



# Chagas in SOT

Lynne Strasfeld, MD

February 4, 2026

# The case

██████████ with HFrEF and VT, s/p ICD (201██████), s/p myomectomy for ventricular aneurysm (“Batista Repair”) in El Salvador in 200██████

- Admitted ████████ 2024 with syncope in the setting of VT, transferred to CVICU on hospital day 7 with pulseless VT → CPR/shock with ROSC
- Listed for heart transplant early June
- Impella placed 1 month into admission
- Transplant ID consult day -1 for heart transplant: management for Chagas cardiomyopathy
- Patient confirms knowledge of Chagas diagnosis dating back to 2015
- Lived in concrete home with "paper roof" in El Salvador, recalls "chinch bugs"





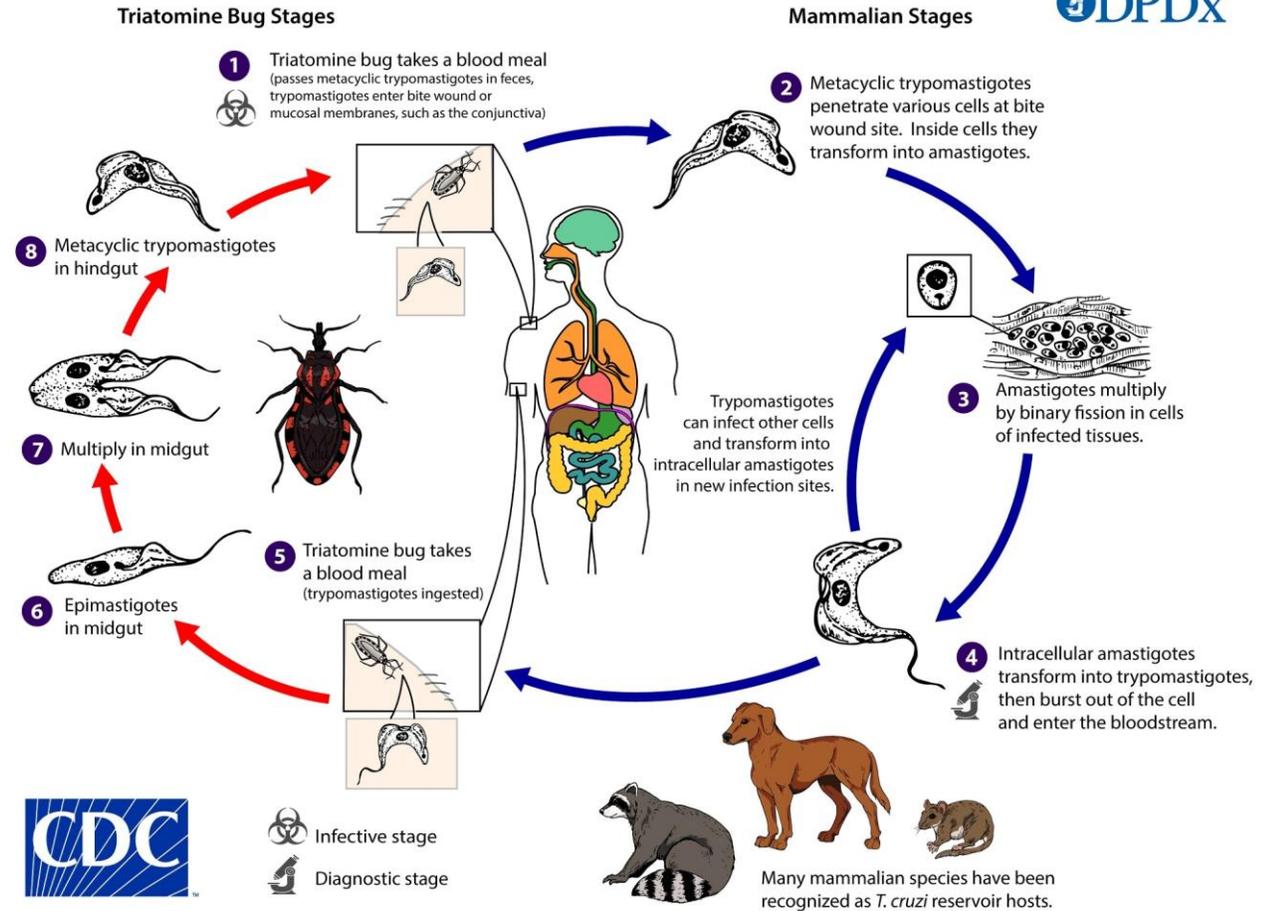
### About Chagas Disease

KEY POINTS

- Chagas disease is caused by the parasite *Trypanosoma cruzi*. It usually spreads through contact with triatomine bugs.
- Chagas disease is most common in rural areas of Mexico and Central and South America.
- The early stage, or acute infection, of Chagas disease often has mild symptoms or goes unnoticed. Chronic infection can lead to serious heart and digestive system issues.

