Quality Assurance Testing of Some Malaria Rapid Diagnostic Tests Procured from Open Markets in Lagos State, Nigeria

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Abstract: **Malaria rapid diagnostic tests (MRDTs) have the potential of significantly improving the diagnosis of malaria in developing countries, especially where there is no adequate microscopy service for the diagnosis of malaria or act as a back-up to microscopy for inexperience personnel. However, the absolute reliance of these tests remains a problem due to uncertainty of the quality of the test and lack of confidence since there is no regulation and proper quality control. The remarkable decline in the performance of the MRDTs can be adversely affected by the high temperatures to which they were exposed to in a tropical country, manufacturer's defects, poor storage facility, mishandling in the course of transportation and use of sub- standard materials in production. There is need for proper regulatory body to regulate the manufacturing and importation of RDTs against any unwholesome practice. Also, there is need to consider the importance of stability of diagnostic test during procurement.**

***Key words*: Malaria, Rapid Diagnostic Test, Quality Control samples, Quality Assurance Testing and Procured**

I. INTRODUCTION

The mainstay of malaria diagnosis has previously been clinical diagnosis and malaria microscopy. However, parasite-based diagnosis is now recognized as vital for good case management of febrile illness, to reduce anti-malarial drug wastage, and for monitoring of malaria prevalence and the impact of anti-malaria interventions. Rapid diagnostic tests RDTs have gained increasing importance in addressing this need, in areas where good-quality microscopy is unavailable (WHO, 2014).So as to ensure RDTs contribute to management, it is essential to ensure the accuracy of products prior to disseminating to the field where quality monitoring is often difficult. Rapid diagnostic tests are increasingly becoming a paradigm for both clinical diagnosis of malaria infections and for estimating community parasite prevalence in household malaria indicator surveys in malaria-endemic countries

Malaria remains endemic in 109 countries, and while parasite-based diagnosis is increasing, most suspected cases of malaria are still not properly identified, with accurate diagnosis and disease monitoring consequently remaining elusive (WHO, 2010). Nigeria accounts for a quarter of all malaria cases in the WHO African Region (WHO, 2016). Transmission occurs all-year round in the South, and more seasonal in the North (WHO, 2013). It is one of the principal causes of sickness and death in Nigeria and imposes an enormous socio-economic burden on the country. *Plasmodium falciparum* is the commonest of the five human *Plasmodium species* and it is found in virtually all parts of Africa accounting for up to 98% of the cases in Nigeria (WHO, 2016).

World Health Organization recommends that malaria case management be based parasitological confirmation of malaria in all cases, through quality-assured diagnosis in all settings before treatment commenced. Treatment solely on the basis of clinical suspicion should only be considered when a parasitological diagnosis is not accessible (WHO, 2010). Prompt diagnostic confirmation of malaria can be achieved through good quality microscopy. Since this is not feasible in many situations, quality-assured malaria RDTs represent suitable alternatives for the diagnosis of *Plasmodium falciparum* infections, and a number of products can also detect most cases of non-falciparum malaria (WHO, 2013; Okangba, 2019).

Malaria RDTs are so-called immunochromatographic tests that detect *Plasmodium* antigens in the blood by an antigen-antibody reaction on a nitrocellulose strip (Bell *et al.*, 2006). The antigen-antibody complex is conjugated to colloidal gold, and a positive result is visible as a cherry- or purple-red coloured line. Apart from a control line, there are one, two or three test lines: the so-called two-band tests comprise a control line and a single test line, and are mostly designed to diagnose *Plasmodium falciparum* (Sani *et al*., 2013; Okangba *et al.*, 2016). Their targets are either histidine-rich protein-2 (HRP-2) or *P. falciparum*-specific parasite lactate dehydrogenase (Pf-pLDH). Three-band RDTs display a second test line mostly targeting antigens common to the four

species such as pan-*Plasmodium*-specific parasite lactate dehydrogenase (pan-pLDH) or aldolase (WHO, 2018). The four-band RDTs have an additional third test line targeting *Plasmodium vivax*-specific pLDH (Pv-pLDH). Malaria RDTs are faster, simple to perform, do not require electricity or specific equipment and could generate stable results of high sensitivity and specificity (Jorgensen *et al*., 2007).

