

FIRST MOLECULAR DIAGNOSTIC TEST LAUNCHED FOR THE DETECTION OF MALARIA CAUSED BY *PLASMODIUM VIVAX* PARASITES

- *Plasmodium vivax* accounts for more than half of all malaria cases outside sub-Saharan Africa, but its clinical characteristics make it particularly difficult to detect
- Malaria-LAMP is the first molecular test for malaria that can identify *P. vivax* infections even in low-transmission settings, making an important contribution to global elimination efforts

Wiesbaden, Germany; Tokyo, Japan; and Geneva, Switzerland – 23 April 2019 – Human Diagnostics Worldwide (HUMAN), EIKEN CHEMICAL CO., LTD. (EIKEN) and the Foundation for Innovative New Diagnostics (FIND) announced today the launch of the first commercially available molecular diagnostic test for the detection of malaria caused by *Plasmodium vivax* parasites. Malaria-LAMP is a molecular test that works using loop-mediated isothermal amplification (LAMP), developed by EIKEN with exclusive distribution by HUMAN. FIND evaluated the prototype test in collaboration with the Hospital for Tropical Diseases in London, UK, and coordinated in-country clinical performance studies in Colombia and Peru. The test was unveiled at the sixty-seventh annual meeting of the American Society of Tropical Medicine and Hygiene in November 2018.

“Eliminating malaria is a global health priority, but without effective diagnostics it just cannot happen,” said Catharina Boehme, CEO of FIND. “*P. vivax* is challenging to diagnose, and this test represents an important new tool that can support elimination efforts.”

Malaria is an urgent public health threat, with 2.5 billion people at risk globally.¹ Of the five malaria species, *P. vivax* is geographically the most widespread form of disease. It accounts for more than half of all malaria cases outside sub-Saharan Africa, but control strategies to date have focused on *Plasmodium falciparum*. *P. vivax* malaria is not easy to detect, largely due to much lower densities of parasites in the blood compared with *P. falciparum* and, unlike *P. falciparum*, *P. vivax* parasites can lie dormant in the liver and cause relapses. However, the proportion of malaria due to *P. vivax* is increasing in many regions; in 2017, a total of about 7.5 million cases of *P. vivax* occurred worldwide.²

To control malaria caused by *P. vivax*, sensitive and reliable tools are needed, especially in areas close to elimination. Different species require different treatment strategies, but while current diagnostic tests can identify *P. falciparum*, they are generally not able to differentiate between the various malaria species. There is currently no diagnostic that can effectively detect inactive parasites in the liver – which is why effective and highly sensitive blood-stage diagnosis is key.

Malaria-LAMP is a comprehensive molecular solution introduced for the diagnosis of malaria. The test can differentiate between *Plasmodium* *pan* species, *P. falciparum* and *P. vivax*, and has a sensitivity of 84–94%, a specificity of >92% and a limit of detection of 1–2 parasites/μL.

¹ Howes RE *et al.* *Am J Trop Med Hyg* 2016; 95(6 Suppl):15–34.

² World Health Organization. World Malaria Report 2018.

<https://apps.who.int/iris/bitstream/handle/10665/275867/9789241565653-eng.pdf?ua=1> (accessed 22 February 2019)

“We are pleased to be the exclusive distributor for EIKEN’s newly developed test for detecting *P. vivax* infections and to provide access to a reliable diagnosis through our worldwide network,” said Dr. Petra Rehberger, Vice President Marketing & Strategic Purchase at HUMAN.

For more information about Malaria-LAMP, please visit www.human.de/lamp.

FIND’s contribution to this initiative was supported by the German government (KfW) and Australian aid (DFAT).

About EIKEN

EIKEN CHEMICAL CO., LTD. was established in 1939 and was the first Japanese company to successfully commercialize the manufacture of powdered culture media for microbiological investigations. The company has established itself as a leader in the clinical diagnostics market, and has a strong commitment to research and development toward global products and technologies that fulfill needs at the cutting edge of contemporary medicine. The LAMP technology, developed at EIKEN in 1998, is now a core technology being exploited to develop a range of products. For more information, please visit www.eiken.co.jp/en/

About HUMAN

HUMAN, founded in 1972, is a Germany based privately owned company which develops, manufactures and distributes a wide range of IVD Diagnostics and laboratory equipment. The comprehensive portfolio of more than 400 products covers almost all areas of modern laboratory including Autoimmune and Molecular Diagnostics. With its strong network of partners in 160 countries and with six regional offices around the globe, HUMAN maintains probably the broadest distribution and service network, especially in developing and emerging countries. For more information, please visit www.human.de

About FIND

FIND is a global non-profit organization that drives innovation in the development and delivery of diagnostics to combat major diseases affecting the world’s poorest populations. Our work bridges R&D to access, overcoming scientific barriers to technology development; generating evidence for regulators and policy-makers; addressing market failures; and enabling accelerated uptake and access to diagnostics in low- and middle-income countries (LMICs). Since 2003, we have been instrumental in the development of 24 new diagnostic tools. Over 50 million FIND-supported products have been provided to 150 LMICs since the start of 2015. A WHO Collaborating Centre, we work with more than 200 academic, industry, governmental, and civil society partners worldwide, on over 70 active projects that cross six priority disease areas. FIND is committed to a future in which diagnostics underpin treatment decisions and provide the foundation for disease surveillance, control and prevention. For more information, please visit www.finddx.org

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