



Diagnostic accuracy of two malaria rapid tests against PCR in Kinshasa: clinical patterns and implications for laboratory quality assurance

[Exactitude diagnostique de deux tests rapides du paludisme par rapport à la PCR à Kinshasa : profils cliniques et implications pour l'assurance qualité des laboratoires]

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Abstract

Malaria remains a major public health concern in the Democratic Republic of the Congo, where rapid diagnostic tests are widely used in routine care. Their value depends not only on the test itself, but also on the conditions in which it is stored, performed and interpreted. This study compared an Abbott malaria rapid diagnostic test (RTDR1NX) with the routine rapid diagnostic test (RTDR2) used in selected healthcare facilities in Kinshasa, using polymerase chain reaction (PCR) as the analytical reference. We analysed data from 498 patients with suspected malaria who were enrolled in the Bandalungwa and Kasa-Vubu health zones between April 2022 and September 2023. The analysis examined test positivity, associations with age, sex and axillary temperature, and diagnostic performance based on sensitivity, specificity, predictive values and kappa agreement. PCR was positive in 57.0% of participants, compared with 34.9% for RTDR1NX and 25.9% for RTDR2. RTDR2 positivity was associated with sex and axillary temperature, whereas RTDR1NX positivity was associated with temperature. PCR positivity was not associated with age, sex or temperature. RTDR1NX showed a sensitivity of 38.7% and a specificity of 70.1%, while RTDR2 showed a sensitivity of 28.9% and a specificity of 78.0%. Agreement with PCR was poor for both tests ($\kappa = 0.08$ and 0.06). RTDR1NX identified more PCR-positive cases than RTDR2, but with lower specificity. Both rapid tests missed a substantial proportion of PCR-positive participants. These findings highlight the need to verify RDT performance locally and to pay close attention to quality assurance, storage, test handling, staff competency and confirmatory testing when clinically appropriate.

Mots-clés : Point-of-care testing; molecular reference method; diagnostic accuracy; quality assurance; febrile illness.

Résumé

Le paludisme reste un problème majeur de santé publique en République démocratique du Congo, où les tests de diagnostic rapide sont largement utilisés dans la prise en charge courante. Leur fiabilité dépend non seulement des performances du test, mais aussi des conditions de stockage, de réalisation et d'interprétation. Cette étude a comparé un test de diagnostic rapide Abbott (RTDR1NX) au test rapide de routine (RTDR2) utilisé dans des structures de santé sélectionnées à Kinshasa, en prenant la réaction en chaîne par polymérase (PCR) comme référence analytique. L'analyse a porté sur 498 patients suspects de paludisme recrutés dans les zones de santé de Bandalungwa et Kasa-Vubu entre avril 2022 et septembre 2023. Elle a examiné la positivité des tests, les associations avec l'âge, le sexe et la température axillaire, ainsi que les performances diagnostiques à partir de la sensibilité, de la spécificité, des valeurs prédictives et de la concordance kappa. La PCR était positive chez 57,0 % des participants, contre 34,9 % pour le RTDR1NX et 25,9 % pour le RTDR2. La positivité du RTDR2 était associée au sexe et à la température axillaire, tandis que celle du RTDR1NX était associée à la température. La positivité de la PCR n'était liée ni à l'âge, ni au sexe, ni à la température. Le RTDR1NX présentait une sensibilité de 38,7 % et une spécificité de 70,1 %, contre respectivement 28,9 % et 78,0 % pour le RTDR2. La concordance avec la PCR était faible pour les deux tests ($\kappa = 0,08$ et $0,06$). Le RTDR1NX a identifié davantage de cas positifs à la PCR que le RTDR2, mais avec une spécificité plus faible. Les deux tests ont manqué une proportion importante de participants positifs à la PCR. Ces résultats soulignent la nécessité de vérifier localement les performances des TDR et d'accorder une attention particulière à l'assurance qualité, au stockage, à la manipulation des tests, aux compétences du personnel et à la confirmation diagnostique lorsque la situation clinique l'exige.

Keywords: Dépistage au point de soins ; méthode moléculaire de référence ; exactitude diagnostique ; assurance qualité ; syndrome fébrile.

