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TGen seeks emergency FDA approval of new swine flu test

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The Phoenix-based non-profit Translational Genomics Research Institute (TGen) announced today that, along with a business collaborator, it will submit a request to the U.S. Food and Drug Administration for emergency use of a new test to diagnose the 2009 H1N1 swine flu virus.

Details about TGen's test will be presented Sunday (Nov. 1) at the 47th annual meeting of the Infectious Diseases Society of America (IDSA), being held today through Sunday (Oct. 29-Nov. 1) in Philadelphia.

The new test, developed at TGen's Pathogen Genomics Division (TGen North) in Flagstaff, can not only detect influenza — as some tests do now — but also can quickly inform doctors about what strain of flu it is and whether or not it may be resistant to oseltamivir (sold under the brand name Tamiflu; Roche), the primary anti-viral drug on the market to treat H1N1.

As with other influenza strains, H1N1 flu can be expected to show signs of resistance to oseltamivir, and new treatments will be needed to respond to this and future pandemics.

"The problem with influenza is that it is becoming resistant to the antiviral drugs that are out there," said Dr. Paul Keim, a Professor of Biology at Northern Arizona University and Director of TGen North. "Because it is a virus, it mutates easily and becomes resistant."

David Engelthaler, Director of Programs and Operations for TGen

North, said this would be the only resistance test available that uses a standard molecular technique that rapidly makes exact copies of specific components of H1N1's genetic material.

"So far, it looks like this assay is very effective with strains in the U.S., and we expect it to have the same accuracy with strains around the world," said Engelthaler, the former State Epidemiologist for Arizona and former State of Arizona Biodefense Coordinator.

The assay, or test, for H1N1 flu was developed by TGen and a company called PathoGene LLC, which is a partnership that includes a group of Flagstaff business people as well as Engelthaler and Keim.

"We're very excited to work with TGen and the FDA to try to get these tests out to the public. We think we can really help make a difference," said William Gibbs, PathoGene's managing partner.

PathoGene and TGen officials hope to secure emergency FDA approval for the H1N1 flu test as soon as possible.

Currently, only the U.S. Centers for Disease Control Prevention (CDC) and a few select labs can look for resistance, using cumbersome and time intensive technology, Engelthaler said.

"This new test would put the power in the hands of the clinician to determine if their drugs will work or not. This is really important moving forward. When this outbreak first started (in April), everything was 100 percent sensitive to Tamiflu. But now, we're starting to see isolated cases of resistance pop up," Engelthaler said.

The World Health Organization has identified more than three-dozen instances of resistance to Tamiflu in the H1N1 swine flu virus.

TGen also is working with a Bay Area pharmaceutical firm, Adamas Pharmaceuticals, which is developing a unique triple-drug combination to treat influenza and to impede resistance.

"TGen's diagnostic test has been a useful tool in our research and is an important contribution to the influenza field," said Gregory T. Went, Ph.D., Chief Executive Officer and Chairman of Adamas Pharmaceuticals, headquartered in Emeryville, Calif.

At most doctors' offices, there is no readily available test for H1N1 flu. Those tests are generally being done by state and federal health agencies, and usually for those patients who require hospitalization and appear at high risk because they have a suppressed immune system or they have a chronic disease.

"The novelty in our study is the use of increasingly common laboratory tools to rapidly and accurately detect resistance to anti-influenza drugs. Until now, nearly all this work has required highly sophisticated laboratory procedures not readily available to most clinical labs and has really only been used for broad public health surveillance," Engelthaler said. "Our testing procedure measures very minute amounts of virus and minute changes to the virus. Not only does it detect when resistance is occurring, but it also detects it at the earliest onset possible."

Source: The Translational Genomics Research Institute