Chagas Immunochromatographic Strip Test

Health need

Chagas disease (American trypanosomiasis), caused by the parasite *Trypanosoma cruzi*, is one of the most significant neglected diseases in the developing world. It is found throughout Latin America and is primarily transmitted by insects native to this region. Untreated chronic Chagas disease can lead to serious cardiac and digestive complications, resulting in loss of productivity and ultimately death. An estimated 10 million people are infected with *T. cruzi* worldwide, and more than 25 million are at risk of being infected every year according to the World Health Organization. Adding to the burden, the highest incidence of Chagas disease is found in poor and rural settings, where a tremendous diversity of parasite reservoirs and vectors combine with inadequate housing conditions to greatly facilitate disease transmission. As such, Chagas disease dramatically and disproportionally impacts the poorest and most disadvantaged populations.

The use of two or more diagnostic tests is currently recommended for confirmation of infection. However, the diagnostic tests most commonly used—enzyme-linked immunosorbent assays (ELISA) and immunohemaggulination assays (IHA)—require well-equipped laboratories, skilled technicians, and/or refrigeration, making it difficult for these tests to be used in low-resource settings.

Technology solution

The Chagas Immunochromatographic Strip (ICS) Test has the potential to become an effective and appropriate tool for detection of Chagas disease because ICS tests offer many advantages for use in low-resource settings. They provide test results quickly and require neither sophisticated laboratories nor extensive training. The successful use of ICS tests by trained community health workers is widely recognized as evidenced by the use of ICS tests in HIV and malaria clinical management throughout resource-poor communities around the globe.

Current status and results

PATH has conducted an evaluation of the Chagas ICS Test in our laboratory using 375 previously characterized clinical specimens from a Chagas endemic region. These analyses showed that the Chagas ICS Test had a sensitivity of 99.5% and specificity of 96.8%. The results to date are promising, and we will soon begin a field evaluation of test performance with whole blood specimens. Simultaneously, we are working to establish partners who will manufacture and distribute the Chagas ICS Test at a price lower than other point-of-care tests.

PATH/Rebecca Barney

Prototype Chagas ICS Test, positive (right) and negative (left) results.

The need for an affordable, accurate Chagas diagnostic has been reiterated by every Chagas regional initiative. To address this need PATH is developing a rapid test for Chagas disease that combines a well-accepted and inexpensive format ICS test, with a *T. cruzi* antigen that is proprietary to a private company in Argentina.

Availability

For more information regarding this project, contact Mutsumi Metzler at mmetzler@path.org.

Donor support

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