However, the functioning and accuracy of RDTs can be affected by several factors, including manufacturing defects, storage, transport, operator error (Tavrow *et al*., 2000; Murray *et al*., 2008) and antigenic polymorphism (Baker *et al*.,2005) and damage to the RDT itself with storage under field conditions or during transport. RDTs are vulnerable to extremes of temperature and high humidity, thus stability of the kit affects its sensitivity (Jorgenson *et al*., 2006). Malaria diagnostic tests need to be highly accurate because false negative and false positive diagnosis have medical , social and economic consequence such as prolongation of illness, increase in morbidity and mortality, and loss of credibility of health services (Reyburn *et al*., 2004; Murray *et al*., 2008). The storage and use of MRDTs in remote areas presents a new challenge to many health systems. Exposure of MRDTs to high temperatures has the potential to degrade RDTs. Most manufacturers recommend storage between 4-30^{o}C , and shelf life is based on this assumption, but refrigeration and air-conditioning are commonly unavailable in malaria endemic areas where RDTs are intended for use (Chiodini *et al.,* 2007).

World Health Organization (WHO) recommends that RDTs be implemented with a comprehensive quality control strategy. First, RDTs should be purchased from a manufacturer that follows good manufacturing practices (GMP). Second, each lot of RDTs should be tested on arrival in the country of use to ensure that the tests were not exposed to extreme temperatures or other conditions that may affect RDT performance. RDT performance is measured by testing known dilutions of parasites (typically 200 and 5,000 parasites/µL) and a negative control (WHO, 2010).

The absolute reliance of these tests remains a problem due to the uncertainty of the quality of the test and lack of confidence since there is no regulation and proper quality control. Hence the objectives of this study are to assess the performance of procured malaria RDTs in the open market using quality control samples.

II. MATERIAL AND METHODS

2.1 Study Site and Area

This study was a cross sectional study design. This study was carried out in Babcock University, Ilishan-Remo, Ogun State, which is located along the Sagamu-Lagos expressway, Ikenne Local Government Area, Ogun State, Nigeria. Its headquarters are in the town of Ikenne at 6°52′N 3°43′E. It has an area of 144 km^2 and a population of 118,735 at the 2006 census. The quality assurance testing for these MRDTs was conducted in the Department of Medical Microbiology and Parasitology, Benjamin Carson (SNR.) School of Medicine, College of Health and Medical Sciences Babcock University, Ilisan Remo, Ogun State, Nigeria.

2.2 Sample Collection.

The malaria RDTs used for this study were commercially procured from the open market: Ojax Medics Ltd Iga idunganran, Isale-Eko, idumato- Lagos, Lagos state, Ubastic itire road, Surulere, Acon laboratory inc, Bundi international diagnostic Ltd, Lascon Pharma Ltd, Global Nig Ltd. The prepared quality control samples at 200parasites/uL and at 2000parasites/uL were procured from Field Approach Consult, Lagos, Nigeria

2.3 Ethical Consideration

Approval was gotten to conduct this study from Ethics and Research Committee, Benjamin Carson (SNR.) School of Medicine, Babcock University, Ilishan-Remo, Ogun state with the reference number, BUHREC583/18. Informed consent were given to the individuals on the purpose of the study. They were also informed of their right to withdraw from the study. The entire study was conducted in line with Good clinical laboratory practice and Good clinical practice.

2.4 Data Analysis

The data generated from the study were analyzed using EPINFO 2002 statistical software (CDC Atlanta, USA). Tests for associations and differences were done by chi square analysis. Test of statistical significance was set at P value less than 0.05 at 95% confidence interval

2.4 Initial Quality Control Testing

Each test kit was checked for any sign of moisture and the colour of the dessicant that came with each kit was checked for colour changes. Four different Pf QC samples (A-D), each with dilutions of 200 p/µl and 2000 p/µl were selected. For each of the samples with dilution 200 p/µl, 2 test kits of each of the different malaria RDTs were used, while for each of the samples with dilution 2000 p/µl one test kit of the different RDTs were used to perform malaria test. Also ten (10) negative QC samples (I-R) were used for each of the different RDTs. The procedure was strictly adhered to, according to manufacturer' instructions insert.

