PRESS RELEASE

Signing of Joint Research Agreement for the Designing of a universal Rapid Diagnostic Test Kit for Chagas Disease with Nagasaki University, Tulane University, and IS Global; Supported by GHIT Fund

The research group led by Prof Hirayama Kenji at Nagasaki University School of Tropical Medicine and Global Health has entered into a joint research agreement with Tulane University School of Public Health and Tropical Medicine in the United States and the Barcelona Institute for Global Health (ISGlobal) in Spain. This joint research project aims to design a rapid diagnostic test kit for chronic Chagas disease that can be broadly applied across the Americas. The project has been selected by and receive funding from the Global Health Innovative Technology Fund (GHIT Fund).

1. Project Title: Design of a universal Rapid Diagnostic Test for the detection of chronic *Trypanosoma cruzi* infections.
   Designated Development Partner: Nagasaki University School of Tropical Medicine and Global Health (Japan)
   Collaboration Partners: Tulane University School of Public Health and Tropical Medicine (USA), Barcelona Institute for Global Health (Spain)

2. Background and Summary
   Chagas disease is one of the Neglected Tropical Diseases (NTDs) as defined by the World Health Organization (WHO), a parasitic infection that affects an estimated 7 million people, mainly in Latin America, and kills around 12,000 people each year. The parasite *Trypanosoma cruzi (T.cruzi)* is transmitted to humans by a blood-sucking insect called the kissing bug. In the acute phase of infection, symptoms such as itching and swelling appear, which resolve spontaneously. However, if untreated, the infection can remain. After more than a decade, it moves into a chronic phase, which can seriously affect life by developing serious complications in the heart and intestinal tract. The initial symptoms of infection are minor and therefore easily missed, and many infected people go undiagnosed.
   Diagnosis in the early stage of infection is performed by collecting blood samples and detecting the parasites under a microscope. In the chronic phase, the parasite is almost completely absent from the blood and cannot be diagnosed by this method. Instead, two or more serological tests such as IFA (Indirect Immunofluorescence Assay) and ELISA (Enzyme-Linked Immunosorbent Assay) are used for diagnosis. However, the genetic diversity of *T.cruzi* and cross-reacting with infectious diseases such as leishmaniasis may prevent reliable test results. In such cases, additional tests are required, but these tests often require specialized techniques and equipment, resulting in significant costs for the areas affected by the spread of infection.

3. Project Objective

The ultimate objective is to achieve a prototype RDT (Rapid Diagnostic Tests) to detect chronic *T. cruzi* infections that render a very good performance regardless of the geographic origin of the clinical samples to analyze. For that, we envisage the following specific objectives:

(1) To sequence and assemble the whole genome of underrepresented *T. cruzi* isolates from Mesoamerica.

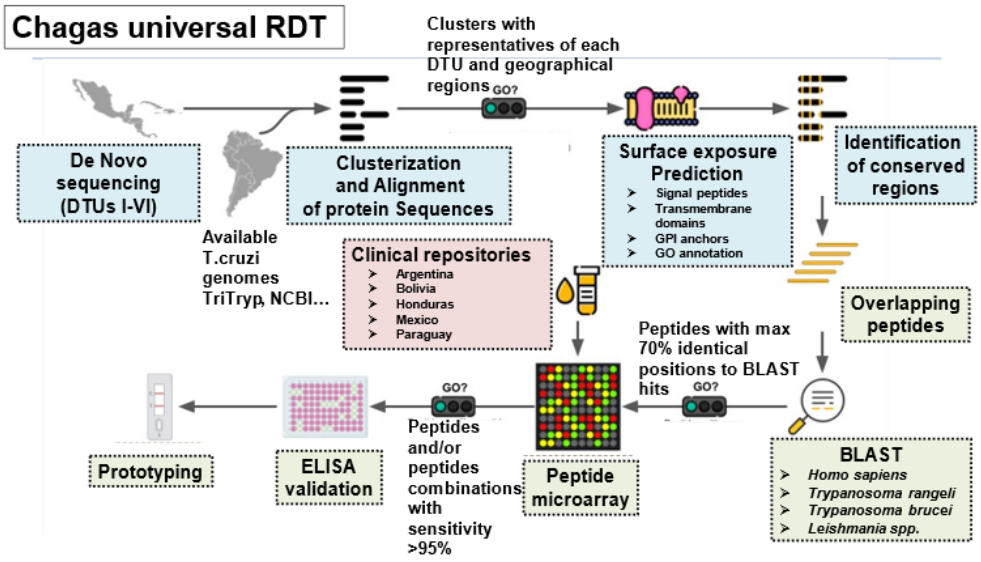
(2) To analyze, with the assistance of computational methods, all available *T. cruzi* protein sequences for prioritization of diagnostic antigens.

(3) To address the reactivity against those selected antigens by arraying them with plasma/serum samples originating from multiple Chagas disease endemic countries.

(4) To print the ultimately prioritized antigens on immunochromatographic (IC) strips for their analytical evaluation, and qualification, as a prototype POC (Point of Care) RDT.

4. Project design

To reach the goal of analytically validating a new RDT prototype that hypothetically works in all regions, we will first need to obtain the whole genome sequences of under-represented isolates circulating in Central America and Mexico, where it is acknowledged that currently available tools have a poor performance. Using a computing program, antigenic epitopes will be predicted that are useful for diagnosis; which are common to isolates in Central and South America and react with the infected individuals in various regions, including genomic information from other regions. In order to evaluate the obtained peptide sequences, synthetic peptide microarrays will be created, and screening will carry out for reactivity using blood collected from infected individuals in various regions and non-infected controls from the same regions. Finally, the peptide antigen that covers the largest regions and produces the highest signal will be selected, and a prototype RDT will be created by printing the antigen on a filter so that the positive band can be seen.



※This text has been translated from the Japanese version of the press release.