



Alere Launches the Alere™ Malaria Ag P.f, the First-Ever Rapid Test to Screen Malaria Infection in Asymptomatic Individuals

New test provides powerful tool to help meet malaria eradication goals

WALTHAM, Mass., April 25, 2017 – Alere Inc. (NYSE: ALR), a global leader in rapid diagnostics, today announced the launch of its Alere™ Malaria Ag P.f, a major technological breakthrough in high-sensitivity rapid testing versus currently available malaria RDTs (rapid diagnostic tests).

The Alere Malaria Ag P.f offers a greater than tenfold improvement in the detection of histidine rich protein II (HRP-II) antigen of *Plasmodium falciparum*, which will enable better identification of individuals with very low parasitemia, many of whom may be without evident symptoms of malaria infection. This highly sensitive diagnostic will help healthcare workers screen individuals who are asymptomatic but may be carrying the parasite, and thus can aid the implementation of surveillance and mass screen-and-treat programs that are critical for accelerating malaria elimination.

The development of the Alere Malaria Ag P.f was supported by the [Bill & Melinda Gates Foundation](#), which has identified a test to uncover the asymptomatic reservoir as a key component of its malaria strategy. Alere and the Gates Foundation are partnering to generate field data to demonstrate the public health value of the test, particularly in elimination settings. Clinical evaluation and technical support was also provided by [PATH](#) and [FIND](#).

“Breaking the cycle of malaria transmission requires identifying all infected individuals, but until now point-of-care diagnostic tests have not been sensitive enough to reliably detect asymptomatic infections,” said Avi Pelossof, Alere Global President of Infectious Disease. “The Alere Malaria Ag P.f represents a game-changing tool to empower healthcare workers to identify asymptomatic individuals in even the most remote settings, contributing to a reduced malaria reservoir in communities – key strategies in eliminating this devastating disease.”

“We are excited by the potential for this product to address one of the barriers identified on the path to malaria eradication – the non-acute disease reservoir that complicates efforts to stop transmission,” said Dr. Bruno Moonen, Deputy Director of the Malaria program at the Bill & Melinda Gates Foundation. “Until now, we haven’t had a tool to tackle this challenge in low-transmission settings. Added to existing RDTs, prevention methods and treatments that reduce disease burden in high- and medium-transmission settings, this test will add a new tool to the fight against malaria.”

“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,” said Gonzalo Domingo, Scientific Director and lead of malaria diagnostics, PATH. “We now have an opportunity to better understand where and how this test can best impact the reduction of the malaria burden world-wide.”

“Elimination of malaria rests on our ability to identify asymptomatic malaria infections,” noted Catharina Boehme, CEO of FIND. “This test is a valuable addition to the malaria elimination toolkit. Looking forward, we are excited to see the results of our forthcoming demonstration studies, as these will provide valuable insights into how this test can have the biggest positive impact.”

The Alere Malaria Ag P.f was granted CE marking in December 2016, and was evaluated during Round 7 of the WHO FIND Malaria RDT Evaluation Program.

About the Alere Malaria Ag P.f

The Alere Malaria Ag P.f is a highly sensitive test that detects histidine-rich protein II (HRP-II) antigen of *Plasmodium falciparum* malaria in human whole blood within 20 minutes. The test has a greater than tenfold sensitivity improvement over currently available rapid tests, while offering improved time to result, portability and ease of use compared to molecular assays. The Alere Malaria Ag P.f has the potential to support elimination programs that actively seek and treat infections to reduce the malaria reservoir in the community and thereby drive down transmission, and will help to significantly increase the detection of P.f infection in screening programs. The test also has potential for use in the detection of malaria during pregnancy and in surveillance programs. For more information on the Alere Malaria Ag P.f, see www.alere.com/malaria-POC.

About Malaria

Malaria is a life-threatening disease caused by parasites that are transmitted to people through the bites of infected female Anopheles mosquitoes. According to the World Health Organization, nearly one half of the world's population is at risk of malaria. In 2015, 91 countries and areas had ongoing malaria transmission, leading to 212 million cases and 429,000 deaths.^[i] A significant portion of infected individuals have minimal or no symptoms and these may not be detected by existing RDTs or microscopy but may continue to transmit the disease. Global efforts to eliminate malaria, such as the Bill & Melinda Gates Foundation's "From Aspiration to Action" (<http://www.endmalaria2040.org/>) have identified diagnosing malaria infection in asymptomatic people as a key principal for elimination.^[ii]

About Alere

Alere believes that when diagnosing and monitoring health conditions, **Knowing now matters.**[™] Alere delivers on this vision by providing reliable and actionable information through rapid diagnostic tests, enhancing clinical and economic health outcomes globally. Headquartered in Waltham, Mass., Alere focuses on rapid diagnostics for infectious disease,

cardiometabolic disease and toxicology. For more information on Alere, please visit www.alere.com.

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^[i] World Health Organization (WHO). Malaria. <http://www.who.int/mediacentre/factsheets/fs094/en/>.

^[ii] Bill & Melinda Gates Foundation. Malaria: strategy overview. <http://www.gatesfoundation.org/What-We-Do/Global-Health/Malaria>