Low-cost TB test means quicker, more reliable diagnosis for patients

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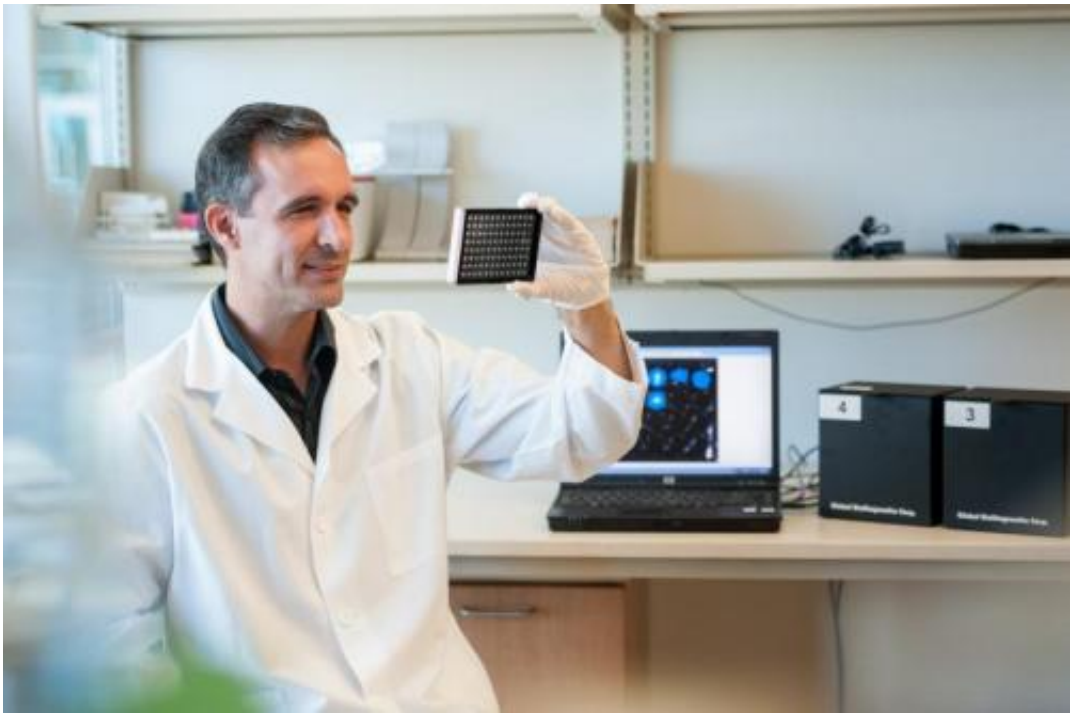

Credit: Texas A&M Health Science Center

(Medical Xpress)—A new test for tuberculosis (TB) could dramatically improve the speed and accuracy of diagnosis for one of the world's deadliest diseases, enabling health care providers to report results to patients within minutes, according to a study published this week in the journal *Angewandte Chemie*.

Jeffrey Cirillo, Ph.D., professor at the Texas A&M Health Science Center College of Medicine, in collaboration with GBDbio, a Texas A&M spinoff company, and investigators at Stanford University, have identified a new chemical compound to spot the bacteria that cause TB with a level of sensitivity that currently takes months to produce; and results of the first human clinical trial data are promising. Findings show the test can determine that a patient has tuberculosis with 86 percent sensitivity and 73 percent specificity. Smear microscopy, the most widely used test in the world, has a significantly lower ability to detect TB, ranging between 50 to 60 percent sensitivity.

Although preventable, TB claims three lives every minute, making it the second leading cause of mortality from an infectious disease in the world. Spread through the air when an individual with active TB infection coughs or sneezes, reports show that if left untreated, a person with active TB infects an average of 10 to 15 people each year, leaving a great need for faster, more reliable testing.

Cirillo's latest breakthrough perfects the technology behind the test. Using a fluorescent substrate, the device targets BlaC –an enzyme produced by the bacteria that cause TB – as an indicator of the bacteria's presence. Until now, it has not been possible to target a specific TB enzyme for diagnosis.

Once sputum samples are combined with the reactive substance, a battery-powered, portable tabletop device, the TB REaD™, is then used to detect any fluorescence and deliver the diagnosis in as little as 10 minutes.

"It's simple. Take a sputum sample, treat it with the solution and put it inside the reader," Cirillo said. "A camera inside looks for a reaction between the sample and solution that produces light. No light, no infection."

Currently, there is no diagnostic tool comparable to this and while others exist, they take several months to produce the same level of sensitivity; and come with a high price tag. The latest FDA-approved model cost upwards of $20,000. The target price tag on Cirillo's test is less than $1000 for the reader and less than $5 per test. Additionally, the one-step test will require little technical expertise or resources, should take less than 30 minutes to carry out, and is easily transportable, making it an ideal candidate for field diagnosis in developing countries.

The device significantly undercuts current diagnostic methods, important, given the staggering statistic that if left untreated – a common scenario in countries lacking infrastructure or resources to efficiently screen and follow up with infected patients – a person with active TB has only a 50 percent chance of survival, Cirillo notes.

"Interrupting disease transmission will require early and accurate detection paired with appropriate treatment," Cirillo said. "Our new, rapid point-of-care TB test dramatically reduces the current delays in diagnosis with incredible accuracy, accelerating appropriate treatment and reducing the death rate of the highly infectious disease. We're looking at a low-cost, easy-to-use test that has the potential to eradicate TB."

The test is currently in the later stages of clinical trials with plans to go to market in the next 18 months. Although the first applications will be in TB, Cirillo's detection platform – Reporter Enzyme Fluorescence - could be applied to many other respiratory diseases and infectious agents.

The research project, previously published in *Nature Chemistry*, has garnered support from the Foundation for Innovative New Diagnostics, the Clinton Health Access Initiative and is supported with major funding from the Wellcome Trust.