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1. Introduction

Malaria continues to place a heavy burden on the Democratic Republic of the Congo (DRC). According to the latest WHO country profile, the entire reported population lives in high-transmission areas. In 2024 alone, the country reported 29.8 million confirmed cases, while WHO estimated about 35.2 million cases and 67,700 deaths ([World Health Organization, 2026](#)). In such a setting, an accurate diagnosis is more than a clinical formality. It guides treatment, helps clinicians consider other causes of fever, and influences the quality of the malaria data used for surveillance and planning.

WHO recommends confirming suspected malaria parasitologically before treatment, either by quality-assured microscopy or by a rapid diagnostic test (RDT) ([World Health Organization, 2025](#)). RDTs are particularly useful where reliable microscopy is not always available. They are simple to use, provide results quickly and make parasite-based diagnosis possible closer to the patient. Yet that simplicity should not be mistaken for robustness under all conditions. During transport and storage in tropical settings, RDTs may be exposed to heat and humidity beyond the limits recommended by manufacturers, with possible consequences for test stability ([Albertini et al., 2012](#)).

What happens at the testing bench matters just as much. In a national external quality assessment involving 1,849 laboratory health workers from 1,014 facilities in the DRC, errors were common when participants had to recognise invalid or negative tests or interpret faint test lines. Half of the participating facilities had not received RDT training, and workers who had been trained performed better ([Mukadi et al., 2013](#)). In other words, a technically sound test can still lead to the wrong clinical decision if it is performed or interpreted poorly.

The wider diagnostic environment also deserves attention. An assessment of 88 clinical laboratories in Kinshasa found important weaknesses in malaria microscopy despite generally good reported familiarity with standard procedures. Only 56.8% of the laboratories reported using internal quality control, and performance in cross-checking routine slides remained low ([Mukadi-Kaningu et al., 2024](#)). Earlier work in the DRC had already pointed to shortages in infrastructure, staff training, equipment, supervision and quality control ([Linsuke et al., 2020](#)). This broader context matters when diagnostic tests are evaluated under

routine service conditions rather than in a tightly controlled laboratory setting.

Evidence from Kinshasa also shows that RDT performance can vary from one product and patient group to another. [Muhindo et al. \(2012\)](#) evaluated two RDTs against expert microscopy in 12 health zones and reported sensitivities of 79.7% and 87.8%, with specificities of 97.0% and 91.6%. In children, [Ilombe et al. \(2014\)](#) found sensitivity above 95% for an HRP2-based RDT, although specificity was lower, especially in community screening. Among pregnant women, [Kabalu et al. \(2023\)](#) reported 81.7% sensitivity and 95.2% specificity for a conventional RDT against quantitative PCR. Taken together, these findings show why the performance of a rapid test should be judged in the population and conditions in which it is actually used.

Recent studies underline that this is not only a laboratory issue. Using longitudinal data from Kinshasa Province, [François-Zafka et al. \(2026\)](#) documented both false-positive and false-negative RDT results when PCR was used as the reference. Misclassification was linked to factors such as parasite density, symptoms, recent treatment and transmission intensity. [Sugg et al. \(2026\)](#) also found that some healthcare providers in the DRC were reluctant to trust negative RDT results and sometimes turned to clinical judgement or additional testing. When confidence in a test result is weak, the value of test-based treatment can also be undermined.

PCR is more analytically sensitive than routine antigen-based RDTs and can detect infections with parasite densities that some rapid tests may miss. This makes it useful as a reference method in diagnostic research, even though it serves a different purpose from a point-of-care test. The relevant question, therefore, is not whether PCR can detect more infections, but whether an RDT performs well enough under routine conditions to support reliable clinical decisions.

Against this background, we compared an Abbott malaria RDT, coded RTDR1NX, with the routine RDT used in selected healthcare facilities in Kinshasa, coded RTDR2, using PCR as the analytical reference. We assessed overall test positivity, associations of test positivity with age, sex and axillary temperature, and diagnostic performance using sensitivity, specificity, predictive values and Cohen's kappa. The primary aim was comparative estimation of diagnostic performance; the study design does not establish causal effects of participant characteristics on test performance.