III. RESULTS

None gave 100% sensitivity at dilutions 200p/µl and 2000p/µl for the results of initial Quality Control testing of the 5 products of malaria RDTs. The five RDTs; Paracheck®, Wondfo®, Global device®, CTK Biotech® and SD Biotech® gave percentage (%) positive of 16.7%, 33.3%, 33.3%, 8.3% and 83.3% respectively. The negative QC samples were 100% negative for all the RDTs (Paracheck®, Wondfo®, Global device ®and CTK Biotech®) except for SD Bioline® which was 80% percentage negative.

Table 2: Results of Quality Assurance testing of Procured MRDTs using Quality Control Samples

Names of MRDTs/ QC Samples		**200**	**para**	**sites/**	**uL**				**2000**	**para**	**sites/**	**uL**	
	A1	A2	B1	B2	C1	C2	D1	D2	A	B	C	D	Negative QC (ten) Samples E-N
Abon	1+	1+	2+	1+	1+	1+	1+	1+	1+	1+	2+	2+	Neg
Accurate	2+	2+	2+	3+	2+	2+	1+	2+	3+	3+	2+	2+	Neg
Carestart	1+	2+	1+	2+	1+	1+	2+	2+	3+	3+	2+	2+	Neg
Clearview	1+	2+	1+	1+	1+	1+	1+	2+	2+	2+	2+	2+	Neg
Firstline	2+	2+	1+	2+	2+	1+	2+	2+	2+	2+	2+	2+	Neg
Gima	2+	2+	2+	2+	2+	1+	1+	2+	3+	3+	3+	3+	Neg
Health check	1+	1+	1+	1+	1+	1+	1+	1+	3+	3+	3+	3+	Neg
Micropoint	1+	1+	1+	1+	1+	1+	1+	1+	1+	1+	1+	1+	Neg
Paracheck	1+	1+	1+	1+	1+	1+	1+	2+	2+	3+	3+	3+	Neg
Ritcher	1+	1+	NEG	NEG	1+	NEG	1+	1+	NEG	1+	NEG	NEG	Neg
SD Bioline P.f (Control RDT)	1+	1+	1+	1+	1+	1+	1+		3+	3+	3+	3+	Neg
SD Bioline HRP2/pLDH	1+	1+	1+	1+	1+	1+	1+	1+	2+	2+	2+	2+	Neg

Percentage Positive /Negative of initial QC testing of the five malaria rapid diagnostic tests (MRDTs) Positive Samples Negative Samples (%) Initial Total Positive (%)

	Positive Samples		Negative Samples (%)	Initial Total Positive (%)
RDTs	200p/µl (%)	2000p/µl (%)		
CTK	0	25	100	8.3
Paracheck	0	50	100	16.7
Wondfo	12.5	75	100	33.3
Global	25	50	100	33.3
SD Bioline	5	100	80	83.3
ICT Combo				
(Stock)	100%	100%	100%	100%

IV. DISCUSSION

The WHO and the Foundation for Innovative New Diagnostics test the performance of RDTs systematically in the Product Testing Programme, using panel detection scores (PDS) as a guide to test sensitivity and specificity, and currently recommend that only RDTs with a panel detection score of over 75% are procured by national malaria control programmes (NMCP) (Tjitra *et al*.,2001) (although over the period 2011–2014, many NMCPs were not completely adherent to this criteria, especially amongst RDTs supplied to the private sector (Incardon *et al*., 2017). A number of the RDTs included in this analysis fall below the PDS
threshold, although this threshold has moved over time, and many RDTs that currently fall below the PDS threshold were acceptable at the time the study was conducted.

