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Diagnostic performance of ultrasensitive rapid diagnostic test for the detection of Plasmodium falciparum infections in asymptomatic individuals in Kisangani, Northeast Democratic Republic of Congo

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Objectives:

The ultrasensitive rapid diagnostic test (usRDT) improves detection of low-density Plasmodium falciparum infections. Its performance remains unevaluated in the Democratic Republic of Congo (DRC). This study assesses the diagnostic accuracy of usRDT for malaria in asymptomatic individuals under field conditions in Kisangani, northeastern DRC.

Methods:

A cross-sectional study involving 312 asymptomatic individuals was carried out in Kisangani from June to August 2022. Capillary blood was tested using microscopy, RDTs, and nested PCR. Alere™ usRDT and SD Bioline cRDT detected HRP2 antigen for P. falciparum. Diagnostic performance of usRDT was compared with cRDT, microscopy, and PCR.

Results:

The prevalence of asymptomatic P. falciparum malaria was 40.4%, 42.0%, 47.1% and 54.2% by cRDT, microscopy, usRDT, and PCR, respectively. By using PCR as a reference, usRDT had sensitivity and specificity of 87.0% (95% CI 81.4–91.7) and 100.0% (95% CI 97.5–100.0), respectively, whereas the cRDT had sensitivity and specificity of 74.6% (95% CI 67.3–80.9) and 100% (95% CI 97.1–100.0), respectively. By using microscopy as a reference, usRDT had sensitivity and specificity of 96.9% (95% CI 92.4–99.2) and 89.0% (95% CI 83.5–93.1), respectively, while the cRDT had sensitivity and specificity of 96.2% (95% CI 92.3–98.7) and 100% (95% CI 97.9–100.0), respectively.

Conclusion:

The usRDT showed better diagnostic performance with higher sensitivity than the cRDT, which is currently in use as a point-of-care test. Further research is necessary to assess the accessibility and cost-effectiveness of US RDTs for use in malaria surveillance.