is difficult to miss any malaria parasite, even in minute quantities, because almost all RDTs are based on immunochromatographic strip (ICS) technology and have been developed to identify any malaria species: P. falciparum alone, P. vivax alone, or any mix thereof. (Wilson,2013)

Malaria Rapid diagnostic test kits (RDTs) are a very new and evolving method that, in remote regions where microscopy is not easily supported, control over test storage conditions is limited, and where user supervision is lacking, can provide a parasite-based diagnosis. RDTs utilized in these circumstances must be straightforward, dependable, and stable.

(WHO, 2004)

### 1.8 TYPES OF MALARIA RDTs

Malaria RDTs, also known as malaria rapid diagnostic devices (MRDDs) or dipsticks, identify particular antigens (proteins) that the parasites that cause malaria produce. Those who have recently contracted the virus or those who are chronically sick have these antigens in their blood. An absorbent nitrocellulose strip's color changes to show the presence of antigen. Certain RDTs are limited to identifying a single species, Plasmodium falciparum, and typically do so by looking for either the parasite-specific lactate dehydrogenase (pLDH) or the histidine-rich protein 2

(HRP2). RDTs typically come in three formats. Some malaria RDTs are able to diagnose more than one of three species of parasites that cause malaria in humans (Plasmodium vivax, Plasmodium ovale, and Plasmodium malariae) by detecting different antigens.

A dipstick is the most basic type, where the absorbent nitrocellulose strip is inserted into wells that hold buffer or blood. In addition, the nitrocellulose strip can be used in more user-friendly but typically more expensive plastic cassettes or cards. Some products, when in good condition, can reach a sensitivity of about 100 parasites µl–1, which is comparable to that often attained by good field microscopy. Nonetheless, the sensitivity can differ amongst products; for P. falciparum, the suggested sensitivity is ≥95% at ≥100 parasites µl–1.

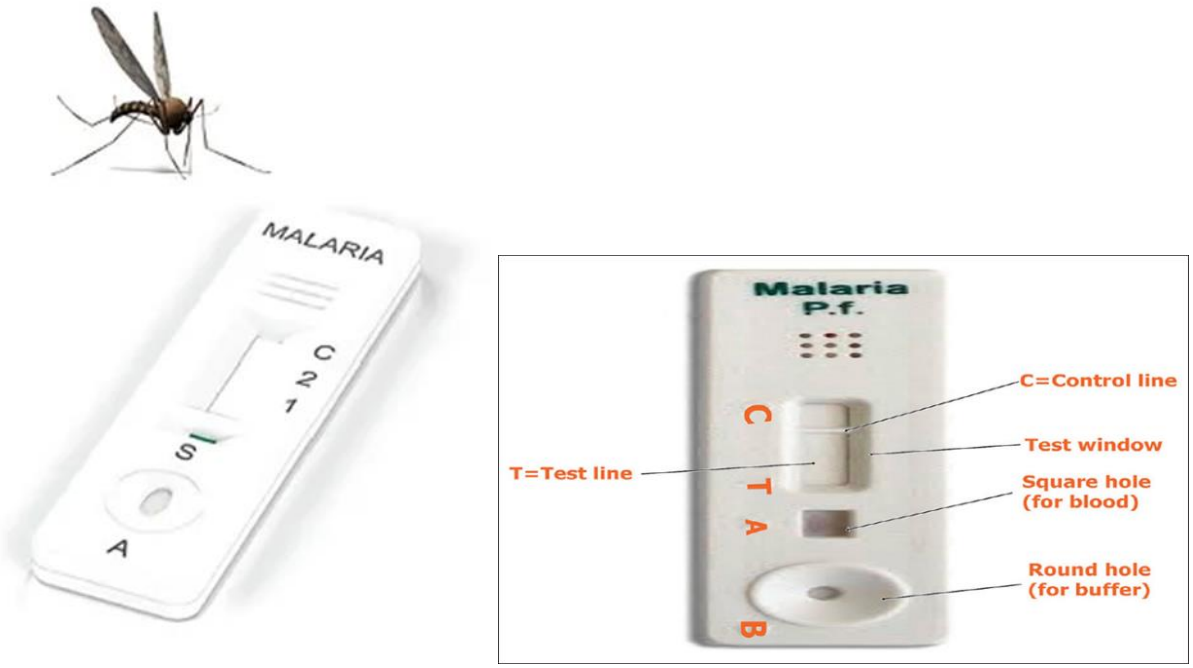


*Figure 1.3 showing some malaria rdts*

## 1.9 PROBLEM OF THE STUDY

In Ghana, malaria continues to pose a serious threat to public health because to its high rate of morbidity and mortality. Correct and timely diagnosis is essential for the right course of action and care. Rapid Diagnostic Tests (RDTs) have variable performance, despite its promise of speedy and simple-to-understand results. It is important to comprehend the efficacy of various

RDTs in precisely identifying malaria inside Ghanaian contexts to guarantee that patients have prompt and suitable medical attention.