WHO (2008), algorithm for RDTs Quality Control (QC) testing states that for a RDT kit to pass ,both initial and longtime quality control testing, the percentage positive must be 100%. However, the result from the study showed that the five locally purchased malaria rapid diagnostic test MRDTs failed the QC test at the initial QC testing. Among the 5 MRDTs used (Paracheck®, Global device®, Wondfo biotech®,

CTK Biotech®, and SD Bioline®), SD Bioline® (MSP-based) RDTs showed some false negative result on the *Plasmodium falciparium* (Pf) QC samples at 200p/µl dilution and these samples were positive on ICT Combo® (Stock) RDT. This suggests that the threshold of detection of the MSP-RDTS was low compared to the stock RDT, this was also stated by WHO. (2008). SD Bioline also gave the highest percentage positive of 83.3% compared to Paracheck®, Global device® Wondfo biotech®, and CTK Biotech® RDTs that gave percentage positive of 16.7%, 33.3%, 33.3% and 8.3% respectively.

MSP-based RDT also gave a false positive result of 20% with the some of the negative QC samples that were confirmed by microscopy (being the "gold standard") and ICT Combo (Stock RDT) to be negative while the other locally purchased MRDTs were all negative. The explanation to this is that the SD Bioline® RDT detects antibodies and there is possibility of long persistence of antibody in the circulation after treatment which gave a false positive result unlike the other 4 MRDTs that detects antigens. There was a decline of the percentage positive during the stability testing for all the 5 MRDTs used. This suggests that the deterioration could be as a result of substandard materials used in producing these kits or poor storage facility and exposure to heat which could possibly reduce sensitivity and shell life of the kit (Tekola *et al*., 2008)

In heat stability testing of 5 locally purchased MRDTs, the MSP-based RDTs stored at 40^{o}C showed percentage positive of 25% while Wondfo biotech®, Global device® and CTK Biotech® stored at 40^{o}C and 45^{o}C and Paracheck® stored at 45^{o}C and 50^{o}C all showed percentage positive of 0%. This result is different from the study carried out by Chiodini *et al*., (2007) where HRP2 based RDT tested gave 100% positivity and pLDH based RDT fell well below 80% positivity. This poor performance may be due to the fact that heat induces denaturation of antibodies in the test membrane and this may thus prevent their binding to the target antigen (Chiodini *et al*., 2007). Another possibility is damage to the nitrocellulose membrane forming the strip, changing its flow characteristics or causing the antibody to detach from the membrane. Damage of the membrane could be the cause of reduced sensitivity. Different membrane products may account for some between-product variability (Chiodini *et al*., 2007).

The effect of temperature as illustrated in heat stability study, has shown that in our country, Nigeria and in Africa where the temperature is usually hot, RDTs stored in warehouses and other storage facilities tend to lose their sensitivity, and this might be as a result of deterioration of monoclonal antibody and antibody dye used in the production of the RDTs. Mismanagement could also affect the sensitivity and specificity of the RDT and defects in the device membrane as stated by Reyburn *et al*., (2007)

Through out this study, the controls bands were seen in all the MRDTs. This confirms the integrity of the antigen gold conjugate indicates the visible lines, but does not confirm the ability of the RDTs parasite antigen and antibodies. The appearance of the control line in all the MRDT kit can mislead the end user with the fact that the test was working satisfactorily, when in fact, its performance is well below acceptable levels. The test and control lines were likely to have different sensitivity to heat in the case of these five locally purchased RDTs. Among the locally purchased MRDTs, MSP-based antibody detection malaria RDT can only be useful in providing epidemiological information on community wide exposure, to malaria, particularly in low transmission area for evaluating the effectiveness of control program. However, using MSP-based RDTs for the diagnosis of malaria in hospitals is not reliable, as it was seen that the test gave false positive and false negative results. These false results have medical consequences such as wrong diagnosis by the clinicians which can result to loss of credibility of health services, prolongation of illness, abuse of drugs, drug resistance and increase in morbidity and mortality.

RDTs can only be considered for use in the diagnosis of malaria in the field if they are able to work day in day out at a high level of reliability under the prevalent conditions, notably high ambient temperature. Generally, specific factors that need to be considered in introducing MRDTs should include performance characteristics, operational characteristics and cost (Murray *et al*., 2008) However, the results from this study shows that the performance characteristics of the five local MRDTs was low because of its inability to pass 100% initial QC testing and also their operational characteristics were poor because of the difficulty encountered in the course of carrying out this test, and the MRDTs inability to withstand high temperature.

