Field evaluation of a rapid immunochromatographic assay for *Trypanosoma cruzi* infection using whole blood in Sucre, Bolivia

Paul Roddy¹, Javier Goiri¹, Laurence Flevaud¹, Pedro Pablo Palma¹, Silvia Morote¹, Nines Lima¹, Luis Villa¹, Faustino Torrico², Pedro Albajar-Viñas¹,³

¹Médecins Sans Frontières, Barcelona, Spain; ²Centro Universitario de Medicina Tropical, Facultad de Medicina, Universidad Mayor de San Simón, Cochabamba, Bolivia; ³Laboratório de Doenças Parasitárias, Instituto Oswaldo Cruz, Fiocruz, Rio de Janeiro, Brazil

Contact: paul.roddy@barcelona.msf.org

**Background** Diagnostic classification of seropositive individuals, followed by treatment and supportive therapy, is an established component of Chagas disease control in endemic areas. However, most Chagas-infected patients live in peri-urban and rural areas where neither equipped laboratories nor skilled human resources are widely available. The use of a valid rapid diagnostic test (RDT), when using whole blood samples and performed by trained, non-laboratory health workers, is the best option for Chagas disease control. A high sensitivity and specificity for the Chagas Stat-Pak™ RDT (Chembio Diagnostic Systems, Inc., Medford, NY) has been reported when assayed with serum and plasma under reference laboratory conditions but, prior to this study, the validity of the RDT for the detection of antibodies to *Trypanosoma cruzi* infection in whole blood was unknown.

**Methods** This cross-sectional study measured the sensitivity and specificity of the Chagas Stat-Pak™ RDT when using whole blood and used conventional serological assays as a comparison. The inter-observer reliability in the interpretation of the Chagas Stat-Pak™ results and ‘ease of use’ criterion needed to perform the Chagas Stat-Pak™ and conventional assays were also measured. Enrolment of the 1,913 study participants began on 18 April 2007 and ended on 12 July 2007 (12 weeks).

**Results** Using whole blood, the Chagas Stat-Pak™ RDT yielded a high specificity [99.0%, (95% CI, 98.4–99.4%)] but, when compared to the sensitivity of the RDT using serum or plasma samples under reference laboratory conditions, a relatively low sensitivity [93.4%, (95% CI, 87.4–97.1%)]. The inter-observer reliability was excellent [kappa (n=1,913)=0.999, (p<0.0001)] and quantified ‘ease of use’ criterion suggested that the Chagas Stat-Pak™ is a simple RDT that can be performed by trained, non-laboratory personnel.

**Conclusion** Despite the distinguished attributes of the Chagas Stat-Pak™, it is not, when using whole blood, an ideal diagnostic test for the population investigated in this study due to its relatively low sensitivity and high cost. The sensitivity and specificity of the RDT using whole blood should approach the sensitivity and specificity of conventional assays that are conducted under reference laboratory conditions using plasma or serum. The Chagas Stat-Pak™ also compares less favourably with whole blood RDT diagnosis of other parasitological vector-borne diseases, such as the rK39 RDT (DiaMed-IT-Leish), which reported 100% sensitivity for the diagnosis of visceral leishmaniasis and the Paracheck-Pf RDT (Orchid Biomedical Systems, Goa, India), which reported 99% sensitivity for the diagnosis of uncomplicated *Plasmodium falciparum* malaria. The false negative rate of 6.6% found in this study suggests that a substantial number of individuals remain undiagnosed, resulting in missed treatment opportunities and increased likelihood of chronic-stage disease sequelae. The RDT manufacturer is called upon to improve the test if the international community hopes to make progress in controlling Chagasic infections in endemic areas of Latin America.