## 1.10 JUSTIFICATION

In Ghana, malaria is one of the main causes of death. However, the related mortality and morbidity can be greatly decreased with an early and precise diagnosis. Because of their simplicity of use and quick results, RDTs are quickly replacing other diagnostic tools in distant and resource-poor settings. By evaluating the effectiveness of various RDT models, governments and healthcare professionals may make informed decisions and choose the most accurate and efficient instruments possible, improving patient outcomes. An extensive analysis of RDT performance in Ghana can serve as a model for comparable assessments in other endemic areas, encouraging best practices and efficient use of resources.

## 1.11 AIM

To evaluate and contrast the efficacy of different Malaria Rapid Diagnostic Test (RDTs) kits in New Juabeng North Municipality.

## 1.12 OBJECTIVES

- Literature Review: To review existing literature on the types of RDTs available for malaria diagnosis and their reported efficacy globally and specifically in Ghana.
- Data Collection: To collect data on the sensitivity, specificity, and accuracy of the RDTs used in selected health facilities and laboratories in the New Juabeng North Municipality.
- Performance Evaluation: To analyze the data to determine the relative performance of each RDT with microscopic examination.
- Environmental and Operational Factors: To examine if external factors, such as storage conditions or user training, influence the performance of the RDTs.

- Recommendations: Based on the findings, to provide recommendations for the selection and use of RDTs in Ghana, ensuring that the most effective tools are used for malaria diagnosis.

# CHAPTER TWO

## 2.0 Literature Review

Of the 432 specimens evaluated, 208 (representing 48.2% of the specimens) were reactive for malaria using all four assays. Leishman staining, AO fluorescent microscopy, and RDT microscopy were used to examine all of the samples. Of these, 180 (representing 41.6%) tested positive for malaria by Leishman staining, 186 (representing 43%) by AO fluorescent microscopy, and 208 (representing 48.2%) by RDT microscopy. However, out of the 124 samples that were subjected to PCR, 79 (63.7%) yielded positive results.

However, the gold standard for diagnosing malaria remains peripheral blood smears. However, this study discovered that more modern RDT for malaria performed more well as a diagnostic tool than clinical microscopy, suggesting a greater role for it in clinical practice and diagnosis.

(Sharma C. et.al 2021)

The malaria quick diagnostic test results were read with 94.1% sensitivity by the Deki Reader and 93.9% sensitivity by eye interpretation. The results of the malaria quick diagnostic test have a specificity of 71.8%, while human interpretation of the same data showed a 72.0% specificity. The Deki Reader and visual interpretation showed the malaria RDT results as 75.8% for the positive predictive value and a negative forecasting value of 92.8 and 92.4%, respectively. When read visually and by DR, RDT's accuracy was 82.6 and 82.1%, respectively.

When RDTs were read visually by inexperienced healthcare professionals or by automated DR, there was no discernible difference in the results. Nevertheless, in spite of the similarity in performance metrics, the apparatus has been beneficial as it offers stepwise guidance on processing RDT, data transfer and reporting. (Kalinga. et al 2018)

The gold standard for diagnosing malaria will always be malaria microscopy; however, the long turnaround times and scarcity of malaria microscopists associated with this method continue to negatively affect the quality of services provided by the laboratory, particularly the turnaround time, which is used as a quality indicator to assess laboratory quality systems. In the midst of a period of high malaria transmission, the longer turnaround time and shortage of malaria microscopists associated with resource constraints led us to look for an alternative to the gold standard. In order to ascertain its significance in the laboratory diagnosis of malaria, multi-species were assessed using the fast diagnostic test. The quick diagnostic test kit (SD Bioline – FK80) utilized in this study was compared to conventional malaria microscopy and is based on the detection of Plasmodium falciparum, histidine rich protein-2 (HRP–2), and Plasmodium vivax-specific lactose dehydrogenase (Pv-pLDH). Data on the utilization of microscopy and quick diagnostic tests for the diagnosis of malaria in an urban secondary health institution with a laboratory component was intended to be provided by the evaluation. 939 people in all who visited the outpatient department had clinical evaluations and were thought to have malaria. Both methods were then applied to blood samples from those patients. For P. falciparum, the corresponding sensitivity and specificity were 75.2% and 80.4%, respectively. The test's accuracy was 76.8%. The fast diagnostic test was found to be a viable initial screening test for malaria diagnosis; in the event that the test yields a negative result, microscopy confirmation is required. As a result, this will be better than treating patients for malaria without having laboratory results to support clinical evaluation as it stands now.. (Ameh 2012)

