



Evaluation of malaria diagnostic tests by WHO and partners finds variation in test performance

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GENEVA – The largest-ever independent, laboratory-based evaluation of rapid diagnostic tests (RDTs) for malaria has shown that some tests on the market perform exceptionally well in tropical temperatures and can detect even low parasite densities in blood samples, while other tests were only able to detect the parasite at high parasite densities.

The evaluation was co-sponsored by the WHO Regional Office for the Western Pacific (WPRO), WHO-based Special Programme for Research and Training in Tropical Diseases (TDR) and the Foundation for Innovative New Diagnostics (FIND). Testing was performed at the US Centers for Disease Control and Prevention (CDC). Forty-one commercially available RDTs went through a blinded laboratory evaluation.

The findings will serve as a tool for countries to make informed choices, from among the dozens of tests commercially available, on the purchase and use of rapid diagnostics that are best suited to local conditions.

This performance evaluation will also inform procurement and prioritization for diagnostic test entry into WHO Prequalification Diagnostics Programme and WHO Procurement Schemes. Donor agencies also regularly refer to WHO recommendations on diagnostics when making their own purchases.

“This is an important first step in establishing a broader system of diagnostics surveillance and quality assurance to ensure sound and accurate diagnosis of malaria in poor and remote settings,” said Dr Robert Ridley, Director of TDR. “These evaluations provide us with a mechanism to evaluate RDT performance in a standardized way so that WHO, donors and country health ministries can identify those tests that perform best for their needs and particular settings,” he added.

“While some tests clearly outperform others in terms of identifying malaria in populations of low parasite density, such as newborns or people sleeping under bednets, there are a whole range of criteria related to local conditions of malaria transmission and illness that need to be considered in country and donor procurement decisions,” said Giorgio Roscigno, CEO of FIND.

In addition to product testing WHO, TDR and FIND have also collaborated to establish procedures and quality assured facilities for routine lot testing of rapid diagnostics in Asia and Africa.

During the evaluation, samples of blood from patients infected with *P. falciparum* and *P. vivax* (the two major Plasmodium species that cause malaria) in diverse geographic locations were diluted to achieve both a low parasite density (200 parasites/ μ l)* and high parasite densities (2000 or 5000 parasites/ μ l). At low parasite density, samples were tested against two rapid tests per lot (2 lots) and at high parasite density samples were tested against one rapid test per lot (2 lots).

Among the concrete findings:

- Several RDTs demonstrated consistent detection of malaria at low parasite densities (200 parasites/ μ l), have low false-positive rates, are stable at tropical temperatures, are relatively easy to use, and can detect *P. falciparum*, *P. vivax* infections, or both.
- Performance between products varied widely at low parasite density (200 parasites/ μ l); however, most products showed a high level of detection at 2000 to 5000 parasites/ μ l.
- *P. falciparum* tests targeting the histidine rich protein 2 (HRP2) antigen demonstrated the highest detection rates, but some tests targeting Plasmodium lactate dehydrogenase (pLDH) also exhibited high detection rates.
- Test performance varied between lots, and widely between similar products, confirming the advisability of lot testing post-purchase and prior to use in the field.
- The results highlight the need for manufacturers to have adequate reference materials for product development and lot-release. The WHO-FIND Malaria RDT Evaluation Programme, in collaboration with the CDC, will soon offer quality standard panels to manufacturers to assist in this process.

A second round of performance evaluations for 29 products is currently being carried out by TDR, FIND and CDC, with results due to be published in 2010. An executive summary of findings along with the detailed evaluation of test performance results are provided in the report available online at <http://www.who.int/tdr>.

* μ l = microlitre or one millionth of a litre

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About WHO/TDR:

The Special Programme for Research and Training in Tropical Diseases (TDR) is a global program of scientific collaboration established in 1975, sponsored by the United Nations Children's Fund, United Nations Development Programme, World Bank and World Health Organization, and based at WHO in Geneva, Switzerland. Its focus is research into neglected diseases of the poor, with the goal of improving existing approaches and developing new ways to prevent, diagnose, treat and control these diseases. For more information, visit: www.who.int/tdr

About FIND:

FIND, based in Geneva, Switzerland, is a not-for-profit Swiss foundation dedicated to the development of improved diagnostic tests that will have a measurable impact on infectious disease morbidity and mortality, particularly in high-endemic countries. Since its establishment in 2003, FIND has received endorsement from WHO for three new TB technologies that are currently being rolled out in 16 high burden MDR-TB countries. FIND's mission is to drive the development and implementation of accurate and affordable diagnostic tests that can be used as near as possible to where patients first seek care. At this time, the FIND's disease portfolio includes TB, malaria and human African trypanosomiasis. Current donors are the Bill & Melinda Gates Foundation, the European Union, the Government of the Netherlands, UNITAID, Irish Aid and other institutions and private donors. FIND is ISO 9001:2000 and ISO 13485:2003 certified. www.finddiagnostics.org



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