2. Material and methods

2.1. Study design and setting

We conducted a cross-sectional diagnostic-accuracy study in selected healthcare facilities in the City-Province of Kinshasa, DRC. Participants were recruited from the Bandalungwa and Kasa-Vubu health zones between April 2022 and September 2023.

2.2. Study population and sampling

The study included patients presenting with clinical suspicion of malaria. Consecutive sampling was used throughout the study period. Patients who had recently received antimalarial treatment or who declined participation were not included. Informed consent was obtained before enrolment, and 498 participants were included in the final analysis. The manuscript does not report a formal sample-size calculation or the number of otherwise eligible patients who were not enrolled; these items should be verified from the original study records if available.

2.3. Diagnostic procedures

A blood sample was collected from each participant. Each participant was tested with the Abbott malaria RDT (RTDR1NX), the routine malaria RDT used at the participating facilities (RTDR2), and PCR. The two RDTs were performed according to the manufacturers' instructions and standardized procedures, and PCR was used as the analytical reference for the performance analysis. The available manuscript does not provide the complete commercial identification and antigen target of each RDT, lot numbers, specimen-processing details, the complete PCR protocol, positivity criteria, or whether index-test interpretation was blinded to PCR results. These methodological details are necessary for full reproducibility and should be completed from the original protocol or laboratory records rather than inferred.

2.4. Variables and statistical analysis

The main outcomes were the RDT and PCR results, recorded as positive or negative. We also examined whether test positivity varied by age, sex and axillary temperature. To remain consistent with the original analysis, age was dichotomized at 33 years and axillary temperature at 36.7°C. These cut-offs were analytical categorizations rather than established clinical thresholds; in particular, 36.7°C should not be interpreted as a standard definition of fever. Because dichotomization can reduce information, the rationale

for the 33-year cut-off should be verified from the original analysis plan.

Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and Cohen's kappa were calculated using PCR as the analytical reference. Pearson chi-square tests were used to examine associations between categorical participant characteristics and test results. Statistical significance was assessed at the 5% level. A few values printed in the original cross-tabulations were inconsistent with the corresponding totals or diagnostic indicators. In those cases, values were recalculated directly from the reported counts only when the intended value was unambiguous; no participant observations were added or removed. Ninety-five percent confidence intervals for sensitivity, specificity, PPV and NPV were calculated from the reported 2×2 tables using the Wilson method. The manuscript does not specify the statistical software or version used; this information should be added from the original analysis records.

2.5. Ethical considerations

Ethical approval, informed consent and protection of participant confidentiality are reported for the source study. However, the name of the approving ethics committee/institutional review board and the approval or reference number are not provided in the available manuscript. These details should be verified from the original ethics documentation and inserted before submission; no approval number should be inferred or created.

3. Results

3.1. Sociodemographic and clinical profile

A total of 498 participants were included. The mean age was 33.0 ± 17.1 years, with a median of 32 years and a range of 4–86 years. Participants aged 33 years or younger represented 56.8% of the sample. Women accounted for 57.0% and men for 43.0%. Mean body weight was 64.0 ± 18.2 kg, with a median of 65 kg and a range of 15–110 kg. Bandalungwa contributed 293 participants (58.8%) and Kasa-Vubu 205 (41.2%). At health-area level, 272 participants (54.6%) were from Lodja, 205 (41.2%) from Asosa and 21 (4.2%) from Adula. Mean axillary temperature was $36.7 \pm 0.68^\circ\text{C}$, with a median of 36.9°C and a range of 36.0 – 38.7°C .

Table I. Sociodemographic and clinical characteristics of participants (*N* = 498)

Characteristic	Category / summary	n (%)
Age (years)	Mean 33.0 ± 17.1; median 32; range 4-86	498
Age group	≤33 years	283 (56.8)
	>33 years	215 (43.2)
Weight (kg)	Mean 64.0 ± 18.2; median 65; range 15-110	498
Sex	Female	284 (57.0)
	Male	214 (43.0)
Health zone	Bandalungwa	293 (58.8)
	Kasa-Vubu	205 (41.2)
Health area	Lodja	272 (54.6)
	Asosa	205 (41.2)
	Adula	21 (4.2)
Axillary temperature (°C)	Mean 36.7 ± 0.68; median 36.9; range 36.0–38.7	498

3.2. Overall positivity of the diagnostic methods

PCR identified 284 positive participants (57.0%), compared with 174 (34.9%) for RTDR1NX and 129 (25.9%) for RTDR2. The positivity rate was therefore 22.1 percentage points higher with PCR than with RTDR1NX and 31.1 points higher than with RTDR2. While PCR classified the majority of participants as positive, both rapid tests classified most as negative.

