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Swine flu test developed here gets 'emergency' OK

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Technology checks many pathogens, speeds treatment

Although it can take years for federal regulators to approve a new drug or medical test, the Food and Drug Administration has granted the Huntsville-produced Diatherix H1N1-09 influenza test "emergency use authorization."

The rapid-response test was developed by Dr. Jian Han, faculty investigator at the HudsonAlpha Institute for Biotechnology. It was developed in May, shortly after the Centers for Disease Control and Prevention warned that an H1N1 - or swine flu - pandemic was imminent.

The test can differentiate among H1N1, Influenza A and B, meningitis, staph, strep, pneumonia and a host of other bacterial and viral illnesses in less than six hours.

Under the rules of Clinical Laboratory Improvement Amendments, Diatherix Laboratories has been able to use its new swab test to determine if "hundreds and hundreds" of patients across the country had swine flu, company CEO Dennis Grimaud said.

"This gives us the ability to say that the FDA has reviewed our data and that we meet its criteria for emergency use," Grimaud said Wednesday. "It validates us.

"From a user perspective, that is huge."

The test uses Diatherix's proprietary molecular technology, known as target enriched multiplex polymerase chain reaction. The ability to check for multiple pathogens at one time, and to do it quickly, are huge benefits for patients, Grimaud said.

He said the majority of H1N1 deaths have involved "co-infected" patients, meaning that they had swine flu plus another infection. Because the Diatherix test checks for nearly two dozen other viruses and bacteria while checking for H1N1, doctors can know within 24 hours how to treat their patients for multiple infections.

Quicker diagnosis can "mitigate many of the negative economic and social impacts associated with a pandemic influenza outbreak," he said.

Grimaud said his company has expanded from 10 employees to 30 in the past four weeks to keep up with the demand created by the test.

The emergency use authorization is good through April 26 but can be renewed if the pandemic continues.

Diatherix is based at HudsonAlpha in Cummings Research Park. Its parent company, Diagnostix Network Alliance, is based in the Nashville suburb of Brentwood.

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