Treatment for malaria should still only be started following laboratory confirmation. The diagnosis of malaria can be made using various primary techniques. Every one of these approaches has drawbacks. In situations where laboratory testing is not easily accessible, presumed therapy for malaria is commonly used. For the diagnosis of malaria infection, microscopy of thick and thin

blood films stained with Giemsa is still the gold standard. The estimation of parasite density and stages, as well as the methods for slide preparation, staining, and reading, are widely accepted and standardized. Due to costs, a shortage of qualified personnel, the need for reagents and accessories, and other factors, microscopy is not always possible or available at basic health services in settings with limited resources. Rapid diagnostic tests (RDTs) are a promising technique for parasite-based diagnosis because of their ease of use and accuracy in identifying malaria infections. The test relies on utilizing monoclonal antibodies raised against the malaria antigen target to collect the parasite antigen produced from parasitized red blood cells. More sensitive than microscopy, Polymerase Chain Reaction (PCR) relies on DNA amplification techniques. PCR is not commonly utilized because it lacks a consistent methodology, is expensive, and requires highly skilled personnel.. (Siahaan 2018)

We used the malaria RDT lots that were available to evaluate a total of 65 blood specimens that were microscopically verified, consisting of 13 Plasmodium vivax, 13 P. falciparum, and 2 mixed. Only 10 of the 50 blood specimens with P. falciparum infections were found to be positive, 80% of the PfHRP-2 detecting RDT batches had false negative results [41/51]. The Northern Red Sea region had a 100% false negative result [12/12] for the PfHRP2 antigen, while the Gash Barka region had a 65% false negative result [11/17].. The investigation confirmed that PfHRP-2's capacity to identify RDTs had a notable false-negativity rate and excluded operator error, RDT quality, handling, and storage as potential sources of the issue. Therefore, it is strongly advised to investigate if parasite traits might be regarded as potential sources of false negative results by molecularly characterizing P. falciparum. (Berhane 2017)

The devastating effects of malaria on public health must be controlled, which requires the creation of a quick and accurate diagnostic test to identify those who have the disease. During an outbreak in the Iranian province of Chabahar, Sistan and Balouchestan, this study evaluated the ability of the BIOTEC Malaria P.v/P.f fast device, a rapid diagnostic test for malaria, to distinguish Plasmodium vivax and Plasmodium falciparum malaria. Twenty-five patients who were suspected of having malaria provided whole blood samples. The readings from one hundred fields of thick blood film stained with Giemsa were compared to the results from these kits. This test for malaria detection is quick (15 minutes). Monoclonal antibodies directed against the isomer of the parasitic enzyme lactate dehydrogenase of P. vivax and P. falciparum histidine rich protein-2 (PfHRP2) are coated on the device (PLDH).

54% of samples (136 out of 250) tested positive for malaria using a P.V./P.f. rapid device, while 55% of samples (138 out of 250) tested positive for malaria using blood films. The blood film showed that 81% (112 of138) and 19% (26 of138) of the patients tested positive for P. vivax and P. falciparum, respectively. 79.6% (110 of 138) of the samples tested positive for P. vivax, while 1.4% (2 of 138) of the samples tested negative, according to the malaria P.v/P.f rapid equipment. Of the 138 samples, P. falciparum was detected in 19% (26 samples). These results demonstrated that the malaria P.v/P.f fast gadget has a 98.5% sensitivity and a 100% specificity when compared to conventional blood films. The fast malaria P.v/P.f gadget demonstrated a strong association with conventional blood films for the identification of P. falciparum and P. vivax malaria. Currently, this kit is more costly than microscopy for the diagnosis of malaria in endemic areas. However, it is highly helpful in isolated locations where access to the facilities required for microscopic inspection is limited. (Abdolahi 2010)