Table II. Overall positivity by diagnostic method

Method	Positive, n (%)	Negative, n (%)
PCR	284 (57.0)	214 (43.0)
Abbott RTDR1NX	174 (34.9)	324 (65.1)
Routine RTDR2	129 (25.9)	369 (74.1)

3.3. Age, sex and axillary temperature in relation to routine RTDR2 results

RTDR2 positivity did not differ significantly between the two age groups ($\chi^2 = 1.91$, $p = .167$). A clear difference was observed by sex: 91 of 284 women (32.0%) were RTDR2-positive compared with 38 of 214 men (17.8%; $\chi^2 = 12.97$, $p < .001$). RTDR2 positivity also differed across the study's temperature categories. Among participants with axillary temperature $\geq 36.7^\circ\text{C}$, 53 of 260 (20.4%) were positive, compared with 76 of 238 (31.9%) among those below 36.7°C ($\chi^2 = 8.63$, $p = .003$).

Table III. Associations between participant characteristics and routine RTDR2 results

Variable	Category	Negative n	Positive n	Positive %	χ^2	p
Age	≤33 years	176	107	37.8	2.37	.123
	>33 years	148	67	31.2		
Sex	Female	175	109	38.4	3.44	.064
	Male	149	65	30.4		
Axillary temperature	$\geq 36.7^\circ\text{C}$	192	68	26.2	18.47	<.001
	< 36.7°C	132	106	44.5		

Note. The source table reports $p = .71$ for the association between sex and RTDR1NX result despite $\chi^2 = 3.44$. Recalculation from the displayed 2×2 counts gives $p = .064$

(Pearson chi-square, without continuity correction), which is the value reported here.

3.5. Age, sex and axillary temperature in relation to PCR results

PCR positivity showed no statistically significant association with age ($\chi^2 = 1.46$, $p = .227$), sex ($\chi^2 = 0.13$, $p = .720$), or the study's temperature categories ($\chi^2 = 0.35$, $p = .553$). PCR positivity was 59.4% among participants aged 33 years or younger and 54.0% among older participants. It was 56.3% in women and 57.9% in men. The corresponding proportions were 55.8% in participants with axillary temperature $\geq 36.7^\circ\text{C}$ and 58.4% in those below 36.7°C .

Table V. Associations between participant characteristics and PCR results

Variable	Category	Negative n	Positive n	Positive %	χ^2	p
Age	≤33 years	115	168	59.4	1.46	.227
	>33 years	99	116	54.0		
Sex	Female	124	160	56.3	0.13	.720
	Male	90	124	57.9		
Axillary temperature	$\geq 36.7^\circ\text{C}$	115	145	55.8	0.35	.553
	< 36.7°C	99	139	58.4		

Note. The source RTDR2 cross-table reports 207 false negatives, which would yield a total of 503 observations and is incompatible with $N = 498$. Given 82 true positives among 284 PCR-positive participants, the internally consistent false-negative count is 202 ($284 - 82$). This value also reproduces the reported sensitivity of 28.9%; the correction is therefore based on an arithmetic identity rather than an assumed participant record.

RTDR1NX was 9.8 percentage points more sensitive than RTDR2, whereas RTDR2 was 7.9 percentage points more specific. The PPVs were similar (63.2% and 63.6%), and the NPVs were low for both tests (46.3% and 45.3%). Kappa values were close to zero, indicating very weak agreement with PCR beyond chance. No formal statistical test comparing the paired sensitivities or specificities of the two RDTs is reported; therefore, these between-test differences should be interpreted descriptively.

4. Discussion

The clearest finding was the large gap between PCR and the two rapid tests. Both RDTs showed low sensitivity against the molecular reference. RTDR1NX detected more PCR-positive participants than RTDR2, but RTDR2 was more specific. The expectation that the Abbott test would perform better across all indicators was therefore only partly supported. Its gain in sensitivity came at the cost of more false-positive results.

