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US issues patent for Valley Fever detection technology

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Valley Fever, a potentially deadly dust-borne fungal disease, should be easier to diagnose and treat thanks to a testing technology developed by the Translational Genomics Research Institute (TGen) and Northern Arizona University (NAU), and now protected by a patent issued today by the U.S. Patent and Trademark Office.

TGen and NAU have exclusively licensed this technology to DxNA LLC, a company based in St. George, Utah, which plans to make this Valley Fever Test commercially available to hospitals and clinics upon completion of FDA clinical trials and a subsequent FDA 510(k) submission for review and clearance later this year.

Valley Fever is endemic to Phoenix and Tucson, but also is spreading throughout the arid regions of North and South America. It is an infection caused by the microscopic fungus *Coccidioides*, a pathogen that lives in desert soils and typically enters the body through the lungs. An estimated 150,000 Americans are infected annually by Valley Fever, and as many as 500 die each year.

"Currently, there is no definitive test for Valley Fever. Our new rapid, 1-hour, genetic-based test will provide physicians and patients with a precise diagnosis, enabling prompt treatment and preventing this disease from becoming more serious," said Dr. Paul Keim, Director of TGen's Pathogen Genomics Division, or TGen North, based in Flagstaff.

"For the past decade, TGen has worked to develop better tools and

technology to address Valley Fever, and we think it is critical to be able to apply our cutting-edge science to problems in our own backyard," said Dr. Keim, who also is the Cowden Endowed Chair of Microbiology at NAU, and Director of NAU's Center for Microbial Genetics and Genomics (MGGen).

Valley Fever most commonly causes a progressive lung infection, but can also spread to other parts of the body, including the skin, bone, brain and the rest of the nervous system.

Nearly 60 percent of those infected by Valley Fever—including other vertebrates, and especially dogs—develop no significant symptoms. However, some patients develop highly debilitating symptoms, such as cough, fever and fatigue. These symptoms are similar to other respiratory diseases caused by bacteria or virus, and often lead to delayed diagnoses and inappropriate treatment. Very severe Valley Fever can require lifelong treatment with antifungal drugs, and even result in death.

This new genetic-based test can precisely identify both strains of Valley Fever: Coccidioides posadasii, found in Arizona, New Mexico, Texas and much of Latin America, and Coccidioides immitus, which is found in California, Washington and Baja Mexico.

Most infections occur in central and southern Arizona. Each year on average, there are an estimated 150,000 cases in Arizona, resulting in more than 1,700 hospitalizations at a cost of more than $86 million.

"These high costs are driven to a significant degree by the high level of misdiagnosis, resulting in an average time to diagnosis of 5 months from when a patient first seeks care," said David Taus, CEO of DxNA LLC. "Our test provides definitive results in 60 minutes, dramatically improving the diagnosis of the disease over current methodologies, both

in terms of time and accuracy."

The intellectual property used in DxNA's Valley Fever Test is exclusive to DxNA LLC, and covers both human and veterinary applications, Taus said.

Provided by The Translational Genomics Research Institute