Out of 271 blood samples, multiplex real-time PCR was utilized to identify 69 malaria cases as infections with Plasmodium falciparum, 16 as infections with Plasmodium vivax, and 3 as mixed infections. Of the total samples, light microscopy revealed that 33 were P. falciparum, 18 were P. vivax, and one sample had a mixed infection. RDT determined that 17 of the samples were P. vivax and 43 were P. falciparum. Using light microscopy as the reference test, multiplex real-time PCR's sensitivity and specificity were 100% (95% CI (93–100)) and 83.2% (95% CI (77.6–87.9)), respectively. Using multiplex real time PCR as a reference, the sensitivity of light microscopy was 58% (95% CI 46.9–68.4) and 67% (95% CI 56.2–76.7); for RDT, it was 100% (95% CI 98–100) and 98.9% (95% CI 96–99.9). A kappa value of 0.65 indicated a substantial degree of agreement between the results of PCR with multiplex real-time and microscopy. When there is minimal malaria transmission, multiplex real-time PCR performed better than microscopy and RDT in parasite detection and species identification on samples from feverish patients. In particular for community-based epidemiological samples, It is a highly accurate diagnostic test for malaria that can be used in projects to eradicate the disease. Even though RDT and microscopy were not as effective as multiplex real-time PCR. they were still able to diagnose malaria cases on patient samples in clinical facilities. (Belachew 2022)

According to the malaria antibodies (serum) approach, 100% of the 200 patients in the current study had positive RDT results. In the current study, 118 of the 200 patients tested positive for diluted Giemsa and Lieshman ocular microscopy (59%), whereas 128 of the 200 patients tested positive for RDTs based on malaria antigen (whole blood) approach (64%). Each patient who received a positive microscopy result also received a positive result from an antigen-based RDT. All patients were not febrile and received antimalarial medicine on the second follow-up day.

We conclude from the current study that RDTs based on the whole blood approach for malaria antigen are at least as specific as conventional microscopy. Antibody (serum)-based RDTs ought not to be pushed because they lack specificity. Since Africa is an endemic region, it might not be unusual for certain amounts of malaria antibodies to develop. The present investigation strengthens the argument that a sizable fraction of fever episodes are not caused by malaria. Though we agree with the WHO's assessment of the cost-effectiveness of RDTs, we advise that only the antigen-based approach be used in Africa and other endemic malaria regions of the world. (Azikiwe 2012)

# CHAPTER THREE

## 3.0 METHODOLOGY

Data analysis was done in conjunction with a random sample technique used for the investigation. The Abbot RDT and the First Response RDT were the two types of malaria RDTs used in this investigation.

### 3.1 POPULATION SAMPLE AND SAMPLING PROCEDURE

According to Saunders et al. (1997), a population is defined as the complete collection of cases from which a sample is taken. Our study's objective is to compare the effectiveness of malaria fast diagnostic test kits in the recently established Juaben North municipality.

### 3.2 SAMPLE SIZE

For computing sample size, the Slovin's formula was applied. Philippine Statistician, Vol. 1, 2012 making use of Slovin's formula to determine sample size:

$$n = \frac{N}{1+Ne^2}$$

Where, n = sample size

N = population size

e = margin of error

### 3.3 SAMPLING TECHNIQUE

By using sampling, a researcher can make inferences about a population from the sample's characteristics. Often, gathering statistics from the entire population is not feasible. We selected blood samples for our investigation from three distinct clinics in the New Juabeng North Municipality using a random sampling technique.

## 3.4 DATA COLLECTION PROCEDURE AND RESEARCH INSTRUMENT

Data collecting methods are the various techniques used to gather information for a research survey. Saunders et al. (1997) state that the data collection strategy must be relevant to the objectives and problems of the research. Consequently, two malaria rdt kits were used, along with microscopy, which was used as the control experiment, to gather data.

The two rdts were utilized to test for malaria in each blood sample that was drawn, and the results were compared to those obtained by microscope inspection.

Results for every test that was conducted were documented, including the microscope examination and each rdt.

## 3.4 TOOLS FOR DATA ANALYSIS

According to Yin (1994), there are two strategies used in data analysis. Both cross-case analysis and within-case analysis are these. While inside case refers to the process of comparing data to the theory used, cross case analysis compares data from one case to data from another. Within-case analysis was utilized in this study to reduce the amount of data. Every question about the objectives of the study and the corpus of literature was taken into account. The study was performed using the Statistical Package for Social Science (SPSS V22). To determine the most appropriate statistical method to use and to verify the accuracy of the responses, a normality test was run on the collected data. Descriptive statistics and the Cronbach's Alpha reliability test were utilized to assess the data. The Pearson's correlation test was used to assess the link between the two selected categories. The proper tables and charts were used to represent the data. After debating the result, inferences are made using the data.