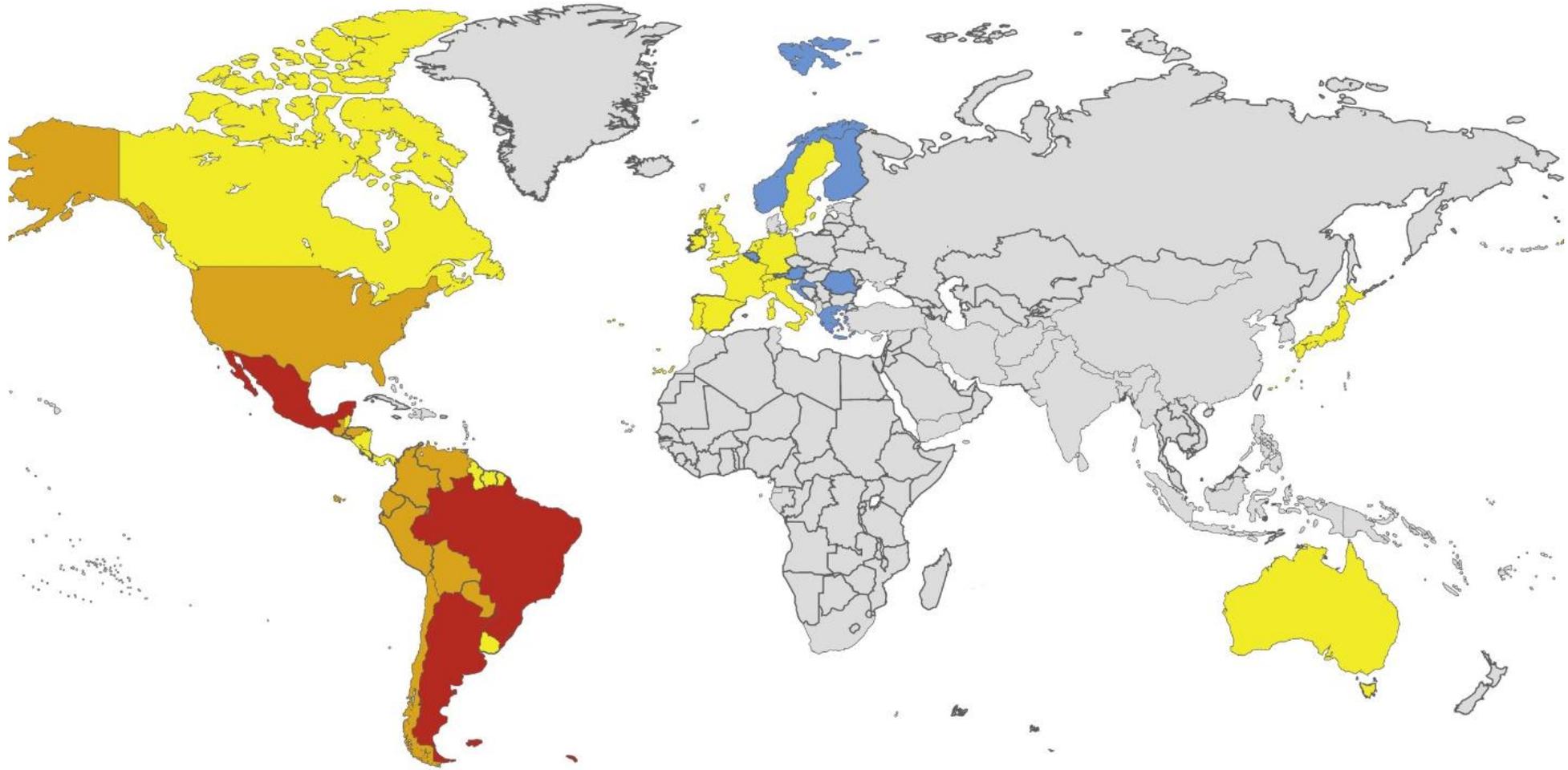


## Trypanosoma cruzi



- Epidemiology: approximately 8 million globally & >300,000 in US
- Other routes of transmission: blood transfusion, organ transplant, in utero vertical transmission (congenital), consumption of contaminated food or drink

# Global distribution of cases of chagas disease, based on official estimates, 2006–2010



Estimated number of *T. cruzi*-infected cases



Trends in Parasitology

# Recommendations for Screening and Diagnosis of Chagas Disease in the United States

Colin J. Forsyth,<sup>1,○</sup> Jennifer Manne-Goehler,<sup>2,○</sup> Caryn Bern,<sup>3</sup> Jeffrey Whitman,<sup>4</sup> Natasha S. Hochberg,<sup>5,6,7</sup> Morven Edwards,<sup>8</sup> Rachel Marcus,<sup>9,10</sup> Norman L. Beatty,<sup>11</sup> Yagahira E. Castro-Sesquen,<sup>12</sup> Christina Coyle,<sup>13</sup> Paula Stigler Granados,<sup>14</sup> Davidson Hamer,<sup>5,15,○</sup> James H. Maguire,<sup>2</sup> Robert H. Gilman,<sup>12</sup> and Sheba Meymandi<sup>16</sup>; US Chagas Diagnostic Working Group

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**Background.** Chagas disease affects an estimated 326 000–347 000 people in the United States and is severely underdiagnosed. Lack of awareness and clarity regarding screening and diagnosis is a key barrier. This article provides straightforward recommendations, with the goal of simplifying identification and testing of people at risk for US healthcare providers.

**Methods.** A multidisciplinary working group of clinicians and researchers with expertise in Chagas disease agreed on 6 main questions, and developed recommendations based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology, after reviewing the relevant literature on Chagas disease in the United States.

**Results.** Individuals who were born or resided for prolonged time periods in endemic countries of Mexico and Central and South America should be tested for *Trypanosoma cruzi* infection, and family members of people who test positive should be screened. Women of childbearing age with risk factors and infants born to seropositive mothers deserve special consideration due to the risk of vertical transmission. Diagnostic testing for chronic *T. cruzi* infection should be conducted using 2 distinct assays.