Further work is required for all the five local MRDTs to define the temperature and true parameters within which the MRDTs can be expected to perform satisfactorily. The inclusion of a temperature effect indicator, ideally on the individual RDTs or on their packaging should be considered.This study highlights need for standardized product testing, quality control by the manufacturer and continuous external quality assessment when the RDTs are in routine clinical use. Good storage and quality control need to be established in all situations where RDTs are deployed. There is need to also consider the importance of stability of diagnostic test during procurement. The quality assurance testing of the procured MRDTs showed a substantial performance when compared to previous studies

V. CONCLUSION

In conclusion, from the results obtained in the investigation carried on five locally purchased MRDTs, it can be deduced that the five locally MRDTs purchased are not suitable for malaria diagnosis. This may be due to lack of regulation governing the importation of these kits, suppliers are not health personnel and they do not know the implication of misdiagnosis and exposure to high temperature. The use of these RDTs should be discouraged in an endemic country

such as Nigeria where the consequences of failing to treat malaria can be grave.

REFERENCE

[1] Agomo, O. Chimere, Oyibo, A. Wellington, Anorlu, I Rose, Agomo, U. Philip (2009). Prevalenve of Malaria in Pregnant Women in Lagos, South-West Nigeria. Korean Journal of Parasitology 47(2): 179-183

[2] Baker, J., McCarthy, J., Gatton, M., Kyle, D. E., Belizario, V., Luchavez, J., Bell, D., Cheng, Q., (2005). Genetic diversity of Plasmodium falciparum histidine-rich protein-2 (PfHRP2) and its effects on the performance of PfHRP-2 based rapid diagnostic tests. Journal of Infectious Disease 192: 870-877

[3] Bell D., Wongsrichanalai C., Barnwell J.W (2006). Ensuring quality and access for malaria diagnosis; how can it be achieved? Nat .Rev. Microbiology 4: S7-S20

[4] Chiodini,P ,L., Katherine B, Pernille J, John W. B, Katherine K. G, Jenny L, Anthony H. Moody, Audie C, and David Bell (2007). The heat stability of Plasmodium lactate dehydrogenase-based and histidine-rich protein 2-based malaria rapid diagnostic tests. Transaction of the Royal Society of Tropical Medicine and Hygiene 101: 331-337

[5] Federal Ministry of Health (2015): National Antimalarial Treatment Guidelines National Malaria. Abuja, Nigeria.

[6] Jorgenson, P., Chantap, L., Rebueno, A., Tsuyuoka, R., Bell, D. (2007) Malaria rapid diagnostic tests in tropical climates: the need for cool chain. American Journal of Tropical Medicine and Hygiene 74: 750-754

[7] Moody Anthony (2002). Rapid diagnostic tests for malaria parasite. Clinical Microbiology Review 15(1): 66-78

[8] Murray, C. K., Robert, A. Gasser, Jr., Alan, J. Magil, and R. Scott Miller (2008). Update on Rapid Diagnostic Testing for Malaria Microbiology Reviews P. 97-110

[9] Nmadu P.M., Peter E., Alexander P., Koggie A.Z., Maikenti J.I (2015). The prevalence of Malaria in Children between the ages 2-15 Visiting General Hospital Life Camp, Abuja, Nigeria. Journal of Health Sciences 5 (3): 47-51

[10] Nwaorgu O.C., Qrajaka, B.N (2011). Prevalence of malaria among children age 1-10 years old in Communities in Akwa North Local Government Area, Anambra State, Nigeria

[11] Okangba, C. Chika Charles J. Elikwua,, Emmanuel O Shobowalea, Opeoluwa Shonekan, Victor Nwadike, Babatunde Tayoa, Azubuike C. Omeonua, Bibitayo Faluyia, Chiamaka Meremikwua, Oyindamola Faladea, Demilade Osobaa, Tolulope Binuyo, Akinboboye Olutosin (2016). Histidine rich protein 2 performance in determining the prevalence of Malaria among patients presenting with clinical symptoms of Malaria. Scientific Journal of Pure and Applied Sciences. 5(1) 339-350

[12] Okangba, Chika Celen, (2019). Importance of quality assurance testing of malaria rapid diagnostic test in the case management of malaria Scientific Journal of Pure and Applied Sciences (2019) 8(5) 858-875

