

# Highly sensitive tests for malaria

Identifying the final cases in areas close to elimination



## Detecting low-density infections

Many countries that have implemented successful malaria control programs are now close to achieving the goal of elimination. In these areas, a significant portion of infected individuals have low-density parasite infections with minimal or no symptoms but are still capable of transmitting malaria. However, these low-density infections may not be detected by existing rapid diagnostic tests. The next generation of malaria diagnostic tools must be sensitive enough to detect these infections at the point of care so that they can be treated, and the cycle of transmission impeded.

PATH and our partners are advancing the availability of highly sensitive diagnostic tests for malaria to support elimination strategies. PATH takes a portfolio approach, using a rigorous process to identify, advance, commercialize, and scale up the most promising solutions to malaria diagnostic challenges in low-resource, near-elimination settings.

## Ten times the sensitivity

The first product in the pipeline of next-generation highly sensitive malaria tests was launched in April 2017. The Alere™ Malaria Ag P.f is an in vitro, qualitative, and ultra-sensitive test developed by Abbott to aid in the diagnosis of *Plasmodium falciparum* malaria infection. It has a greater than ten-fold improvement in detecting the histidine-rich protein 2 (HRP2) antigen of *P. falciparum* malaria in human whole blood over current rapid tests, which will enable better identification of infected individuals with very low parasitemia.<sup>1</sup>

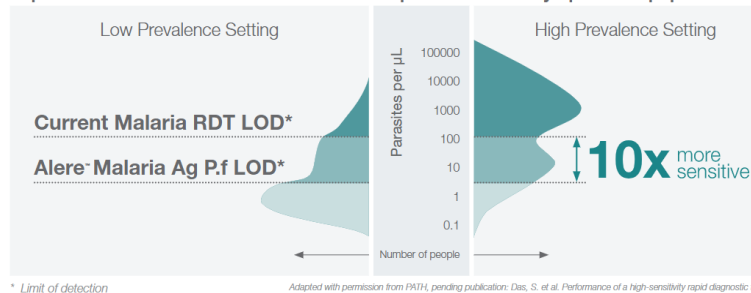
Abbott's Alere™ Malaria Ag P.f is fast, portable, and easy to use, and can produce immediate sensitive results even in rural and remote areas. This highly sensitive diagnostic may help health care workers to screen asymptomatic cases, enabling the implementation of surveillance and mass screen-and-treat programs that are critical to accelerating malaria elimination. It is a more scalable option as compared to molecular assays that detect parasite genetic material, and it can detect a significant portion of the infectious pool in near-elimination settings. Currently, PATH, the Foundation for Innovative New Diagnostics (FIND), Abbott, and the Bill & Melinda Gates Foundation are supporting studies to demonstrate detection of infection in endemic populations using the Alere™ Malaria Ag P.f test as well as programmatic impact studies to demonstrate the value of the test in elimination strategies.

Abbott manages ordering, manufacturing, and distribution of the Alere™ Malaria Ag P.f. Visit [www.abbott.com](http://www.abbott.com) for more information and to order.



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. Image: Abbott.

## Improved identification of individuals with low parasitemia in asymptomatic populations



\* Limit of detection

Adapted with permission from PATH, pending publication: Das, S. et al. Performance of a high-sensitivity rapid diagnostic test for *Plasmodium falciparum* malaria in asymptomatic individuals from Uganda and Myanmar and naive human challenge infections.

## The future of malaria diagnostics

To facilitate the development of new diagnostics for *P. falciparum* malaria, PATH and Precision Antibody collaborated to develop and bring to market custom monoclonal antibodies to HRP2. These antibodies have demonstrated equivalent or better binding properties compared to current commercial antibodies for HRP2 detection, representing a robust asset to help rapid diagnostic test manufacturers develop highly sensitive next-generation tests for malaria.

Currently, PATH is conducting research into biomarkers for *P. falciparum* and *Plasmodium vivax* infections to guide development of new diagnostics. Using clinical samples collected from endemic populations, PATH measured HRP2, lactate dehydrogenase, and parasite nucleic acids throughout the course of malaria infection and applied this information to determine the target performance for new diagnostics for malaria. PATH also completed proof of feasibility of early prototypes tests that address HRP2 and HRP3 deletions, which the Alere™ Malaria Ag P.f cannot detect.

### A highly sensitive reference test

In 2019, PATH and Quansys Biosciences, Inc. launched the Q-Plex™ Human Malaria Array, a highly sensitive quantitative immunoassay designed to help researchers tackle the challenge of ensuring detection and treatment of malaria. The tool supports researchers in creating more sensitive malaria rapid diagnostic tests and aids in public health surveillance by simultaneously measuring multiple malaria antigens.

The Q-Plex™ array uses a single sample to measure the most commonly used markers for current tests—HRP2 and Plasmodium lactate dehydrogenase—at low concentrations, as well as quantifying *P. vivax*- and *P. falciparum*-specific lactate dehydrogenase (LDH) epitopes to distinguish between species and C-reactive protein as an indicator of inflammation. This allows researchers to use the diagnostic to evaluate tests in the pipeline that detect malaria infections with low parasite concentrations and address the challenge of diagnosing strains that do not produce HRP2 and are not detected by tests designed to identify the antigen.



Photo: Quansys Biosciences

The Q-Plex Human Malaria Array (5-Plex) can be ordered by researchers directly from Quansys Biosciences. Visit [QuansysBio.com](http://QuansysBio.com) for more information.

### About our work in malaria

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.

### Contact

To learn more about PATH's work in malaria diagnostics, visit <http://www.path.org/programs/diagnostics> or contact Gonzalo Domingo, scientific director and lead of malaria diagnostics, at [dxinfo@path.org](mailto:dxinfo@path.org).

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### Reference

1. Das S, Jang IK, Barney B, et al. Performance of a high-sensitivity rapid diagnostic test for *Plasmodium falciparum* malaria in asymptomatic individuals from Uganda and Myanmar and naive human challenge infections. *American Journal of Tropical Medicine and Hygiene*. 2017;97(5):1540–1550. doi:10.4269/ajtmh.17-0245.



[path.org](http://path.org)

PATH is a global organization that works to accelerate health equity by bringing together public institutions, businesses, social enterprises, and investors to solve the world's most pressing health challenges. With expertise in science, health, economics, technology, advocacy, and dozens of other specialties, PATH develops and scales solutions—including vaccines, drugs, devices, diagnostics, and innovative approaches to strengthening health systems worldwide.

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