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IDRI contributes to first point-of-care Chagas disease diagnostic for US

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With Chagas disease becoming more prevalent in the United States, a diagnostic to quickly and easily detect infection is needed. Today, IDRI (Infectious Disease Research Institute) announces that a fusion antigen it developed and patented is being used as part of a Chagas disease diagnostic test created by InBios and recently approved by the U.S. Food & Drug Administration (FDA) for use in the United States. This marks the first point-of-care diagnostic test for Chagas disease available in the United States.

A leading source of heart disease in Latin America, Chagas disease caused by the parasite *Trypanosoma cruzi*. While transmission of Chagas disease most often takes place due to the bite of an infected member of the Reduviidae family of insects—commonly called the "kissing bug"—it can also occur via blood transfers and the disease has been globalized by vector-independent transmission. Although not endemic in the United States, conservative estimates are that Chagas disease-related healthcare costs are in excess of $118 million to the U.S. each year. Most predictions are that about 300,000 symptomatic cases exist in the U.S., although an alternative estimate suggests over one million more cases nationwide. California, Texas, Florida and New York likely each have over 10,000 cases and an additional seven states probably have over 5,000 cases.

Given the possibility of transmission by blood transfusion, blood and tissue products, national screening of the blood supply was instituted in the United States in early 2007. Now, through an assay developed using

IDRI technology, tests will be available in the U.S. to detect Chagas disease infection in individuals.

"At IDRI, our goal is to develop products that are useful for diseases that are prevalent in the developing world, but more often we are seeing these diseases—like Chagas—become a threat in the developed world because of travel or vector-independent transmission, such as blood transfers," said Steve Reed, Ph.D., President, CEO & Founder of IDRI. "Rapid diagnosis is a key step in stopping infectious disease. We're pleased to play a key role in getting this diagnostic to people who might be affected by Chagas disease."

InBios' Chagas Detect Plus Rapid Test Kit (CDP) is a non-invasive diagnostic test for use in a primary care setting by personnel trained to obtain whole blood or serum samples. The two-step rapid diagnostic test is easy to use and results can be obtained in 20 minutes. In several clinical studies, the CDP demonstrated greater than 95 percent sensitively and specificity in both endemic and non-endemic populations.

Estela Raychaudhuri, President of InBios, said, "We are excited to bring this long awaited, fast and affordable point of care Chagas test to the U.S. market, developed in collaboration with the Infectious Disease Research Institute."

Provided by Infectious Disease Research Institute