Jun 03, 2021

Laboratory Protocols

Lyda Pilar Salamanca-Cardozo[1], María-Jesus Pinazo[2], Lluis Armadans-Gil.[3], Sandra Helena Suescun-Carrero[4]

[1]Grupo de Investigación del Laboratorio de Salud Pública de Boyacá, Secretaria de Salud de Boyacá, Tunja, Colombia.;
[2]Barcelona Institute for Global Health (ISGlobal), Hospital Clinic - University of Barcelona, Barcelona, Spain.;
[3]Servicio de Medicina Preventiva y Epidemiología, Hospital Universitari Vall d'Hebron - Universitat Autònoma de Barcelona, Barcelona, Spain.;
[4]Grupo de Investigación del Laboratorio de Salud Pública de Boyacá, Secretaria de Salud de Boyacá, Tunja, Colombia. Doctorado en Metodología de la Investigación Biomédica y Salud Pública, Universitat Autònoma de Barcelona, Barcelona, Spain.

dx.doi.org/10.17504/protocols.io.bttpnnmn

Sandra Helena Suescun-Carrero
Grupo de Investigación del Laboratorio de Salud Pública de B...

ABSTRACT

Objective. To evaluate diagnostic precision of two rapid diagnostic tests (RDT's) on patients with chronic Chagas disease.

Methodology. Prospective study with the following inclusion criteria: subjects older than 3 years, signed informed consent. Exclusion criterion: subjects could not have previously received treatment for infection with *T. cruzi*. The study population were participants in a screening process undertaken in rural and urban zones of the department Boyacá, Colombia. Two RDT's were performed to all participants: the Chagas Detect Plus InBios (CDP) and the Chagas Stat-Pak (CSP) and as a reference standard the ELISA Chagas III GrupoBios and the Chagas ELISA IgG+IgM I Vircell tests wereused.In the case of discordant results between the two ELISA tests, an indirect immunofluorescence was done.

Results. Three hundred-five (305) subjects were included in the study (38 patients with leishmaniasis), of which 215 tested negative for *T cruzi* and 90 tested positive according to the reference standard.The sensitivity of the RDT's were 100% (CI 95% 95.9 – 100), and the specificity of the CDP was 99.1% (CI 95% 96.6 – 99.8) and for CSP was 100% (CI 95% 98.3 – 100). The agreement of CDP was 99.5% and for CSP was 100% with Kappa values of (k=99.1; CI 95% 92.6-99.8%) and (k=100; CI 95% 94.3-100), respectively. RDT's did not present cross-reactions with samples from patients who were positive for leishmaniasis.

Conclusions

The findings demonstrate excellent results from the RDT's in terms of validity, safety, and reproducibility. The results obtained provide evidence for the recommendation for using these tests in a Colombian epidemiological context principally in endemic areas in which laboratory installations necessary to perform conventional tests are not available, or they are scarce and to help in diagnosing chronic Chagas disease in order to provide access to treatment as soon as possible.

EXTERNAL LINK
https://doi.org/10.1371/journal.pntd.0009483

DOI
dx.doi.org/10.17504/protocols.io.bttpnnmn

EXTERNAL LINK
https://doi.org/10.1371/journal.pntd.0009483

Citation: Lyda Pilar Salamanca-Cardozo, MarÃÂa-Jesus Pinazo, Lluis Armadans-Gil., Sandra Helena Suescun-Carrero (06/03/2021). Laboratory Protocols. https://dx.doi.org/10.17504/protocols.io.bttpnnmn

PROTOCOL CITATION

Lyda Pilar Salamanca-Cardozo, María-Jesus Pinazo, Lluis Armadans-Gil., Sandra Helena Suescun-Carrero 2021. Laboratory Protocols. **protocols.io** https://dx.doi.org/10.17504/protocols.io.bttpnnmn

KEYWORDS

null, rapid tests, Trypanosoma cruzi, Colombia, Sensitivity, Specificity

CREATED

Mar 30, 2021

LAST MODIFIED

Jun 03, 2021

PROTOCOL INTEGER ID

48719

MATERIALS TEXT

Chagas Detect Plus InBios (CDP) test
Chagas Stat-Pak (CSP) test
ELISA Chagas III GrupoBios test
Chagas ELISA IgG+IgM I Vircell test
pipettes
racks
ELISA reader kit
Cotton
Alcohol
lancets
chronometer
tubes

SAFETY WARNINGS

Apply laboratory biosafety standards

BEFORE STARTING

- Prepare serum or whole blood samples
- Prepare ELISA tests and rapid tests for the diagnosis of Chagas disease
- Adapt the necessary laboratory equipment for the processing of the tests.

1 The reference diagnostic strategy utilized in the present study is based on conventional serological tests suggested by the National Parasitology Reference Laboratory of the National Health Institute (Instito Nacional de Salud, or INS) of Colombia, and is routinely used in the CD monitoring program of the LDSP. All samples were analyzed using the ELISA Chagas III GrupoBiosÒtests [informed sensitivity, 100%; specificity, 100%] and with the Chagas ELISA IgG+IgM I VircellÒtests [informed sensitivity, 100%; specificity, 98%] [30,31].In cases in which discordant results were found between the two ELISA tests, an IIF test was done, which uses epimastigotes of the Colombian *T. cruzi* strains DTU and TcI as antigens, when the results of this technique were positive, case was considered to be confirmed.The tests were done in serum samples in the LDSP, following the manufacturer's instructions; the laboratory complies with the internal quality control standards of the method, using material for quality control of the MQC and with external quality controls and aptitude tests done by the INS and Proasecal.The results of the tests were interpreted as either positive or negative.

2 There are several RDT's for detecting infection by *T.cruzi* which have the advantages described above over conventional tests and that have high sensitivities and specificities according to several authors. Thus, in the present study, all samples were analyzed using two immunochromatographic diagnostic tests based on different antigens: Chagas Detect Plus (InBios International Inc., Seattle, USA) ÒCDP, which uses a multi-epitope antigen, and Chagas Stat-Pak (Chembio Inc., Medford USA) ÒCSP, which employs a combination of recombinant proteins. Small quantities of whole blood from finger puncture were used to carry out the RDT's. In order to evaluate cross-reactivity with leishmaniasis

Citation: Lyda Pilar Salamanca-Cardozo, MarÃÂa-Jesus Pinazo, Lluis Armadans-Gil., Sandra Helena Suescun-Carrero (06/03/2021). Laboratory Protocols. https://dx.doi.org/10.17504/protocols.io.bttpnnmn