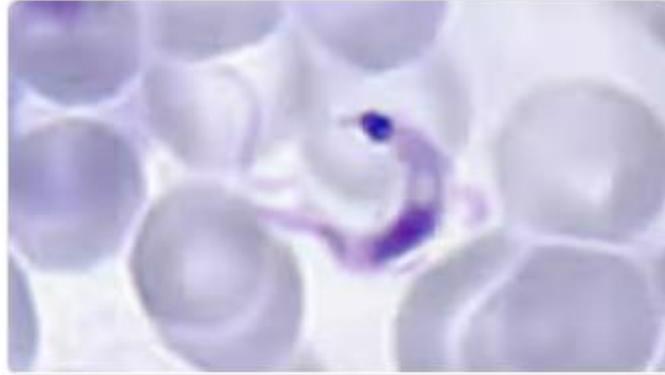
**Conclusions.** Increasing provider-directed screening for *T. cruzi* infection is key to addressing this neglected public health challenge in the United States.

**Keywords.** Chagas disease; *Trypanosoma cruzi*; diagnosis; neglected diseases.

# Diagnostics

## Acute infection:

- microscopy
- PCR
- xenodiagnosis



*Trypanosoma cruzi* parasite (trypomastigote) in a thin blood smear. Credit: DPDx

## Chronic infection:

### Diagnosing Chronic Chagas Disease:

- For chronic Chagas disease, healthcare providers detect antibodies against the parasite using serologic tests.
- Testing protocol:
  - No single test is sufficiently sensitive and specific for diagnosis.
  - Use two or more tests that detect antibodies to different antigens.
  - Common techniques include enzyme-linked immunosorbent assay (ELISA) and immunofluorescent antibody test (IFA).
- Assessing the patient's history for infection risks is also helpful.



Chagas Disease

EXPLORE TOPICS ▾

# Question #1

At your center, who do you screen for Chagas?

- A. All heart transplant candidates
- B. All SOT candidates
- C. All heart transplant candidates with epidemiologic risk
- D. All SOT candidates with epidemiologic risk

# OHSU screening

## **Kidney, liver and heart candidates**

- Screening for Chagas should be performed in all transplant candidates who were born or resided  $\geq$  6 months in Mexico, Central America or South America

## **Living donor (kidney) candidates**

- Screening for Chagas should be performed in all transplant candidates who were born or resided  $\geq$  6 months in Mexico, Central America or South America

Screening serology: two tests based on different antigens or techniques (confirmatory serology)

# From our case patient

(ABNORMAL) \_Miscellaneous Referral Test 1 (11/09/2015 5:10 AM PST)

Component	Value	Ref Range	Test Method
Referral Test 1	SEE NOTE (A)		

Comment:

Test name                      Result Flag Units    RefIntvl

-----  
 Trypanosoma cruzi Antibody, IgG  
    4.30 H                      IV <=1.10

INTERPRETIVE INFORMATION: Trypanosoma cruzi Ab, IgG  
 1.00 IV or less.....Negative - No significant level of  
    Trypanosoma cruzi IgG antibody detected.  
 1.01-1.10 IV.....Equivocal - Questionable presence of  
    Trypanosoma cruzi IgG antibody detected.  
    Repeat testing in 10-14 days may be helpful.  
 1.11 IV or greater...Positive - IgG antibodies to Trypanosoma  
    cruzi detected, which may suggest current  
    or past infection.

This assay should not be used for blood donor screening or associated re-entry protocols, or for screening Human Cell and Cellular Tissue-Based Products (HCT/Ps).

Performed by ARUP Laboratories,  
 500 Chipeta way, SLC,UT 84108 800-522-2787  
 www.aruplab.com, Jerry W. Hussong, MD - Lab. Director



1-800-533-1710

**CHAGS**

Trypanosoma cruzi Total Antibody, Enzyme-Linked Immunosorbent Assay, Serum

Patient ID [REDACTED]	Patient Name [REDACTED]	Birth Date [REDACTED]	Sex M	Age 56
Order Number [REDACTED]	Client Order Number [REDACTED]	Ordering Physician [REDACTED]	Report Notes	
Account Information C7006531 Oregon Hlth Sci Univ L471		Collected 24 May 2024 15:28		

T. cruzi Total Ab, EIA, S



**Reactive**

Abn

Antibodies to Trypanosoma cruzi (Chagas disease) detected. Result is not diagnostic. Supplemental testing by a second, different T. cruzi serologic assay is recommended.

SDL

Reference Value  
Negative

Received: 30 May 2024 12:35

Reported: 03 Jun 2024 10:52

# *Trypanosoma cruzi* – acute and chronic infection

- Acute phase (8-12 weeks, ~ 1-2 weeks after exposure):
  - Most are asymptomatic or have mild, nonspecific symptoms (malaise, fever, hepatosplenomegaly)
  - May see Romaña sign or chagoma at site of inoculation
- Chronic phase (indefinite, in the absence of treatment):
  - Indeterminate form (70-80%)
    - No signs/symptoms of disease, diagnosis by serology, smear negative, PCR variably positive, normal EKG
  - Determinate forms (20-30%)
    - Cardiomyopathy (after 5-30 years of latency)
    - Gastrointestinal disease



roughly 1.9-7% annual progression

Chronic Chagas cardiomyopathy (CC) = serologic + clinical diagnosis:

Positive serology with confirmatory testing

Conduction abnormalities & arrhythmias +/- LV dysfunction, ventricular aneurysm or intracavitary thrombus

Exclusion of ischemic heart disease

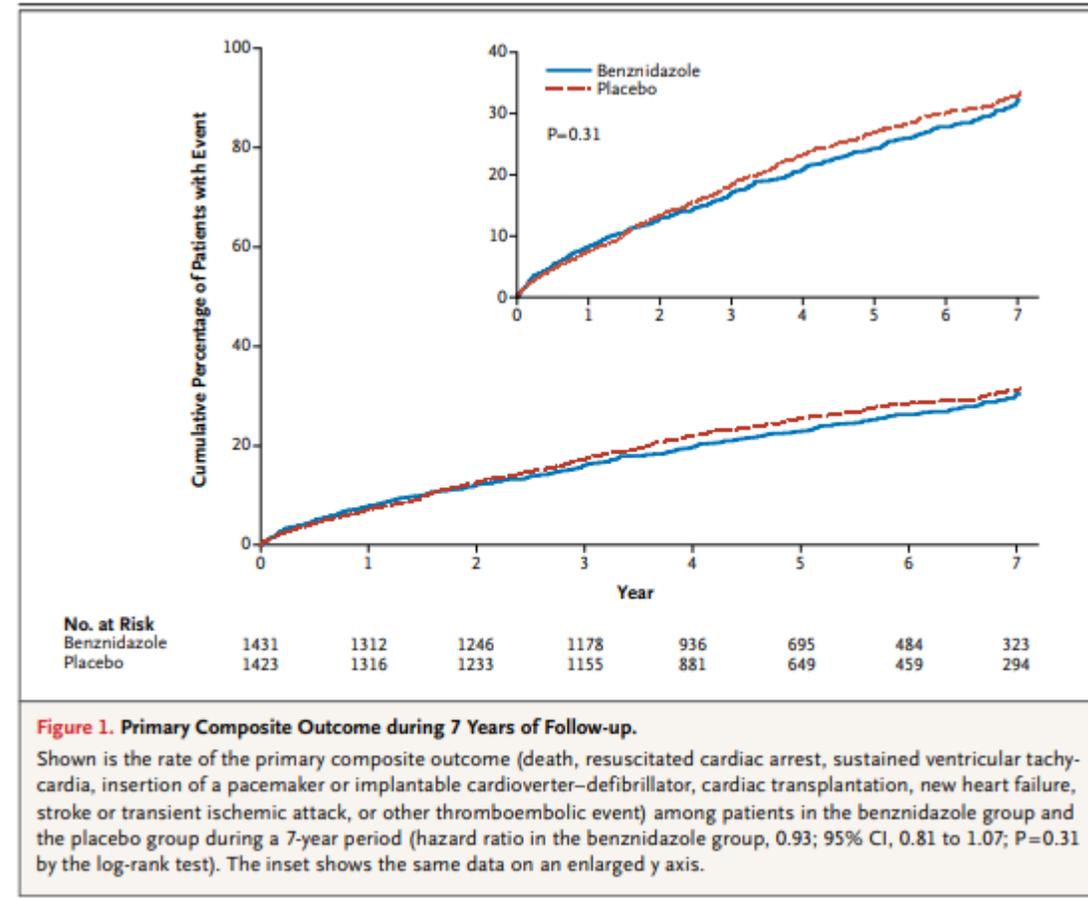
# *T cruzi* – treatment

- Indeterminate phase
  - Age < 50, treatment advised (strong recommendation for those  $\leq 18$  years of age, weak recommendation in adults; ***weak quality of evidence***)
  - Women who wish to become pregnancy, treatment advised prior to conception
  - Monitor for development of cardiac or gastrointestinal dysfunction

\*at risk for transmitting the parasite via any route, including SOT

# *T. cruzi* – treatment

- Acute/congenital infection → trypanocidal therapy (benznidazole or nifurtimox) = parasitologic cure in 60-85%\*
  - AAP: Treatment for all cases of acute, congenital, or “early chronic” infection in children (< 18 yrs)
- \*measured by negative seroconversion
- Chronic phase, established cardiomyopathy – no benefit to trypanocidal therapy
  - Morillo CA, et al. Randomized trial of benznidazole for chronic Chagas’ cardiomyopathy. *NEJM* 2015 (BENEFIT Trial)



- Treatment of choice for refractory CCC = transplantation (3<sup>rd</sup> most common indication for cardiac transplantation in South America)

