A Novel and Sensitive Rapid Diagnostic Test for Chagas Disease

PATH
A catalyst for global health

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Introduction

Chagas disease, caused by infection with the parasite *Trypanosoma cruzi*, is one of the most significant neglected diseases in the developing world. Found throughout Latin America, it is especially prevalent in rural areas where poor housing conditions foster disease transmission from insect vectors. Although an estimated 12 million people are infected with *T. cruzi* and more than 90 million are at risk of becoming infected every year according to the World Health Organization, there is currently no easy and inexpensive way to diagnose Chagas disease.

Diagnosis of Chagas disease is challenging because the recommended practice requires the use of two tests, and no combination of tests commonly employed are appropriate for use at the point of care (POC). In particular, POC tests with high sensitivity are needed to accompany screening programs.

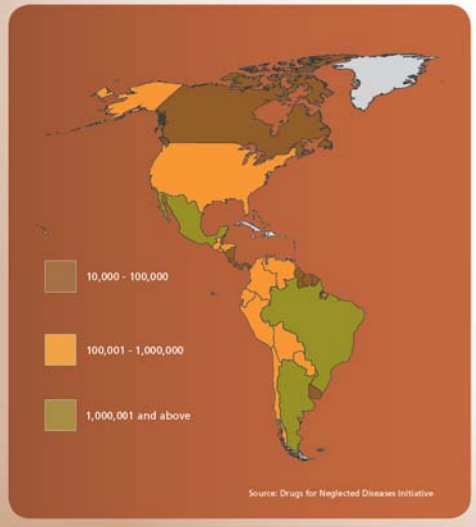

Figure 1. Estimated global population infected by *Trypanosoma cruzi*, 2009

Methods

A new rapid test for Chagas disease is under development at PATH, in collaboration with Laboratorio Lemos of Argentina, utilizing:

- Lemos' novel, multi-epitope, recombinant antigen for detection of antibodies to *T. cruzi*
- An immunochromatographic strip (ICS) format, appropriate for use at the POC

If the sample contains antibodies to *T. cruzi*, a red line will form at the test line, indicating a positive result. In the absence of antibodies to *T. cruzi*, no red line will form in the test line area, indicating a negative result, (Figure 2).

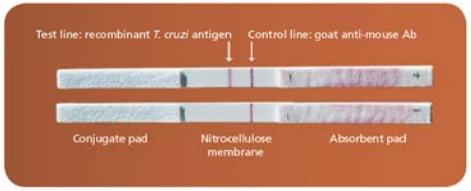

Figure 2. Examples of the PATH-Lemos rapid test with positive (two lines) and negative (one line) test results.

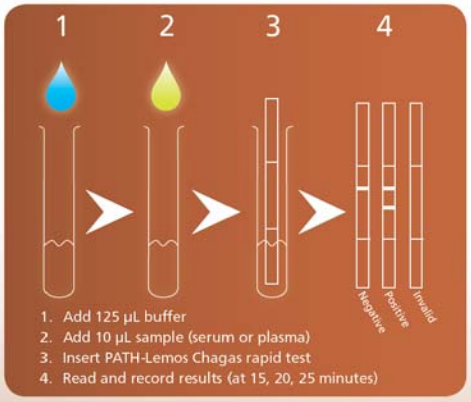

Figure 3. Test procedure

Procedures

To evaluate the performance of the PATH-Lemos rapid test, a total of 375 serum samples from Argentina which had been previously characterized for antibodies to *T. cruzi* were used as shown in Figure 4.

An additional read time of 20 minutes was included for the Chagas STAT-PAK® tests, as it has been reported to improve performance of the test.

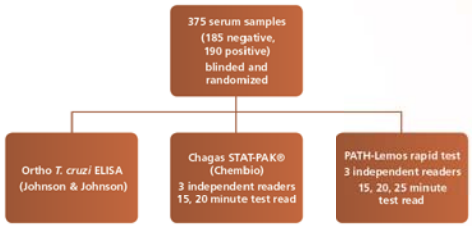

Figure 4. Testing schematic for PATH-Lemos rapid test evaluation.

Data

The results from the Ortho *T. cruzi* ELISA were compared to the previous sample classifications provided by Laboratorio Lemos. Agreement between the Ortho *T. cruzi* ELISA results and results from Laboratorio Lemos was 100%.

Compared to the Ortho *T. cruzi* ELISA test:

- The PATH-Lemos rapid test demonstrated an optimal sensitivity of 99.5% and a specificity of 96.8%
- The Chagas STAT-PAK® demonstrated a sensitivity of only 95.3% and a specificity of 99.5%

Table 1. Performance of the Chagas STAT-PAK® and PATH-Lemos rapid test compared to Ortho *T. cruzi* ELISA

Test Description	Time Read (min)	Sensitivity (%)	Specificity (%)
Chagas STAT-PAK®	15	181/190 (95.3)	184/185 (99.5)
	20	182/190 (95.8)	184/185 (99.5)
PATH-Lemos Chagas rapid test	15	186/190 (97.9)	178/185 (96.2)
	20	189/190 (99.5)	179/185 (96.8)
	25	188/190 (98.9)	174/185 (94.0)

Conclusions

Current guidelines for a Chagas screening test emphasize that clinical sensitivity is of utmost importance because of the need to identify as many true positive infections as possible, while lower specificity is more acceptable because of the requirement for a second, confirmatory test.

Our results indicate that the PATH-Lemos Chagas rapid test has great potential as a highly sensitive diagnostic test for Chagas disease. The next step in development is to optimize and validate the test for use with whole blood samples, which will enable utility at the point of care.