Simplifying diagnosis for people living with Chagas in Colombia: from implementation research to public policy

Andrea Marchiol, Rafael Herazo, María-Jesús Pinazo
Drugs for Neglected Diseases initiative (DNDi), Rio de Janeiro, Brazil

Introduction

Millions of people in Latin America have, or are at risk of, infection with Chagas disease - a major but often neglected public health challenge. Despite the availability of treatment, access to timely diagnosis is a critical bottleneck for disease control and patient care.

Conventional diagnostic algorithms based on serological testing require centralized laboratories, skilled personnel, a cold-chain, and costly infrastructure, which poses substantial barriers in rural, remote, and underserved settings where the Chagas disease burden is highest.

Rapid diagnostic tests (RDTs) are a promising tool to address these gaps by enabling decentralized and rapid diagnosis at the point of care. However, large-scale adoption of RDTs within national diagnostic algorithms requires rigorous evidence on their accuracy, feasibility, usability, and programmatic impact across diverse real-world contexts.

RDTs could improve timely diagnosis and facilitate large-scale screening in the general population, strengthening access to Chagas disease care. Currently <10% of people with the infection are aware of having it, and <1% receive etiological treatment.

This study aimed to evaluate the implementation of RDTs for CD diagnosis in Colombia, generating evidence to support policy change and improve diagnostic coverage.

Conclusions

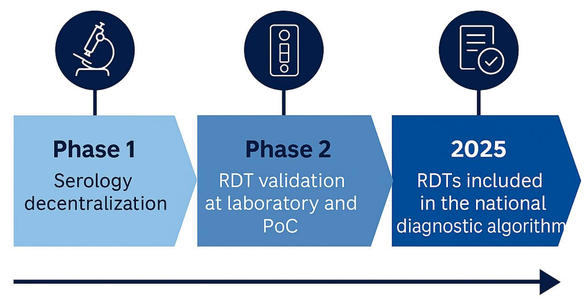
Evidence from Colombia demonstrates that RDTs can **effectively simplify** Chagas disease diagnosis, enhance access, and maintain **high diagnostic accuracy**. The transition from implementation research to public policy exemplifies an evidence-based approach to **health system strengthening**. Colombia's experience serves as a paradigm for other endemic countries, highlighting the need for continued validation, cost-effectiveness analyses, and sustainable supply strategies to ensure long-term impact.

Methods

An implementation research approach was used in close collaboration with national and local stakeholders, which was structured in two complementary phases:

Phase 1 – Health system strengthening

- Validation and decentralizing of serology with two ELISA tests
- Training laboratory and healthcare personnel
- Providing infrastructure and technical support to reinforce laboratory networks



Phase 2 – RDT evaluation in the laboratory and at the point of care

In the laboratory:

- Eleven commercially available RDTs were evaluated using serum samples to assess analytical performance under controlled conditions

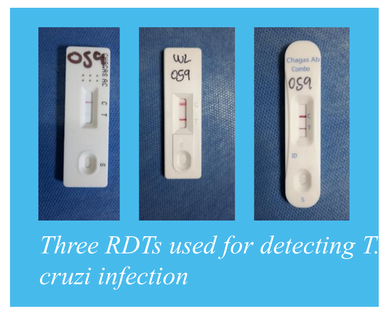
In field conditions, at the point of care (PoC):

- Four RDTs were evaluated in pregnant women within antenatal care settings
- Three RDTs were evaluated in the general population

Studies were reviewed across multiple regions in the country, including hard-to-reach and indigenous communities

Evaluation outcomes included sensitivity (Se),specificity (Sp), usability and operational feasibility at PoC level, concordance with ELISA-based reference algorithms.

Diagnostic simulations compared conventional serology-based algorithms with alternative RDT-based parallel and serial strategies.



Three RDTs used for detecting T. cruzi infection

Results

Phase 1

- A new diagnostic algorithm based on two ELISA assays was officially adopted. Seven new primary health care centers were established for Chagas diagnosis and treatment in endemic areas. Five years after implementation, access to Chagas diagnostic testing increased by 38%.