# Outcomes of heart transplant for CCC

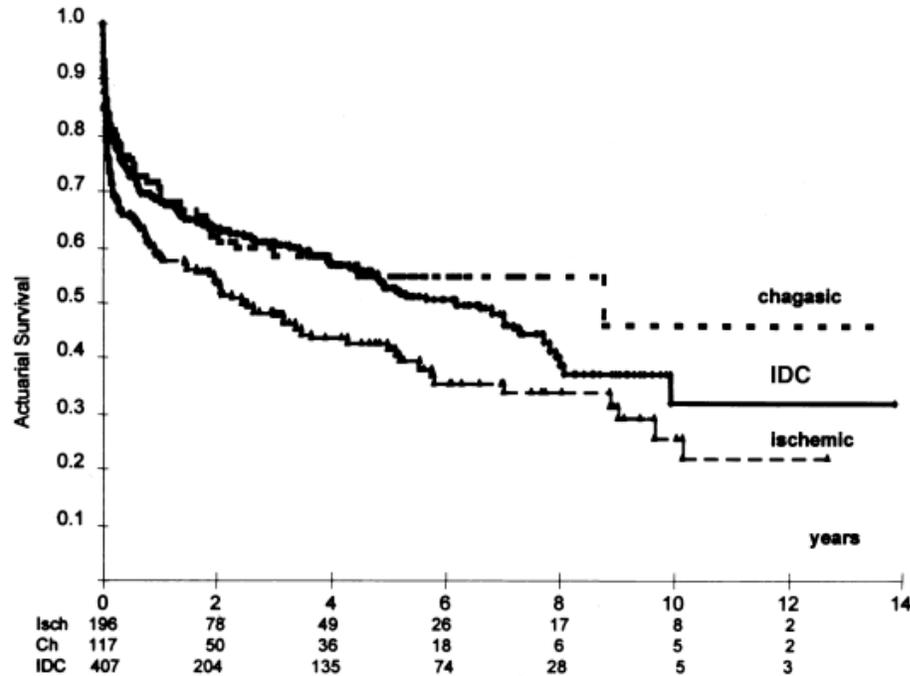
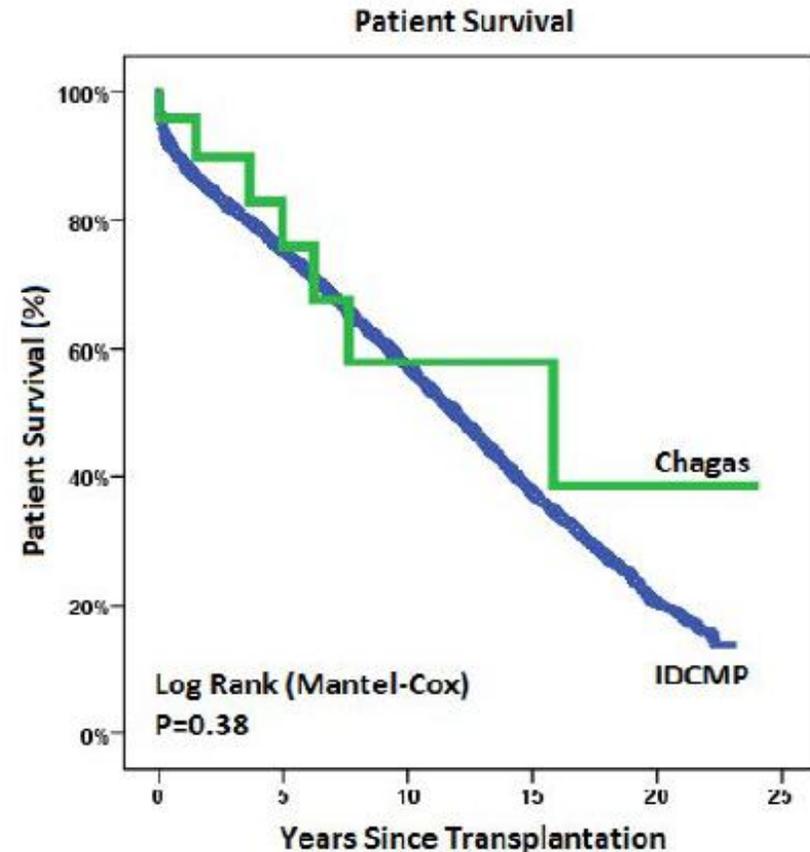


Fig 1. Comparison of estimated survival using the Kaplan-Meier method after primary heart transplantation for the treatment of ischemic (Ischemic), idiopathic dilated cardiomyopathy (IDC), and chagasic etiology (chagasic) ( $p < 0.027$ ).

Bocchi EA and Fiorelli A. The paradox of survival results after heart transplantation for cardiomyopathy caused by *Trypanosoma cruzi*. *Ann Thorac Surg* 2001



Benatti RD, et al. The paradox of survival results after heart transplantation for cardiomyopathy caused by *Trypanosoma cruzi*. *Clin Transplant* 2018

# Reactivation of Chagas disease among heart transplant recipients in the United States, 2012-2016

Elizabeth B. Gray<sup>1</sup>, Ricardo M. La Hoz<sup>2</sup>, Jaime S. Green<sup>3</sup>, Holenarasipur R. Vikram<sup>4</sup>, Theresa Benedict<sup>1</sup>, Hilda Rivera<sup>1</sup>, and Susan P. Montgomery<sup>1</sup>

31 patients with Chagas disease, transplanted in US 2012-2016

- 14/30 from El Salvador, 7 from Mexico, 4 from Honduras
- Transplants in CA (10), NY (4), DC (2), FL (2), NJ (2), TX (2), VA (2), AZ (1), MD (1), MA (1), MN (1), NC (1), UT (1), WI (1)
- Preemptive monitoring strategy with Chagas PCR
  - 19 (61%) developed laboratory evidence of reactivation\* at median 3 weeks (range <1-89 weeks) post-transplant, 18/19 with PCR detected before clinical reactivation
  - 19 treated with benznidazole
  - All 19 alive at follow-up (median 60 weeks, range 11-172 weeks)

\*2 sequential PCRs with signal crossing threshold for MNC & TCZ genes, with decreasing Ct values

# Chagas (indeterminate) in transplant

- Risk for recipient reactivation
  - Highest risk in Chagas+ heart transplant (20-90%)
  - Lower risk in Chagas+ non-heart transplant
  - Higher “net state of immunosuppression” is associated with higher risk for reactivation
- Chagas disease clinical presentation in transplant recipients: myocarditis, acute febrile illness, hepatosplenomegaly, painful skin nodules, inflammatory panniculitis, CNS infection

## Heart Transplantation for Chagas Cardiomyopathy

Maria da Consolação Moreira<sup>1D</sup>, Fabio Morato Castilho,<sup>2D</sup> Renato Braulio,<sup>3D</sup> Guilherme Ferraz Messina de Pádua Andrade,<sup>4D</sup> José Renan da Cunha Melo<sup>5D</sup>

Universidade Federal de Minas Gerais (UFMG), Minas Gerais, MG – Brazil.