# CHAPTER FOUR

## 4.0 DATA ANALYSIS AND DISCUSSION

### 4.1 Introduction

This chapter presents our study's data analysis as well as the study's findings. After that, the key findings are talked about. There were no missing samples among the 200 samples that were taken from the three distinct clinics. Finally, the chapter concludes with a review of the major discoveries concerning the objectives of the research.

## 4.2 Data Analysis

### 4.2.1 Respondents' demographic characteristics

This section discusses the demographic information of the study's participants. 200 samples were received in total, (100%) of which none were missing. Out of the 200 samples collected, 106 are females (53% of the sample) and 94 are males (47% of the sample), according to the gender distribution shown in figure 4.1 below.

**Statistics**

SEX

| | | |
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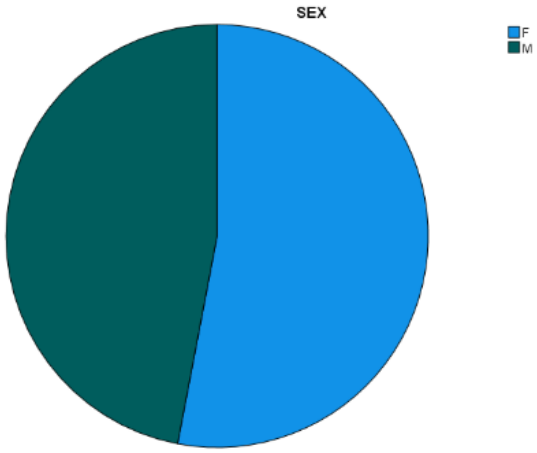
| N | Valid | 200 |
| | Missing | 0 |

*Table 4.1 showing the number of male and female participants*

**SEX**

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | F | 106 | 53.0 | 53.0 | 53.0 |
| | M | 94 | 47.0 | 47.0 | 100.0 |
| | Total | 200 | 100.0 | 100.0 | |




Out of the 200 samples tested for malaria using microscopy examination, 48 of the samples tested positive (24% of the samples) and 152 of the samples tested negative (76% of the samples) as shown in the table 4.2 below.

**Statistics**

CONTROL

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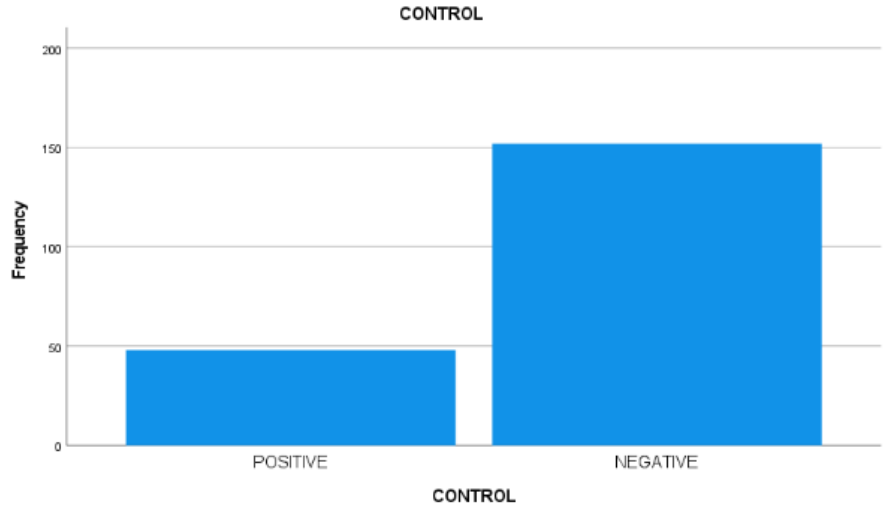
| N | Valid | 200 |
| | Missing | 0 |

*Table 4.2 showing the number of positive and negative cases using the microscopic examination*

**CONTROL**

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | POSITIVE | 48 | 24.0 | 24.0 | 24.0 |
| | NEGATIVE | 152 | 76.0 | 76.0 | 100.0 |
| | Total | 200 | 100.0 | 100.0 | |



