

Press Release

WHO Recommends Loopamp™ PURE MTBC for Diagnosis of Pulmonary TB

23 August 2016 – Tokyo, Geneva – The World Health Organization (WHO) has issued policy guidance on the use of a diagnostic test developed by EIKEN CHEMICAL CO., Ltd. that uses loop-mediated isothermal amplification (LAMP) technology for the detection of pulmonary tuberculosis.

WHO assessed TB-LAMP as a potential point-of-care test for TB in resource-limited settings, based on a review of evidence that came from more than 20 studies conducted across 17 countries. According to the new policy guidance:

“TB-LAMP offers a manual molecular approach to TB detection that seems to be feasible to implement in peripheral microscopy laboratories... it has the advantages of being relatively high-throughput, does not require sophisticated instrumentation, and has the biosafety requirements similar to those for performing sputum smear microscopy.”¹

The policy guidance concluded that TB-LAMP may be used as;

- 1) a replacement to smear microscopy; or
- 2) a follow-on test to smear microscopy, especially when further testing of sputum smear-negative specimens is necessary,

for diagnosis of pulmonary TB in patients with signs and symptoms of the disease. While the LAMP methodology has been used for the detection of malaria and several neglected tropical diseases, this represents the first endorsement of the technology from WHO for use in detecting tuberculosis.

EIKEN, together with FIND, has advanced the development of TB-LAMP since 2005. Following WHO's recommendation, Loopamp™ PURE MTBC products will be produced by EIKEN and directly distributed in China, South Korea, Taiwan, Thailand and Japan. To allow broader access to this valuable diagnostic test, FIND and EIKEN will work with HUMAN (www.human.de) as exclusive worldwide distributor covering remaining countries. The new test will be available to the public sector in low- to middle-income countries at reduced prices.

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About FIND

FIND, established in 2003, is a global non-profit dedicated to accelerating the development, evaluation and use of high-quality, affordable diagnostic tests for poverty-related diseases, including tuberculosis, malaria, HIV/AIDS, sleeping sickness, hepatitis C, leishmaniasis, Chagas disease, Buruli ulcer, and infectious diseases with outbreak potential such as Ebola. Over the last decade, FIND has partnered in the delivery of 14 new diagnostic tools, including eight for tuberculosis, and created an enabling environment for numerous others through the provision of specimen banks, reagent development and better market visibility. FIND also supports better access to new diagnostics through implementation, quality assurance and lab strengthening work. FIND has more than 200 partners globally, including research institutes and laboratories, health ministries and national disease control programmes, commercial partners, clinical trial sites, and bilateral and multilateral organizations, especially WHO. Read more at www.finddx.org

¹ WHO, The use of loop-mediated isothermal amplification of pulmonary tuberculosis: policy guidance, 2016 - ISBN 978 92 4 151118 6 – p.3

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. Read more at www.eiken.co.jp/en/index.htm

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