International Journal of Cardiovascular Sciences. 2020; 33(6):697-704

**Table 1 – Clinical and laboratory monitoring of *T.cruzi* infection reactivation after heart transplantation disease and etiological treatment**

### Procedure

#### Before transplantation

- Serological tests for Chagas disease for the donor
- Serological tests for Chagas disease for the potential recipient with some possibility of Chagas cardiomyopathy

#### After transplantation

- Periodic clinic visits with attention to signs/symptoms of reactivation, including ECG and Echocardiogram
- Routine blood *T.cruzi* test (smear, blood culture) for diagnosis of infection reactivation
- Routine blood test for *T.cruzi* by PCR if available
- Routine periodic endomyocardial biopsies, with *T.cruzi* search (histology, immunohistochemistry, and PCR analysis)
- Search of *T.cruzi* in tissues (skin, bone marrow, among others) in a suspicion of *T.cruzi* infection

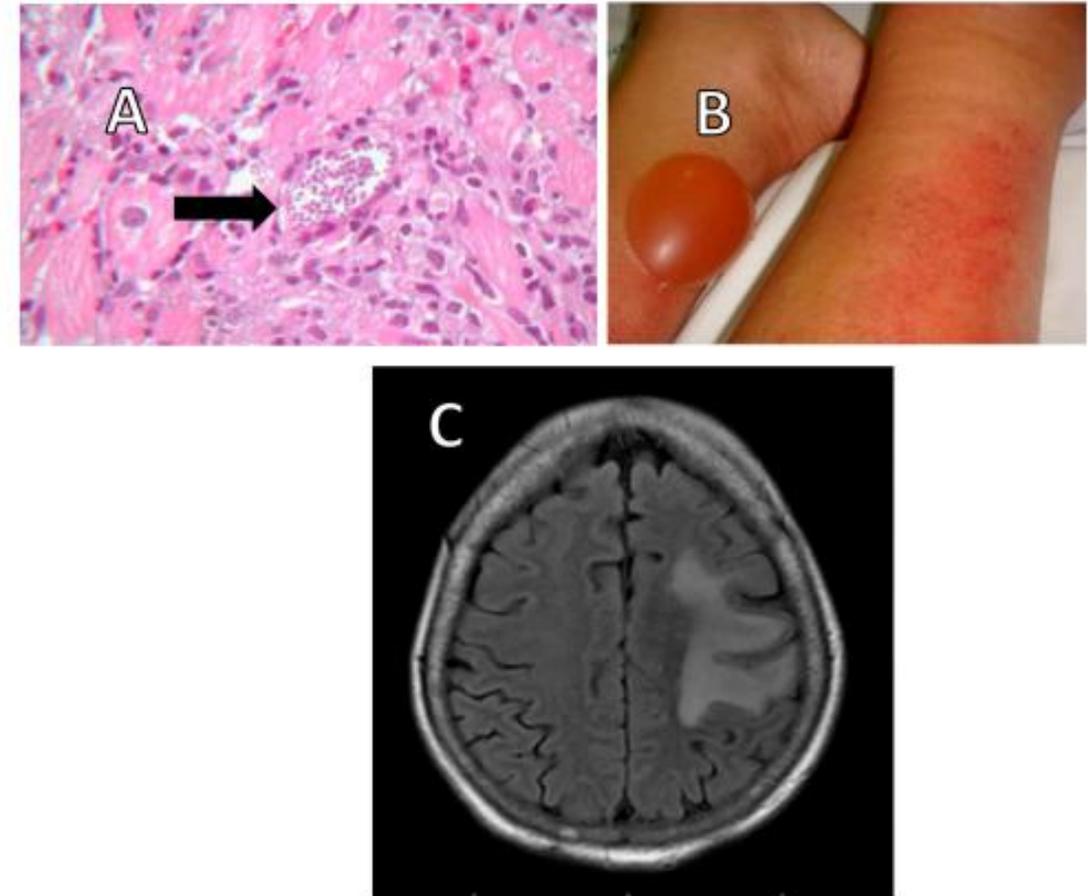
#### Frequency of procedures after transplantation

- First month: weekly
- Second month: every two weeks
- Third to sixth month: monthly
- Seventh to 12th month: every 3 months
- After 12 months: every six months

#### Etiological treatment of reactivation

- Benznidazole 5mg/Kg/day for 60 days

Adapted from references <sup>2,5</sup>, and <sup>26</sup>.