[13] Okangba, C. C, (2019). Evaluating the Performance of Locally Purchased Malaria Rapid Diagnostic Test in the Laboratory, Using Highly Characterized Quality Control Samples. International Journal of Research and Innovation in Applied Science (IJRIAS) | Volume IV, Issue V, 2019|ISSN 2454-6194

[14] Reyburn H, Mbatia R, Drakeley C, Carneiro I, Mwakasungula E, Mwerinde O, Sanganda K, Shao J, Kitua A, Olomi R, Greenwood BM, Whitty C.J (2004). Overdiagnosis of malaria in patients with severe febrile illness in Tanzania: a prospective study. BMJ Clinical research ed. 329: 1212

[15] Tavrow, P., E, Knebel, and L. Cogswell. (2000). Using quality design to improve malaria rapid diagnostic tests in Malawi. Operations Research Results 1: 4

[16] Tekola E, Teshome G Jeremiah N, Patricia M. G, Estifanos B. S, Yshewame brat E, Berhat G, Gedeon Y, Tesfaye T, Ayenew M, Mulat Z, Asrat G, Aryc W. M, Paul M. E, and Frank O. R (2008). Evaluation of light microscopy and rapid diagnostic tests for the detection of malaria under operational field conditions: a household survey in Ethiopia Malaria Journal 7: 118

[17] Sani, U.M., Jiya, N.M., Ahmed, H., (2013). Evaluation of malaria rapid diagnostic test among febrile children in Sokoto, Nigeria. Int. J. Med. Med. Sci., ISSN 2167, 3(5), 434-440.

[18] Ukibe S.N., Ukibe, N.R., Mbanugo J.I., Ikeakor I.R (2017). Prevalence of malaria among pregnant women attending ante natal clinics in hospitals in Anambra State, South East, Nigeria. Nigeria Journal of Parasitology 37(2):240

[19] World Health Organization (2000a). Approaches to the diagnosis of malaria. In: malaria diagnosis. Report of a joint WHO/USAID informal consultation pg 10-18

[20] World Health Organization (2000). New perspective: malaria diagnosis. Report of a joint WHO/USAID informal consultation 25-27 October 1999. World Organization

[21] World Health Organization (2003). Malaria rapid diagnosis, Making it Work. RS/2003/GE/05(PHL)

[22] World Health Organization (2004). Rapid Diagnostic Tests for malaria: Methods Manual for Laboratory Quality Control Testing. Version 2. World Health Organization, Manila

[23] World Health Organization (2005). Interim notes on selection of types of malaria rapid diagnostic tests in relation to the occurrence of different parasite species. Regional office for Africa and Western Pacific

[24] World Health Organization (2006). The role of laboratory diagnosis to support malaria disease management. Focus on the use of rapid diagnostic tests in areas of high transmission. Report of a WHO technical consultation. Geneva, Switzerland

[25] World Health Organization (2008). Methods manual for laboratory Quality Control Testing of Malaria Rapid Diagnostic Tests. UNICEF/UNDP/World Bank/WHO. Special Programme for research and training in tropical disease (TDR). Foundation for Innovative Diagnosis (FIND) 1216 Geneva, Switzerland

[26] World Health Organisation (2009). The use of malaria rapid diagnostic tests. Second edition. WHO Library cataloguing in Publication Data Geneva.

[27] World Health Organization, (2010). Information note on the interim selection criteria for procurement of Malaria rapid diagnostic tests, Geneva Switzerland. WHO, (2011). Universal access to malaria diagnostic testing: An operational manual. 1-138. Available at: www.who.int/malaria. WHO, (2013). World Malaria Report. 1-195. Available at: www.who.int/malaria.

