

CALL FOR TRIAL PARTNERS NOW OPEN TO ADVANCE EVALUATION OF AN INNOVATIVE, SENSITIVE POINT-OF-CARE TEST THAT DETECTS TUBERCULOSIS IN HIV-POSITIVE PEOPLE

- **Fujifilm SILVAMP TB LAM is a novel, urine-based, point-of-care test for tuberculosis diagnosis in people living with HIV in low-resource settings**
- **A Call for Trial Partners is now open for the prospective clinical trials of the test that will generate data for WHO policy review; these trials are being supported by the Global Health Innovative Technology (GHIT) fund and the German Federal Ministry of Education and Research. Development of the test was supported by the governments of the Netherlands and Australia, UK aid from the UK government, and the Bill & Melinda Gates Foundation**

Geneva, Switzerland – 26 September 2018 – The Foundation for Innovative New Diagnostics (FIND) announced today that following positive preliminary data, a call for trial partners is now open for the prospective evaluation of a novel urine test for tuberculosis (TB). The test, co-developed by FIND and Fujifilm (Tokyo, Japan) and known as Fujifilm SILVAMP TB LAM, is a rapid diagnostic test that detects low concentrations of LAM-antigen in the urine of people with TB/HIV co-infection. The announcement was made at a side-event of the United Nations High-Level Meeting on TB that focusses on integrated TB and HIV care, entitled “Leave no-one behind”.

TB is the number one infectious disease killer in the world and it is the most common cause of death for people living with HIV. In 2016, 374,000 HIV-positive people died from TB.¹ But TB is curable, and most deaths from TB can be prevented with early diagnosis and treatment. Most commonly, TB diagnosis is made based on sputum analysis, often conducted using GeneXpert® (Cepheid, Sunnyvale CA, USA) or sputum smear microscopy. HIV infection can affect TB symptoms, sometimes resulting in the absence of a productive cough. Data show that 20–60% of HIV-positive patients presenting for TB diagnosis are unable to produce a sputum sample.^{2,3} Lack of sputum and a true point-of-care test means that many patients cannot be diagnosed in a timely manner.

A urine sample is usually easily accessible. Working in a similar way to a pregnancy test, the Fujifilm SILVAMP TB LAM test has the potential to be particularly well suited to low-resource settings, as it does not need any instrument, does not rely on electricity, and requires limited training. The test takes around 60 minutes to generate a result.

The Fujifilm SILVAMP TB LAM test builds on a decade of research conducted by FIND with partners, and opens a pathway to point-of-care assays that enable highly sensitive antigen detection. Initial positive data of the assay in hospitalized patients with HIV will be published in the near future. While encouraging, these data are

¹ World Health Organization. Global tuberculosis report 2017. http://www.who.int/tb/publications/global_report/en/ (accessed 14 August 2018).

² Huerga H et al. PLoS ONE 12(1): e0170976. <https://doi.org/10.1371/journal.pone.0170976> (accessed 14 August 2018).

³ Lawn SD et al. BMC Medicine 2017;15:67. <https://doi.org/10.1186/s12916-017-0822-8> (accessed 14 August 2018).

preliminary: studies were conducted using frozen urine samples from three cohorts of HIV-positive inpatients in South Africa.

This week, the Global Health Innovative Technology (GHIT) fund announced to support the project with an investment of JPY 422 million. The aim now is to perform prospective evaluations in settings of intended use, obtain stringent regulatory approval, and scale up manufacturing of the test. The trials will generate the evidence package for World Health Organization (WHO) policy development. WHO will evaluate the Fujifilm SILVAMP TB LAM assay as soon as adequate data become available. This will include an initial review of retrospective data generated from stored frozen urine specimens from HIV positive individuals, planned for May 2019. A comprehensive review of data from prospective studies on the use of the assay will follow once the data from evaluation trials in the settings of intended use become available.

Responses to the Call for Trial Partners should be submitted via www.finddx.org/news/fujifilm-lam-rfp. The deadline for submissions is 31 January 2019.

The Fujifilm TB LAM test has been developed by a FIND-led international R&D consortium including Fujifilm; Rutgers, The State University of New Jersey; University of Alberta; Otsuka Pharmaceutical Co. and University of Cape Town. This work was supported by the Global Health Innovation Technology Fund of Japan, the Bill & Melinda Gates Foundation, the governments of Germany, the Netherlands and Australia, and UK aid from the UK government.

About FIND

FIND was established in 2003 as a global non-profit dedicated to accelerating the development, evaluation and delivery of high-quality, affordable diagnostic tests for poverty-related diseases, now including malaria, tuberculosis, HIV/AIDS, sleeping sickness, hepatitis C, leishmaniasis, Chagas disease, Buruli ulcer, non-malarial fever and diseases with outbreak potential, such as Ebola. FIND has partnered in the delivery of 20 new diagnostic tools 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 nearly 200 partners globally, including research institutes and laboratories, health ministries and national disease control programmes, commercial partners, bilateral and multilateral organizations, especially WHO, and clinical trial sites. For further information, please visit www.finddx.org

Media contact

Sarah-Jane Loveday, Head of Communications

T: +41 (0) 22 710 27 88

M: +41 (0) 79 431 62 44

media@finddx.org

#