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# New field laboratory-deployed molecular test could eliminate malaria

April 26, 2017

## ***Field laboratory-deployable molecular test up to 80,000 times more sensitive than current options***

As the global community gathers for World Malaria Day to celebrate successes and plot strategy to eliminate the disease from the face of the earth, a new ray of hope is emerging from a surprising place: the testing side of the equation.

Meridian Bioscience, Inc. of Cincinnati, Ohio has developed ***illumigene***<sup>®</sup> Malaria, a molecular-based, field laboratory-deployed test for malaria that is up to 80,000 times more sensitive at detecting the malaria parasite than current testing options. The test was developed by Meridian with the technical assistance of the Centers for Disease Control and Prevention (CDC) and Cheikh Anta Diop University of Dakar, Senegal.

"***illumigene*** Malaria has the potential to change current practices. Faster and more accurate diagnosis is vital in the fight against malaria," said Professor Daouda Ndiaye, Department of Parasitology-Mycology, Cheikh Anta Diop University. "Earlier diagnosis enables the correct treatment to be prescribed, which leads to better clinical outcomes for the person with malaria and keeps malaria treatments for the right people. And because detecting the malaria parasite in people with a low parasite count has proven difficult, a robust, sensitive and field laboratory-deployable diagnostic tool is needed to track the malaria reservoir in pre-elimination regions. ***illumigene*** Malaria shows this capacity."

***illumigene*** Malaria was awarded first place for innovation in emergency treatment and point-of-care testing at the prestigious Journées Internationales de Biologie /Association des Colloques Nationaux des Biologistes Conference in Paris, and is CE marked for sale in Europe.

Despite a 60% decline in malaria deaths since 2000 due to better prevention and increased control measures, malaria is still one of the top three killers of children worldwide, claiming one life every minute of every day. According to the latest data from the World Health Organization, nearly half of the world's

population is at risk of malaria. In 2015, there were roughly 212 million malaria cases and an estimated 429,000 malaria deaths. Also that year, Sub-Saharan Africa was home to 90% of malaria cases and 92% of malaria deaths. More than two-thirds (70%) of all malaria deaths occur in children under the age of five.

While malaria is preventable and treatable, proper diagnosis is critical. Molecular testing has proven to be more effective than current options in detecting the malaria parasite at very low levels, known as "loads." Identifying low-load individuals has the dual benefit of ensuring they receive treatment and preventing the spread of the disease to others.

"People can be carriers of malaria without showing any symptoms, and detecting these asymptomatic individuals can be challenging," said Slava Elagin, Executive Vice President, Research & Development at Meridian Bioscience. "If testing doesn't identify them, eliminating malaria is impossible because these individuals can spread the disease to others."

That scenario is playing out in the fact that malaria is no longer only a disease of sub-Saharan Africa and southern Asia. Increasing numbers of people emigrating from countries where malaria is endemic have resulted in a higher incidence in Europe and the Middle East. The proportion of imported malaria cases has increased during the last few years from 14% to 86% in more recent studies. On pooling the reports, nearly 43% of malaria cases registered in key European centers occurred in non-nationals. The rates of malaria are much higher in settled immigrants who travel to visit friends and relatives in their country of origin. They can account for up to 70% of the cases in several reports and this increase highlights the need for better diagnostic tools in both non-endemic and endemic countries.

While not a new concept, molecular testing has traditionally been a complex process requiring fully-equipped laboratories and highly trained testing personnel. The breakthrough of *illumigene* Malaria by Meridian Bioscience is that it can be deployed in the field laboratory, where malarial infection is the highest and low load detection most challenging to diagnose and treat. *illumigene* Malaria is user-friendly, doesn't require special training or capital investment, yields results in under one hour and the testing materials can be stored at room temperature.

"This is a major step forward in the fight to bring better care to those infected with malaria and to stop its spread," said John A. Kraeutler, Chief Executive Officer and Chairman of the Board of Meridian Bioscience.

The availability of the field laboratory-deployable and user-friendly, *illumigene* Malaria, will enhance rather than replace existing testing protocols. It will join rapid diagnostic tests (RDTs) and microscopy to create a web of detection protocols that will help direct treatment where it is needed most.

"Malaria is a devastating disease and we are proud to work with all the talented and dedicated individuals around the world in the fight to eliminate it," said Kraeutler.

*illumigene* Malaria will be distributed in the European, Middle Eastern and African regions by Meridian Bioscience Europe and in additional international markets by the Company's global distribution network. It is the tenth assay now available on our *illumigene* platform that is in use in nearly 1,500 institutions around the world.

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**Source:**

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