**Figure 1 – Illustration of Chagas disease reactivation in the heart (A), skin (B), and brain (C) in chagasic patients submitted to HT.**

*A: Endomyocardial biopsy fragment showing myocarditis and a nest of amastigotes in the transplanted heart (hematoxylin-eosin staining). B: Bullous skin lesions and dermatitis in the legs. The bubble fluid analysis showed trypomastigote forms. C: Expansive lesion in the brain as shown by magnetic resonance imaging. A stereotaxic brain biopsy demonstrated nests of amastigotes upon hematoxylin-eosin staining and immunohistochemistry for *T. cruzi* and confirmed the diagnosis (not shown) (Authors file).*

# Interventions to reduce impact of *T cruzi* reactivation in SOT recipients

1. Screen candidates with epidemiological risk factors for *T cruzi* infection
2. Monitor chronically infected patients with PCR after transplant
3. Preemptive treatment for those with positive PCR results and decreasing Ct on serial testing



# Our protocol

## CHAGAS

### **\*\*Notifications that need to happen upon transplant (Send via email)**

- Transplant ID Service Attending (cc Strassfeld)
- Nicole Tate (Supervisor, Specimen Processing)
- Dr. Xuan Qin (Microscopy/Pathology)
- Dr. Luke Streich, Dr. Brinkerhoff, Dr. Kristina Wakeman (CV Pathology)

\*\*HMW will send. If HMW on vacation, RN calling in patient to send notification

### **Immunosuppression**

- No induction at time of transplant
- 1500 MMF in OR
- Start at 1000 BID MMF

### **Surveillance/Taper Schedule**

**PCRs should be drawn as early as possible in the week, as CDC will not accept specimens on weekends or holidays**

Time	Surveillance	Prednisone Dose
Day 0-1		Solumedrol 500 mg iv pre- and intraop, then 125 mg q 8 hrs (3-5 doses)
Day 2		60/60
Day 3		50/50
Day 4		40/40
Day 5		70
Day 6		60
Week 1	Chagas PCR, Thick and thin blood smears	50
Day 8-13		40
Day 14 (Week 2)	EMB, Thick and thin blood smears and Chagas PCR	40
Day 15-20		35
Day 21 (Week 3)	EMB, Thick and thin blood smears and Chagas PCR	
Day 22-27		30
Day 28 Week 4	EMB, Thick and thin blood smears and Chagas PCR	Drop to 25 if bx ok

Week 5	Thick and thin blood smears and Chagas PCR	25
Week 6	EMB, Thick and thin blood smears and Chagas PCR	Drop to 20 if bx ok
Week 7	Thick and thin blood smears and Chagas PCR	20
Week 8	EMB, Thick and thin blood smears and Chagas PCR	Drop to 15 if bx ok
Week 9	Thick and thin blood smears and Chagas PCR	15
Week 10	EMB, Thick and thin blood smears and Chagas PCR	Drop to 10 if bx ok
Week 11	Thick and thin blood smears and Chagas PCR	10
Week 12	EMB, Thick and thin blood smears and Chagas PCR	Drop to 5 if bx ok
Week 14	EMB, Thick and thin blood smears and Chagas PCR	Drop to 2.5 if bx ok
Week 16 (Month 4)	EMB, Thick and thin blood smears and Chagas PCR	Stop Pred if bx ok
Week 18	Thick and thin blood smears and Chagas PCR	
Week 20 (Month 5)	EMB, Thick and thin blood smears and Chagas PCR	
Week 22	Thick and thin blood smears and Chagas PCR	
Week 24 (Month 6)	EMB, Thick and thin blood smears and Chagas PCR	Move to quarterly at month 6
Month 9	EMB, Thick and thin blood smears and Chagas PCR	
Month 12	EMB, Thick and thin blood smears and Chagas PCR	
Month 15	Thick and thin blood smears and Chagas PCR	
Month 18	EMB, Thick and thin blood smears and Chagas PCR	

### **\*\*Orders**

#### **Parasites, Blood (Malaria, Non-Mal) LAB00204**

Under comments: Chagas patient thick and thin blood smears

#### **Chagas PCR to CDC**

Lab Other LAB00906- Use smartphrase CHAGASPCR to populate comments (nurses and APPs all are users)

Notify Dr. Strasfeld and HMW the day prior to Chagas PCR draw (to coordinate with CDC and OSPHL)

Notify Dr. Qin AND CV Pathology team to be aware of incoming specimens

### **\*\* See next section for details**

# Patient update

- Transplant on █/█/24
  - Induction basiliximab
  - Required placement of RVAD, AKI (resolved) requiring RRT, ischemic colitis with Klebsiella & Citrobacter bacteremia
- Weekly Chagas PCR & smear (█ →)
- Chagas PCR positive █, █ (Ct 28.43/27.98 -> 25.93/26.86) → benznidazole (150 mg BID) begun █
- █ & subsequent: Chagas PCR negative
- Nausea/vomiting, headache, tingling sensation fingers, transient facial numbness → benznidazole held 8/29
- Headache and nausea management
- Benznidazole resumed █ (completed 8 weeks of therapy)
- █ visit: hand/foot tingling & heel pain (→ resolved)
- No rejection to date
- Prednisone discontinued █/█/24
- On tacrolimus & sirolimus (previously MMF)
- Subsequent Chagas PCR undetected

# A case I'm working on

- [REDACTED] with positive T cruzi screening antibody, performed in context of evaluation for 2<sup>nd</sup> kidney transplant
  - Hemagen EIA POSITIVE (1.2, at cutoff), Labcorp
- First transplant in 2018, for glomerulonephritis → allograft rejection (high-dose steroids in 2022)
- New diagnosis heart failure in [REDACTED] 2025, TTE 9/11 with EFT 35% and severe left chamber involvement, etc. Angiogram without CAD.
  - ? Chagas cardiomyopathy
- 2<sup>nd</sup> confirmatory Chagas serology obtained
  - Roche cobas Elecsys NEGATIVE, Eurofins Viracor

