

Advancing highly sensitive point-of-care tests for malaria

Project DIAMETER: Diagnostics for Malaria Elimination Toward Eradication

FINDING THE FINAL CASES

Many countries that have implemented successful malaria control programs are now close to achieving the goal of malaria elimination. In these areas, a significant portion of infected individuals have minimal or no symptoms but are still capable of transmitting malaria. However, these cases may not be detected by existing rapid diagnostic tests (RDTs). As control programs increasingly lead to lower prevalence of malaria, diagnostic tools need to be able to detect cases in asymptomatic individuals so that these patients can be treated and the cycle of transmission halted. New, highly sensitive point-of-care tests are needed that can identify these final reservoirs of malaria in near-elimination settings.

PATH and our partners are advancing the availability of more sensitive tests for malaria to support elimination strategies, with a specific aim to more accurately identify asymptomatic people who can transmit the disease. We've used a rigorous approach to identify the most promising solutions to malaria diagnostic challenges in low-resource, near-elimination settings.

A HIGHLY SENSITIVE TEST FOR DETECTING *Pf* MALARIA

In April 2017, a major technological breakthrough in high-sensitivity rapid testing for malaria was launched. The Alere™ Malaria Ag P.f is an in vitro, qualitative, and ultra-sensitive test developed by Alere to aid in the diagnosis of *Plasmodium falciparum* (*Pf*) malaria infection. It has a greater than tenfold improvement in detection of histidine-rich protein II (HRP-II) antigen of *Pf* malaria in human whole blood, which will enable better identification of infected individuals with very low parasitemia.

(Source: Benchmarking results conducted by PATH)

The development of the Alere Malaria Ag P.f was supported by the Bill & Melinda Gates Foundation. PATH and FIND provided clinical evaluation and technical support.



New, highly sensitive diagnostics for malaria will help health workers to identify asymptomatic cases in communities where malaria is approaching elimination. PATH/G. Bienczycki

This highly sensitive diagnostic will help health care workers to screen individuals who are asymptomatic but may be carrying the parasite, and thus it can aid the implementation of surveillance and mass screen-and-treat programs that are critical to accelerating malaria elimination. It is a more scalable option to molecular assays detecting parasite genetic material, and it detects a significant portion of the asymptomatic pool in near-elimination settings. The Alere Malaria Ag P.f is fast, portable, and easy to use, and it can produce immediate sensitive results even in rural and remote areas.

PATH, FIND, Alere, and the foundation are currently seeking to conduct studies that demonstrate detection of infection in asymptomatic patients and programmatic impact studies that demonstrate the value of the test in elimination strategies.

HOW TO ORDER

Alere is handling all ordering, manufacturing, and distribution of the Alere Malaria Ag P.f test. Visit www.alere.com/malaria-POC for more information about the test and to order.

THE FUTURE OF MALARIA DIAGNOSTICS

PATH is conducting research into biomarkers for *Pf* and *Plasmodium vivax* (*Pv*) infections to guide development of new diagnostics. Using clinical samples collected from asymptomatic individuals, PATH measured HRP-II, lactate dehydrogenase (LDH), and parasite nucleic acids throughout the course of *Pf* infection and applied this information to measure the sensitivity of various tests commercially available and in development.

PATH and our partners are evaluating several highly sensitive tests for malaria, including a highly sensitive rapid test for *Pv*. Other test options that are currently under evaluation are an HRP-II ELISA, a *Pf* HRP-II/*Pf* LDH RDT, and a pan-malaria RDT.

ABOUT PATH'S MALARIA WORK

PATH works in partnership with national governments, the private sector, and global stakeholders to make a malaria-free world a reality. PATH pursues this goal by expanding the use of lifesaving tools and developing new strategies to create malaria-free communities; working to ensure a steady, affordable, and high-quality supply of drugs and diagnostics; and bringing together public- and private-sector partners to advance the development of malaria vaccines.

“Improving our ability to detect and define the transmissible reservoir of malaria in a community is critical to inform evidence-based strategies to eliminate malaria. A test that can produce immediate sensitive results even in rural and remote settings represents a significant advance in our ability to do this for Plasmodium falciparum malaria and as such is a valuable tool for malaria elimination. We now have an opportunity to better understand where and how this test can best impact the reduction of the malaria burden worldwide.”

Gonzalo Domingo, scientific director and lead of malaria diagnostics, PATH

CONTACT

To learn more about DIAMETER, visit go.path.org/diameter or contact Gonzalo Domingo, scientific director and lead of malaria diagnostics, PATH, at dxinfo@path.org.

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PATH is the leader in global health innovation. An international nonprofit organization, we save lives and improve health, especially among women and children. We accelerate innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, we take innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together, we deliver measurable results that disrupt the cycle of poor health. Learn more at www.path.org.

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