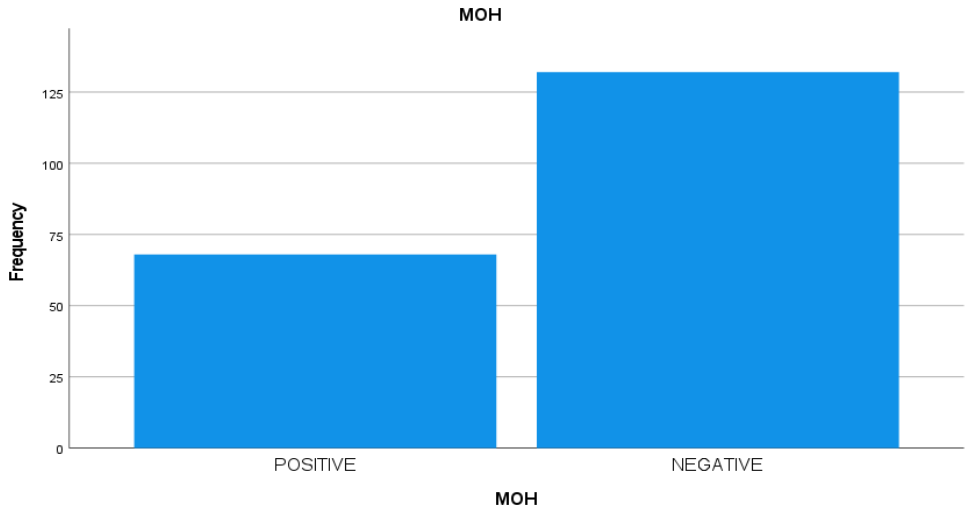

Out of the 200 samples tested for malaria using the First response malaria rdt, 68 of the samples tested positive (34% of the samples) and 132 of the samples tested negative (66% of the samples) as shown in the table 4.3 below.

*Table 4.3 showing the number of positive and negative cases using the first response rdt*

**MOH**

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | POSITIVE | 68 | 34.0 | 34.0 | 34.0 |

| | | | | |
|---|---|---|---|---|
| NEGATIVE | 132 | 66.0 | 66.0 | 100.0 |
| Total | 200 | 100.0 | 100.0 | |




Out of the 200 samples tested for malaria using the Abbot malaria rdt, 47 of the samples tested positive (23.5% of the samples) and 153 of the samples tested negative (76.5% of the samples) as shown in the table 4.4 below.

*Table 4.4 showing the number of positive and negative cases using the abbot rdt*

**ABBOT**

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | POSITIVE | 47 | 23.5 | 23.5 | 23.5 |
| | NEGATIVE | 153 | 76.5 | 76.5 | 100.0 |
| | Total | 200 | 100.0 | 100.0 | |

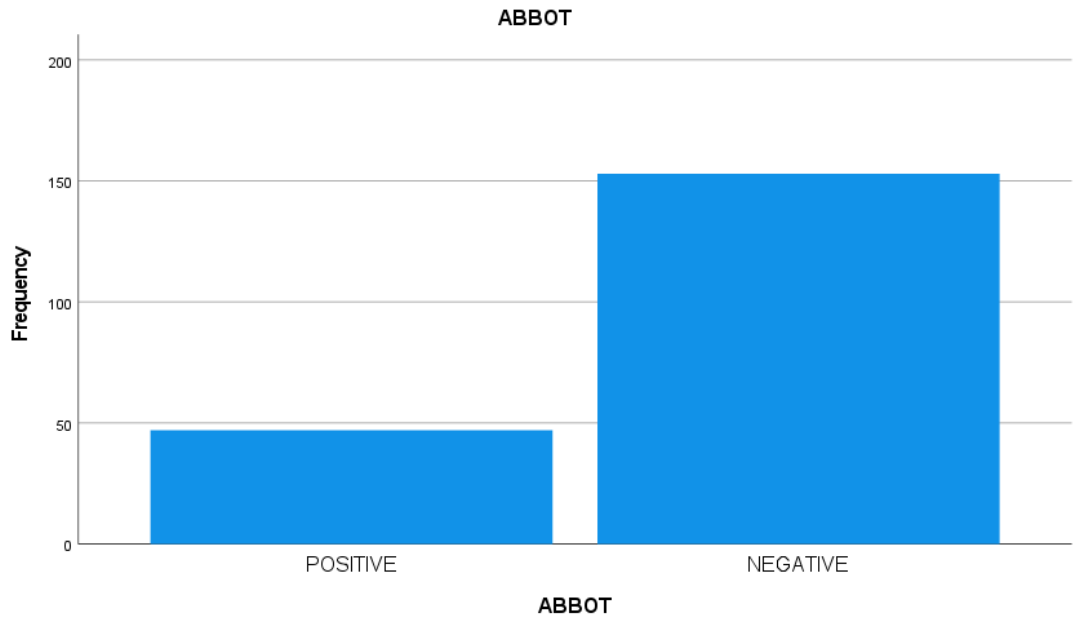



*Table 4.5 showing the correlation coefficients (Pearson's correlation) for the Table 2Table 3 first response rdt and the control.*

