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PARASITOLOGY

Multicenter Pivotal Clinical Trial of Urine Malaria Test for Rapid Diagnosis of *Plasmodium falciparum* Malaria

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ABSTRACT The need to expand malaria diagnosis capabilities alongside policy requirements for mandatory testing before treatment motivates exploration of noninvasive rapid diagnostic tests (RDTs). We report the outcome of the first cross-sectional, single-blind clinical performance evaluation of a urine malaria test (UMT) for diagnosis of *Plasmodium falciparum* malaria in febrile patients. Matched urine and finger-prick blood samples from participants ≥2 years of age with fever (axillary temperature of ≥37.5°C) or with a history of fever in the preceding 48 h were tested with UMT and microscopy (as the gold standard). BinaxNOW (Pf and Pan versions) blood RDTs were done to assess relative performance. Urinalysis and rheumatoid factor (RF) tests were conducted to evaluate possible interference. Diagnostic performance characteristics were computed at 95% confidence intervals (CIs). Of 1,800 participants screened, 1,691 were enrolled; of these 566 (34%) were febrile, and 1,125 (66%) were afebrile. Among enrolled participants, 341 (20%) tested positive by microscopy, 419 (25%) were positive by UMT, 676 (40%) were positive by BinaxNOW Pf, and 368 (22%) were positive by BinaxNow Pan. UMT sensitivity among febrile patients (for whom the test was indicated) was 85%, and specificity was 84%. Among febrile children ≤5 years of age, UMT sensitivity was 93%, and specificity was 83%. The area under the receiver-operator characteristic curve (AUC) of UMT (0.84) was not significantly different from that of BinaxNOW Pf (0.86) or of BinaxNOW Pan (0.87), indicating that the tests do not differ in overall performance. Gender, seasons, and RF did not impact UMT performance. Leukocytes, hematuria, and urobilinogen concentrations in urine were associated with lower UMT specificities. UMT performance was comparable to that of the BinaxNOW Pf/Pan tests, making UMT a promising tool to expand malaria testing in public and private health care settings where there are challenges to blood-based malaria diagnosis testing.

KEYWORDS health care provider, malaria, noninvasive malaria test, *Plasmodium falciparum*, point-of-care diagnosis, primary healthcare setting, rapid diagnostic test (RDT), urine malaria test (UMT)

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