These sensitivity estimates are far below those reported in several earlier studies from Kinshasa.

Muhindo et al. (2012) found sensitivities of 79.7% and 87.8% for two RDTs evaluated against expert microscopy. Ilombe et al. (2014) reported sensitivity above 95% for an HRP2-based test in children, while Kabalu et al. (2023) found 81.7% sensitivity for a conventional RDT against quantitative PCR in pregnant women. The values observed here, 38.7% and 28.9%, are therefore unusually low. Rather than suggesting that RDTs are generally ineffective in Kinshasa, the results point to a performance problem that may be specific to the tests, the study population, the testing conditions or a combination of these factors.

One possible explanation is the greater analytical sensitivity of PCR. Low-density infections can remain PCR-positive even when the parasite burden is below the detection threshold of an antigen-based RDT. There is also evidence from the DRC that some RDT-negative/PCR-positive infections have been associated with *pfhrp2*-deleted parasites, including geographic clustering around Kinshasa (Parr et al., 2017). However, a later longitudinal study in Kinshasa Province did not detect *pfhrp2/3* deletions in successfully genotyped samples collected between 2018 and 2021 (François et al., 2023). For that reason, HRP2 deletion cannot be assumed to explain the false-negative results observed here without testing the study samples directly.

The subgroup findings also need to be read carefully. RTDR2 positivity varied by sex and temperature category, while RTDR1NX positivity varied by temperature but not significantly by age or sex. PCR positivity, however, did not differ significantly across any of these characteristics. These are associations with test positivity, not evidence that sex or temperature altered the intrinsic sensitivity of the RDTs. Demonstrating such an effect would require stratified measures of diagnostic accuracy or models specifically designed to test effect modification.

At first glance, the temperature pattern may seem unexpected. For both RDTs, positivity was higher among participants with axillary temperatures below 36.7°C than among those at or above this value, whereas PCR positivity was similar in the two groups. However, 36.7°C was simply the mean temperature in the sample; it is not a clinical fever threshold. The two groups should therefore not be interpreted as “febrile” and “non-febrile.” Malaria may be present without fever at the time of consultation, and fever can result from many other conditions. This is one reason

parasitological confirmation remains central to malaria case management (World Health Organization, 2025).

The difference by sex should also be interpreted cautiously. Women were more often RTDR2-positive than men, yet PCR positivity was almost identical in the two groups. This does not demonstrate a biological effect of sex on malaria infection or on test performance. Other unmeasured characteristics of this facility-based sample may have contributed. The fact that PCR showed no comparable difference is another reason not to overinterpret the RTDR2 finding.

The negative predictive values were also low: 46.3% for RTDR1NX and 45.3% for RTDR2. In this selected group of patients with suspected malaria, a negative RDT therefore matched a negative PCR result poorly. These figures should not be generalized to community screening or other patient groups because predictive values depend strongly on the underlying frequency of infection. Still, the result is clinically relevant. Sugg et al. (2026) showed that some providers in the DRC already tend to distrust negative RDT results and may turn to clinical judgement or additional testing instead.

The kappa results point in the same direction. Values of 0.08 and 0.06 reflect very weak agreement with PCR and are consistent with the large number of PCR-positive cases missed by both RDTs. Several factors could contribute to this discordance. Low parasite density and persistence of circulating antigen can affect agreement between molecular and antigen-based methods, while the test design and target antigen also matter (Murray et al., 2008). Transport and storage may play a role as well; field monitoring in several tropical countries has documented repeated exposure of RDT supply chains to temperatures above 30°C and very high humidity (Albertini et al., 2012). None of these factors was measured directly in the present study, so they remain possible explanations rather than demonstrated causes.

Operator performance is another part of the picture. A second nationwide external quality assessment in the DRC found repeated problems with faint lines, invalid tests and negative results. Recent training and previous participation in quality assessment were associated with better performance (Mukadi et al., 2015). These findings support regular competency assessment rather than assuming that a simple test is automatically free from operator-related error.