**Correlations**

| | | CONTROL | MOH |
|---|---|---|---|
| CONTROL | Pearson Correlation | 1 | .500** |
| | Sig. (2-tailed) | | .000 |
| | N | 352 | 352 |
| MOH | Pearson Correlation | .500** | 1 |
| | Sig. (2-tailed) | .000 | |
| | N | 352 | 352 |

**. Correlation is significant at the 0.01 level (2-tailed).

*Table 4.6 showing the correlation coefficients (Pearson's correlation) for abbot rdt and the control*

**Correlations**

| | | CONTROL | ABBOT |
|---|---|---|---|
| CONTROL | Pearson Correlation | 1 | .988** |
| | Sig. (2-tailed) | | .000 |
| | N | 352 | 352 |
| ABBOT | Pearson Correlation | .988** | 1 |
| | Sig. (2-tailed) | .000 | |
| | N | 352 | 352 |

**. Correlation is significant at the 0.01 level (2-tailed).

**Case Processing Summary**

| | Cases | | | | | |
|---|---|---|---|---|---|---|
| | Valid | | Missing | | Total | |
| | N | Percent | N | Percent | N | Percent |
| MOH * CONTROL | 352 | 100.0% | 0 | 0.0% | 352 | 100.0% |

*Table 4.7 showing the sensitivity and specificity of the first response rdt in comparison with the control*

**MOH * CONTROL Crosstabulation**

| | | | CONTROL | | |
|---|---|---|---|---|---|
| | | | POSITIVE | NEGATIVE | Total |
| MOH | POSITIVE | Count | 40 | 56 | 96 |
| | | % within CONTROL | 83.3% | 18.4% | 27.3% |
| | NEGATIVE | Count | 8 | 248 | 256 |
| | | % within CONTROL | 16.7% | 81.6% | 72.7% |
| Total | | Count | 48 | 304 | 352 |
| | | % within CONTROL | 100.0% | 100.0% | 100.0% |

**Case Processing Summary**

| | Cases | | | | | |
|---|---|---|---|---|---|---|
| | Valid | | Missing | | Total | |
| | N | Percent | N | Percent | N | Percent |
| ABBOT * CONTROL | 352 | 100.0% | 0 | 0.0% | 352 | 100.0% |

*Table 4.8 shows the sensitivity and specificity of the abbot rdt in comparison with the control*

**ABBOT * CONTROL Crosstabulation**

| | | | CONTROL | | |
|---|---|---|---|---|---|
| | | | POSITIVE | NEGATIVE | Total |
| ABBOT | POSITIVE | Count | 47 | 0 | 47 |
| | | % within CONTROL | 97.9% | 0.0% | 13.4% |
| | NEGATIVE | Count | 1 | 304 | 305 |
| | | % within CONTROL | 2.1% | 100.0% | 86.6% |
| Total | | Count | 48 | 304 | 352 |

| | | | |
|---|---|---|---|
| % within CONTROL | 100.0% | 100.0% | 100.0% |

## 4.3 Discussion Of Results

Based on the data collected in relation to the research objectives, we present and discuss our findings. To help all stakeholders comprehend the data and make educated decisions, information was displayed as tables, bar and pie charts with written descriptions. By evaluating all the 200 samples collected, 106 are females (53% of the sample) and 94 are males (47% of the sample). There were no missing samples.

In all, out of the 200 samples tested for malaria using microscopy examination, 48 of the samples tested positive (24% of the samples) and 152 of the samples tested negative (76% of the samples).

Out of the 200 samples tested for malaria using the First response malaria rdt, 68 of the samples tested positive (34% of the samples) and 132 of the samples tested negative (66% of the samples).

Out of the 200 samples tested for malaria using the Abbot malaria rdt, 47 of the samples tested positive (23.5% of the samples) and 153 of the samples tested negative (76.5% of the samples).

The Pearson correlation coefficient (PCC) is a correlation coefficient used in statistics to evaluate the linear correlation between two sets of data. Because it is the ratio of the covariance of two variables to the sum of their standard deviations, and because the result is always between -1 and +1, it is effectively a normalized measurement of covariance. Similar to covariance, the measure primarily accounts for linear relationships between variables; it

overlooks numerous other types of connections or correlations. A correlation that precisely captures the relationship between two variables is said to have an absolute value of 1. In other words, two items that score strongly (near + 1) are quite comparable.

A Pearson score of almost zero would indicate two uncorrelated objects.

