

The Foundation for Innovative New Diagnostics (FIND) and Eiken Chemical Co. LTD. Announce Collaboration to Develop Rapid Diagnostic Test for Tuberculosis

Seattle, WA (July 29, 2005) –The Foundation for Innovative New Diagnostics (FIND), a Geneva-based non-profit funded by the Bill & Melinda Gates Foundation, and Eiken Chemical Co. Ltd., a Japan-based manufacturer of clinical diagnostics, today announced a collaboration to develop a rapid and simple test for the detection of active tuberculosis (TB). The agreement was announced at the 40th Annual US-Japan Tuberculosis and Leprosy Research Conference taking place in Seattle.

“There is an urgent need for a fast, easy and cost-effective way to diagnose tuberculosis in order to effectively treat and contain this highly contagious bacterium that infects one-third of the world’s population,” said Dr. Giorgio Roscigno, CEO of FIND. “This collaboration will involve the application of Eiken’s leading diagnostic capabilities to develop a TB test that is affordable and useable even in remote locations. It is an important advancement in FIND’s mission to seek out and apply innovative diagnostics to impact diseases in the developing world.”

As envisioned in the joint development agreement signed today, the TB test will use the Loop-Mediated Isothermal Amplification (LAMP) method developed at Eiken and will be designed to detect DNA directly from clinical samples in less than two hours with minimal instrumentation. Molecular amplification methods such as polymerase chain reaction (PCR), are proven technologies for the detection of TB but have not been widely used in remote settings because of the cost and complexity of existing systems.

“Today’s microscopy-based standard TB detection method was developed over a century ago and is time-consuming and frequently inaccurate,” said Dr. Peter Small, Senior Program Officer for Tuberculosis, Bill & Melinda Gates Foundation. “While treatment programs have improved the access of TB patients to effective therapy, diagnostics are now recognized as a primary hurdle in TB control and patient care.”

According to the President and CEO of Eiken, Tadao Kurozumi, the partnership with FIND will provide the critical support to speed the development and validation of the test through clinical trials, in return for Eiken’s commitment to offer their technology at an affordable price to the public health sector in developing countries.

“Eiken has been committed to contributing to public health since its foundation and we are pleased that our core technology can be put to use against a global health scourge such as tuberculosis,” said Mr. Kurozumi.

Mark Perkins, Chief Scientific Officer of FIND, said “Due to its simplicity, LAMP technology could make rapid and sensitive detection of TB possible even at peripheral levels of the health sector. The goal is to develop a test that requires minimal infrastructure, can be used at point-of-care, and still delivers accurate results.”

About TB:

- Tuberculosis (TB) is a contagious disease spread primarily by coughing. It is prevalent in developing countries, and up to a third of the world's population is infected;
- TB is one of the greatest threats to health worldwide, with nearly 9 million new cases and 2 million deaths a year due to the disease.
- The spread of TB has been exacerbated by (i) the large numbers of people from all over the world who travel; (ii) the worldwide rise of multi-drug resistance TB strains; and (iii) the global spread of HIV, with markedly increases susceptibility to tuberculosis;
- Sputum microscopy, currently the most widely used method to detect tuberculosis, is cumbersome and insensitive, leaving many patients undetected. Bacterial culture is more sensitive, but takes 4-6 weeks to complete, and is too complex for most settings where TB patients are seen;
- The HIV pandemic has led to a resurgence of TB as a major public health problem. Immunodeficient HIV-positive patients are particularly vulnerable to TB, which is responsible for the deaths of at least 40 per cent of patients in this group.

About FIND:

The Foundation for Innovative New Diagnostics (FIND) was launched at the World Health Assembly in May 2003 as a non-profit Swiss foundation based in Geneva. Its purpose is to support and promote the health of people in developing countries by sponsoring the development and introduction of new but affordable diagnostic products for infectious diseases. For more information, please visit www.finddiagnostics.org.

About Eiken:

Eiken Chemical Co., Ltd., has over 60 years of experience in medical diagnostics, 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 products and technologies that fill 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.

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