Taken together, these findings show that quality assurance cannot stop at the test kit itself. WHO guidance for malaria rapid testing covers product quality, storage and handling, user training, documented procedures, supervision and corrective action ([World Health Organization, 2022](#)). Its laboratory quality-control manual also recommends systematic verification of RDT performance ([World Health Organization, 2023](#)). More broadly, laboratory quality management includes staff competency, equipment, process control, records, assessment and continuous improvement ([World Health Organization, 2011](#)). These elements are especially important where diagnostic services operate with limited resources.

Findings from conventional microscopy in Kinshasa provide useful context. [Mukadi-Kaningu et al. \(2024\)](#) found that only about one-third of participating laboratories combined adequate procedural scores with acceptable slide-reading performance. This suggests that the challenge is broader than RDT performance alone. Improving malaria diagnosis requires reliable quality across the diagnostic network, not simply replacing one technology with another.

Diagnostic errors can also have consequences beyond the individual patient. [François-Zafka et al. \(2026\)](#) documented both false-positive and false-negative RDT results in Kinshasa Province and showed that misclassification can influence treatment. False negatives may delay appropriate therapy, while false positives may lead to unnecessary antimalarial use and divert attention from other causes of illness. In a country with a high malaria burden, repeated errors can also weaken the quality of routine surveillance data.

This study has several strengths. Both RDTs were evaluated in the same 498 participants, drawn from two health zones, and their performance was compared against the same molecular reference. The data also came from routine healthcare settings rather than a tightly controlled product-testing laboratory. Examining age, sex and temperature separately further showed that some patterns seen with the RDTs were not reproduced by PCR.

Several limitations should be considered. Recruitment was facility-based and restricted to Bandalungwa and Kasa-Vubu, limiting generalizability to other settings in Kinshasa or the DRC. The available records do not provide complete commercial specifications and antigen targets for the two RDTs, lot numbers, parasite density, detailed storage history, a complete PCR protocol, blinding procedures, or the

disposition of potentially eligible patients who were not enrolled. Staff competency and laboratory quality-management practices were discussed but were not measured quantitatively. The 36.7°C cut-off was an analytical split rather than a clinical fever threshold, and dichotomization of age and temperature may have reduced information. In addition, some values in the source tables were internally inconsistent; only discrepancies that could be resolved unambiguously from the displayed counts and totals were corrected, without adding or removing observations. These limitations constrain attribution of the observed discordance to any specific product, biological mechanism, operator factor or quality-system failure.

These findings do not support a simple recommendation to replace one RDT with the other. RTDR1NX was more sensitive but less specific, and both tests missed many PCR-positive participants. Before the results are used to guide procurement or policy, they should be confirmed in a prospective multicentre study that records the exact RDT product and lot, antigen target, storage and transport conditions, operator training, parasite density and a fully documented reference method. That would make it easier to determine whether poor performance is mainly related to the product, the testing environment or both.

5. Conclusion

In the healthcare facilities studied in Bandalungwa and Kasa-Vubu, Abbott RTDR1NX showed higher sensitivity but lower specificity than routine RTDR2 when PCR was used as the analytical reference. Both RDTs had low sensitivity and very weak agreement with PCR in this selected population of patients with suspected malaria. Associations between RDT positivity and sex or the study-specific temperature categories were not reproduced by PCR and should not be interpreted as causal effects on malaria infection or intrinsic test performance. The findings support local verification of RDT performance and reinforce the importance of quality assurance across procurement, storage, testing, supervision and interpretation. Because key product, PCR, parasite-density and quality-system details were unavailable, prospective multicentre evaluation with fully documented diagnostic procedures is warranted before using these results to support replacement of one RDT by another.

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Conflict of Interest

The authors declare that they have no financial, professional, or personal conflicts of interest related to this study.

Ethical Considerations

The study is reported as having followed established ethical principles, including voluntary participation, informed consent and confidentiality. The approving ethics committee/institutional review board and approval/reference number are not stated in the available manuscript and must be verified from the original ethics documentation before submission.

Author Contributions

F.M.M.: conceived the study, conducted the investigation and data analysis, and drafted the manuscript.

B.M.M.: contributed to the methodology, interpretation of the results, and manuscript revision.

K-N.N.: supervised the study, contributed to validation, and critically reviewed the manuscript.

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