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HEALTH

Cepheid unveils fast TB test to aid developing countries

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Gene-based test developer Cepheid of Sunnyvale said Tuesday it has devised a rapid, sensitive diagnostic test for tuberculosis and will make it available at reduced cost in developing countries where the life-threatening disease is widespread.

The automated test for active TB illness, which gives results in two hours or less, also alerts doctors if a patient is infected with a drug-resistant strain of the bacterium that would not respond to standard treatment, Cepheid's chief medical officer Dr. David Persing said.

"Multidrug-resistant TB is becoming increasingly prevalent throughout the world,

making TB harder to treat with the usual treatment regimen that includes Rifampicin," said Persing. Cepheid's DNA-based test would help drug-resistant patients receive alternate treatment immediately rather than getting sicker and passing the infection on to others, he said.

"It is the most technologically advanced test for TB ever developed, yet it is simple enough to

perform in all corners of the world, including resource-limited settings where it is most needed."

Cepheid and its partners in the test's development were looking for a way to improve on a century-old method of confirming a TB diagnosis in people who display symptoms of the disease, which include a

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Dr. David Persing, Cepheid's chief medical officer, holds sample cartridges used for TB tests that take only two hours.

Cepheid's TB test to aid poor nations

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persistent severe cough, chest pain, fever and nausea. With the traditional "smear test," lab workers place sputum from a patient's lungs on a slide and painstakingly search under a microscope for tuberculosis bacteria. The test can fail to detect the disease, and doesn't reveal drug-resistant strains, Persing said. Further tests can pick up more complete information, but they take weeks, he said.

The Sunnyvale company worked with the Foundation for Innovative New Diagnostics, a nonprofit Swiss foundation that seeks better medical tests for poverty-related diseases; the University of Medicine and Dentistry of New Jersey; and the U.S. National Institute of Allergy & Infectious Diseases, which provided funding. Cepheid already makes automated tests for hospital-based infections, including MRSA (methicillin-resistant *Staphylococcus aureus*) a drug resistant strain of the common staph infection. The company's GeneXpert System packs all the lab processes for its tests into a cartridge about the size of a child's wallet. The cartridge is popped into a machine that reads the results.

Cepheid's new TB test detects DNA sequences that are

unique to TB and to drug resistance. GeneXpert System readers can be as small as a fat textbook, so they can be used in mobile clinics for people far from a hospital, Persing said. The company will sell the test in sub-Saharan Africa and other developing regions for the cost of the equipment and other expenses such as shipping, he said. In the United States, the smallest GeneXpert readers cost about \$27,000.

Persing said the heaviest use of the TB test is likely to be in developing nations afflicted with a high TB rate, but Cepheid will also seek Food and Drug Administration clearance for the test in the United States by early 2010. Tuberculosis, which can be spread through the air, was once the leading cause of death in the United States before medicines were discovered in the 1940s, according to the Centers for Disease Control and Prevention. At this point, U.S. cities with an influx of immigrants have to be on guard for TB transmission. San Francisco's rate of TB infection is higher than that of any other U.S. metropolitan area — three times greater than the national average and twice the California state average, according to Cepheid.

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