

**Call for trial partners: Clinical performance evaluation of next-generation malaria rapid diagnostic tests with improved sensitivity for the detection of *Plasmodium falciparum* and/or *Plasmodium vivax* infections in patients with symptoms suggestive of malaria**

Background

*P. falciparum* causes the highest burden of malaria globally. For almost two decades, histidine-rich protein 2 (HRP2)-based rapid diagnostic tests (RDTs) have proven to be of great use for the detection of *P. falciparum* cases, especially at the point of care. Over the last years, reports of parasites that do not carry this antigen have emerged in some parts of South America, Asia, and Africa. An alternative antigen that can be used for detection is lactate dehydrogenase (LDH). However, currently available *Plasmodium* LDH-based (pLDH) tests fail to fully fill this gap due to their relatively poor clinical performance, particularly in subjects with low parasitaemia. Although pLDH is also used to detect *P. vivax*, the most widespread human-infecting *Plasmodium* species outside of sub-Saharan Africa, and other non-*falciparum* infections, the recognized drawback of inadequate test sensitivity has been a key factor limiting the use of these RDTs for the detection of *P. vivax*.

A partnership between FIND, Standard Diagnostics (SD/Abbott), PATH, and BMGF is addressing these limitations by developing two novel, qualitative malaria RDTs with improved sensitivities. The first is a *P. falciparum*-specific test combining the detection of HRP2 and pLDH antigens in a single test line, and the second is a combo test to detect *P. falciparum*/*P. vivax*, targeting the *Pv-specific* LDH antigen. Both tests successfully completed the feasibility stage of development in 2018.

We are now aiming to perform a prospective evaluation of these new tools to assess the clinical performance in their intended use settings (e.g., health posts, health centres, district hospitals) to enable WHO prequalification. The object is to understand the performance of these tests when used by health workers in malaria-endemic countries.

This call for trial partners is to identify partners and sites to conduct relevant trials to assess the clinical performance of next generation malaria RDTs – when used by health workers in malaria-endemic countries – to detect malaria in capillary whole blood samples collected prospectively from patients with symptoms suggestive of malaria when compared with conventional RDTs and microscopy using polymerase chain reaction (PCR) as the reference test. FIND will support the partners and sites both technically and financially for the conduct of the trials.



Requirements for the trial sites are as follows:

- Must be located in low- or middle-income countries in Africa, South-East Asia or Latin America
- Must be in a setting with a high burden of *P. falciparum* and *P. vivax* and must be representative of the regional epidemic
- Ideally, there must be reports on *P. falciparum* parasites with *hrp2/3* deletions
- Must have an on-site laboratory or nearby referral laboratory where expert malaria microscopy is available
- Must be able to enroll a sufficient number of patients (an estimated 1500 patients) to accomplish the study objectives within a short period of time (up to six months of patient recruitment)
- Must have a good laboratory and trial infrastructure and/or experience from previous diagnostic trials
- Must be able to perform a good laboratory and clinical practice (GCLP/GCP)-compliant trial

Timelines:

- An Expression of interest (cover letter) and a site description form (provided separately) must be submitted by 21 December 2018 by e-mail to [seda.yerlikaya@finddx.org](mailto:seda.yerlikaya@finddx.org), with the title “**Clinical Performance Evaluation of Next Generation Malaria RDTs**”.
- A first round of selection will be carried out and the results will be announced mid-January 2019.
- FIND will shortlist the sites, followed by a site assessment visit.
- Decision on the final site selection will be done by mid-February 2019.

This call will close on 21 December 2018. Send your submissions before **17:00 CEST on 21 December 2018** to: Seda Yerlikaya – [seda.yerlikaya@finddx.org](mailto:seda.yerlikaya@finddx.org)

For questions, contact:

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