Phase 2

- Five of the eleven RDTs evaluated, based on Se and Sp under lab conditions, were selected for PoC evaluation.
- The five RDTs (Adbio, Stat Pak, Inbios CDP, Wiener, Bioline Abbot) had performance comparable to ELISA under parallel and serial PoC testing strategies in the general population, including indigenous communities and pregnant women. However, three (Abdio, Stat Pak, InBios) showed superior diagnostic performance and usability.
- **Expert consensus recommendation** to use RDTs for the entire population, prioritizing areas without laboratory access; confirm diagnosis with two different high-performance RDTs using a serial strategy.
- **New Chagas diagnostic algorithm including RDTs officially adopted** in May 2025 by the Colombian Ministry of Health

Fig 1: Sensitivity and specificity of three exemplar RDTs in three settings

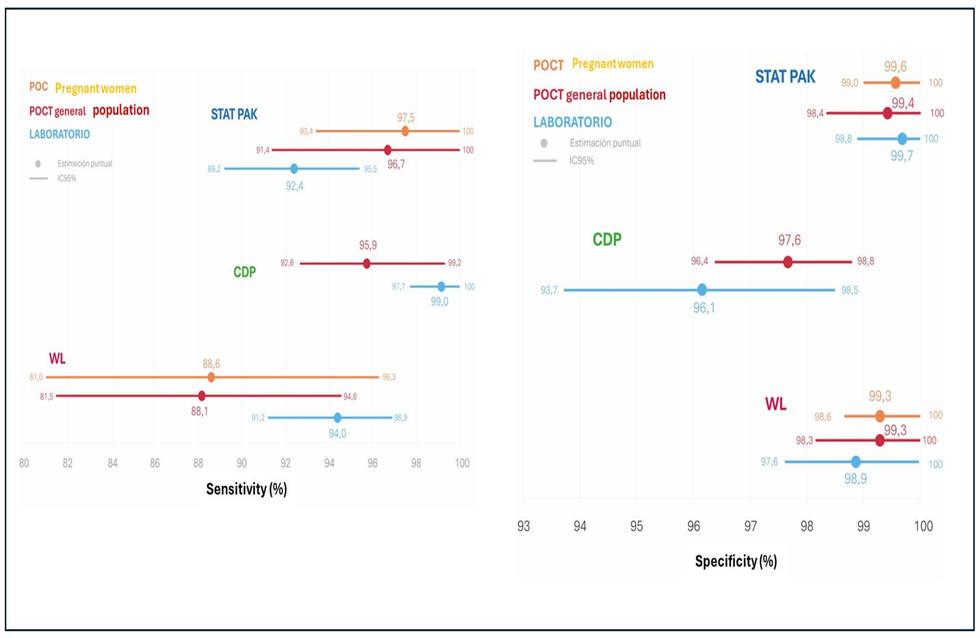


Table 1:Usability score for four exemplar RDTs

RDT	Variable	Category	n	%	RDT	Variable	Category	n	%
STAT PAK	Appearance of background	Clear	750	97.3	BIOLINE	Appearance of Background	Clear	504	65.4
		Dark	21	2.7			Dark	267	34.6
	Band intensity	Intense	755	97.7		Band intensity	Intense	737	95.6
		Weak	16	2.1			Weak	34	4.4
	Ease of reading	Effortless	759	98.4		Ease of reading	Effortess	754	97.8
		Difficult	9	1.2			Difficult	16	2.1
		Very difficult	3	0.39			Very difficult	1	0.1
AD BIO	Appearance of background	Clear	764	99.1	WL	Appearance of background	Clear	757	98.2
		Dark	7	0.9			Dark	14	1.8
	Band intensity	Intense	754	97.8		Band intensity	Intense	748	97.0
		Weak	17	2.2			Weak	23	3.0
	Ease of reading	Effortless	755	97.9		Ease of reading	Effortless	754	97.8
		Difficult	11	1.4			Difficult	7	0.9
		Very difficult	5	0.6			Very difficult	10	1.3

"Colombia leads global adoption of rapid tests for the diagnostic of people with Chagas disease"

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