The Pearson correlation coefficient of two negatively correlated objects (i.e., one rising as the other falls) would be close to zero. The correlation value for the relationship between the first response rdt and the control was 0.500 whereas the Pearson value for the relation between the abbot rdt and the control was 0.988. This implies that the abbot rdt has a closer relationship with the control test compared to the first response rdt.

The accuracy of a test that determines whether a condition is present or absent is mathematically described by its sensitivity and specificity. Sensitivity is how well a test can identify real positives, whereas specificity measures how well a test can identify true negatives, assuming that people with the condition are deemed "positive" and people without it are considered "negative".

- The likelihood of a positive test result, contingent on the subject really being positive, is known as sensitivity (also known as true positive rate).
- The likelihood of a negative test result, contingent on the subject really being negative, is known as specificity (also known as true negative rate).

It is possible to define sensitivity and specificity in relation to an assumed-to-be-correct "gold standard test" in cases where the true status of the condition cannot be determined. There is typically a trade-off between sensitivity and specificity for any testing, including screening and diagnostic tests, meaning that higher sensitivities equate to lower specificities and vice versa. Comparing the first response rdt with control, a Sensitivity (TPR) of 83.3%, Type 2 error (FNR) of 16.7%, type 1 error (FPR) of 18.4% and a Specificity (TNR) of 81.6% were recorded.

Comparing the abbot rdt with the control, the Sensitivity (TPR) recorded was 97.9%, the Type 2 error (FNR) recorded was 2.1%, Type 1 error (FPR) recorded was 0.0% and the Specificity (TNR) recorded was 100%.

Comparing their sensitivities and specificities with the control, abbot rdt has a higher sensitivity of 97.9% compared to 83.3% of the first response rdt and a specificity of 100% compared to 81.6% of the first response rdt.

# CHAPTER FIVE

# CONCLUSION

## 5.1 Introduction

Our study's main objectives were to assess data on the sensitivity and specificity of the RDTs utilized in a few laboratories and healthcare facilities in the New Juabeng North Municipality, and to analyze the data to ascertain how well each RDT performed in relation to microscopic inspection.

## 5.2 Summary of Findings

There were no missing samples among the 200 samples that were gathered from three distinct clinics..

According to the tests performed on the 200 samples for malaria using microscopy examination, 48 of the samples tested positive (24% of the samples) and 152 of the samples tested negative (76% of the samples).

For the tests carried out for malaria using the First response malaria rdt, 68 of the samples tested positive (34% of the samples) and 132 of the samples tested negative (66% of the samples)

Using the Abbot malaria rdt, 47 of the samples tested positive (23.5% of the samples) and 153 of the samples tested negative (76.5% of the samples)

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## 5.3 CONCLUSION

According to the study, The Pearson correlation value for the relationship between the moh rdt and the control was 0.500 whereas the Pearson value for the relation between the abbot rdt and the control was 0.988.

This implies that the abbot rdt has a closer relationship with the control test compared to the moh rdt.

Comparing their sensitivities and specificities with the control, abbot rdt has a higher sensitivity of 97.9% compared to 83.3% of the moh rdt and a specificity of 100% compared to 81.6% of the moh rdt.

Due to the high sensitivity, specificity and correlation coefficient values of the abbot rdt, we can conclude that the Abbot rdt should be the first call of response for any malaria rdt test.

Moreover, its ability to detect two different malaria species; P. vivax and P. falciparum gives it an edge above the first response rdt which can only detect one malaria specie; P. falciparum.

## 5.4 RECOMMENDATIONS

**what can biomedical engineers do to improve RDTs?**

**Antigen selection:** Biomedical engineers can work with researchers and manufacturers to identify and select the most appropriate antigens for RDTs, ensuring high sensitivity and specificity.

**Conjugate and control line development:** The quality and performance of the conjugate and control lines in RDTs are crucial for accurate results. Biomedical engineers can contribute to the

development of improved conjugate and control line materials and configurations, ensuring reliable and consistent performance.

**Collaboration with manufacturers and users:** Biomedical engineers can work closely with RDT manufacturers and end-users to understand their needs, address challenges, and ensure that the developed solutions are practical, effective, and scalable. This collaboration can help bridge the gap between research and implementation, leading to real-world impact in malaria diagnosis and control.

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# APPENDIX


Abbott
Bioline
Malaria Ag P.f/P.v
"MINISTRY OF HEALTH, GHANA - NOT FOR SALE"
FIRST RESPONSE
Malaria Antigen P. falciparum
(HRP2) Card Test
(Whole Blood)
For in vitro Diagnostic Use Only.
QC PASSED