APPENDIX ONE: INITIAL QC TESTING OF COMMERCIALLY PROCURED MRDTs

Positive QC Samples	**A**			**B**			**C**			**D**			**Neg QC Samples: MNI --- MN10**
QC Samples Dilution	200a	200b	2000	200a	200b	2000	200a	200b	2000	200a	200b	2000	Control
ICT(Stock RDT) Combo	Pf2+ Pan 1+	Pf2+ Pan 1+	Pf3+ Pan 1+	Pf2+ Pan 1+	Pf2+ Pan 1+	Pf2+ Pan 1+	Pf2+ Pan 2+	Pf2+ Pan 2+	Pf3+ Pan 2+	Pf3+Pan 2+	Pf3+ Pan 2+	Pf3+ Pan 3+	3+
Global Device	-ve	1+	-ve	-ve	-ve	1+	-ve	1+	-ve	-ve	-ve	1+	3+
Paracheck	-ve	-ve	-ve	-ve	-ve	-ve	-ve	-ve	-ve	-ve	-ve	1+	3+
SD Bioline (Antibody)	1+	1+	1+	1+	-ve	-ve	1+	-ve	-ve	1+	1+	1+	3+
CTK Biotech Malaria Ag Test	-ve	-ve	-ve	-ve	-ve	-ve	-ve	-ve	-ve	-ve	-ve	-ve	3+
Wondfo Biotech	-ve	-ve	1+	-ve	1+	1+	-ve	-ve	1+	-ve	-ve	1+	3+
Acon Biotech	-ve	-ve	1+	-ve	-ve	1+	-ve	-ve	-ve	-ve	-ve	1+	3+
Grand time Device	-ve	-ve	1+	1+	1+	2+	-ve	-ve	-ve	1+	1+	1+	3+
Embassy	-ve	1+	1+	1+	1+	2+	-ve	-ve	-ve	1+	1+	1+	3+
Acon Pf	1+	1+	2+	2+	2+	3+	2+	2+	3+	2+	2+	3+	3+
Accucare Malaria test	-ve	-ve	-ve	-ve	-ve	1	-ve	-ve	-ve	-ve	-ve	-ve	3+
BID Malaria Pf Test	1+	1+	2+	1+	1+	3+	1+	1+	3+	1	1+	3+	3+
BID Malaria Pf/Pan Test	Pf1+ Pan -ve	Pf1+ Pan-ve	Pf2+ Pan-ve	Pf1+ Pan-ve	Pf1+ Pan -ve	Pf 3+ Pan1+	Pf1+ Pan -ve	Pf1+ Pan -ve	Pf 3 Pan 1+	Pf1+ Pan -ve	Pf1+ Pan -ve	Pf3+ Pan 1+	3+
Bioland Malaria Pf Ag	-ve	-ve	1+	-ve	-ve	1+	-ve	-ve	1+	1+	1+	2+	3+
First Response Malaria test	1+	1+	2+	1+	1+	2+	1+	1+	2+	1+	1+	3+	3+
SD Bioline Pf	1+	1+	2+	2+	2+	3+	2+	2+	3+	2+	2+	3+	3+
SD Bioline Pf/Pan	Pf2+ Pan1+	Pf2+ Pan 1+	Pf3+ Pan 2+	Pf2+ Pan 1+	Pf2+ Pan 1+	Pf3+ Pan3+	Pf3+ Pan1+	Pf3+ Pan 1+	Pf3+Pan 3+	Pf2+ Pan1+	Pf2+ Pan 1+	Pf3+ Pan 2+	3+
ICT Pf Malaria Test	1+	1+	2+	1+	1+	3+	1+	1+	3+	2+	2+	3+	3+
Core Malaria test kit	-ve	-ve	-ve	-ve	-ve	-ve	-ve	-ve	-ve	-ve	-ve	-ve	3+

Antec Pf Malaria Test kit	-ve	-ve	-ve	-ve	-ve	-ve	-ve	-ve	-ve	-ve	-ve	1+	3+
Bioland Pf/Pv (Strip) Malaria Test kit	1+	1+	2+	-ve	-ve	1+	-ve	-ve	1+	-ve	-ve	1+	3+
Bioland Pf/Pv (Cassette) Malaria Test kit	-ve	-ve	1+	-ve	1+	2+	1+	-ve	1+	1+	1+	2+	3+
Dr Greg's Malaria Test kit	-ve	-ve	-ve	-ve	-ve	1+	1+	1+	1+	-ve	-ve	-ve	3+

TEN NEGATIVE QC SAMPLES WERE ALSO TESTED ON THE DIFFERENT MRDTs AND IT ALL TURNED OUT NEGATIVE