# Chagas testing options

Test name • Lab(s)	Methodology/target(s)	Diagnostic vs donor screening
<b>Abbott Alinity s Chagas</b>	<ul style="list-style-type: none"> <li>• Chemiluminescent microparticle immunoassay (CMIA)</li> <li>• T cruzi recombinant antigens (FP10, FP6, FP3, TcF)</li> </ul>	Donor screening
<b>Roche cobas Elecsys Chagas</b>	<ul style="list-style-type: none"> <li>• Electrochemiluminescent assay (ECLIA)</li> <li>• T cruzi recombinant antigens derived from FCaBP, FRA and Cruzipain</li> </ul>	Donor screening
• Eurofins Viracor, etc.		
<b>Abbott ESA Chagas</b>	<ul style="list-style-type: none"> <li>• Nitrocellulose strip confirmatory assay</li> <li>• T cruzi recombinant antigens (FP10, FP6, FP3, TcF)</li> </ul>	Supplemental test in donors who test positive with first-line assays, not approved for individual diagnosis
<b>Hemagen Chagas' Kit</b>	<ul style="list-style-type: none"> <li>• EIA</li> <li>• Purified antigens from cultured T cruzi</li> </ul>	Diagnostic
• ARUP, LabCorp, UCSF, NYS PHL, etc.		
<b>Chagatest ELISA recombinant v 3.0, Wiener Laboratories</b>	<ul style="list-style-type: none"> <li>• EIA</li> <li>• Recombinant epimastigote and trypomastigote proteins</li> </ul>	Diagnostic
• ARUP, Kephera, LabCorp, Mayo, Quest, UCSF, NYS PHL, etc.		
<b>Chagas Detect Plus Rapid Test (RDT), InBios</b>	<ul style="list-style-type: none"> <li>• Immunochromatographic strip assay</li> <li>• ITC8.2, recombinant multi-epitope fusion antigen</li> </ul>	Diagnostic
• Mayo, Quest, UCSF, NYS PHL		
<b>Chagas serology - TESA immunoblot</b>	<ul style="list-style-type: none"> <li>• Western</li> <li>• T cruzi trypomastigote excretory secretory antigens</li> </ul>	Diagnostic, confirmatory
• CDC, Kephera		

Gratitude to Sue Montgomery, CDC parasitology branch, for collaboration on this table

# A call from your transplant surgeon

- Local donor, kidney offer
- Donor *T cruzi* antibody positive
  
- Can we proceed??

## 32 organ transplant recipients from 14 seropositive donors in the United States, 2001-2011

- Transmission confirmed in 9 recipients from 6 donors
    - 3/4 (75%) heart recipients
    - 2/10 (20%) liver recipients
    - 2/15 (13%) kidney recipients
  - 13 recipients had no or incomplete monitoring
    - transmission in 5/13
    - 4/5 had symptomatic Chagas disease
    - 4 died (1 death directly related to Chagas disease)
  - 19 recipients had partial or complete monitoring
    - transmission in 4/19, no cases of symptomatic disease
- Liver & kidney transplant from *T cruzi* seropositive donors may be feasible with recommended monitoring and prompt treatment (benznidazole).

Huprikar S, ... Montgomery S. Donor-derived *Trypanosoma cruzi* infection in solid organ recipients in the United States, 2001-2011. *Am J Transplant* 2013.

## Ten years of donor-derived disease: A report of the disease transmission advisory committee

Daniel R. Kaul<sup>1</sup>  | Gabe Vece<sup>2</sup>  | Emily Blumberg<sup>3</sup> | Ricardo M. La Hoz<sup>4</sup>  | Michael G. Ison<sup>5</sup>  | Michael Green<sup>6</sup> | Timothy Pruett<sup>7</sup>  | Michael A. Nalesnik<sup>8</sup> | Susan M. Tlusty<sup>2</sup> | Amber R. Wilk<sup>2</sup>  | Cameron R. Wolfe<sup>9</sup> | Marian G. Michaels<sup>6</sup> 

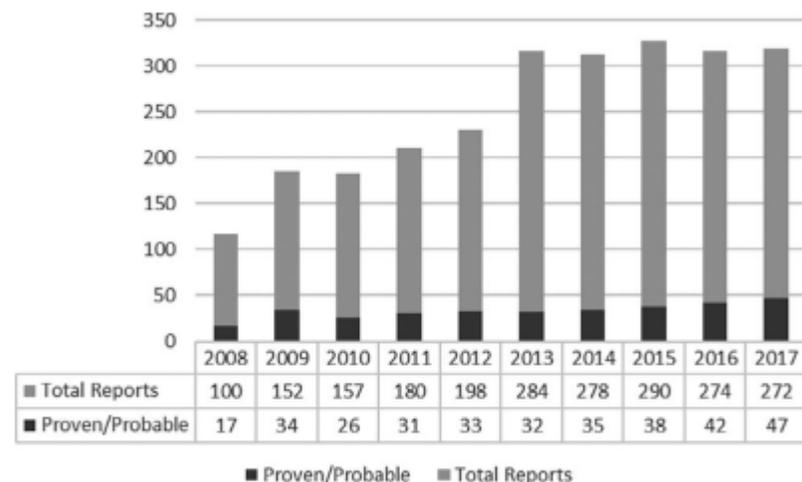
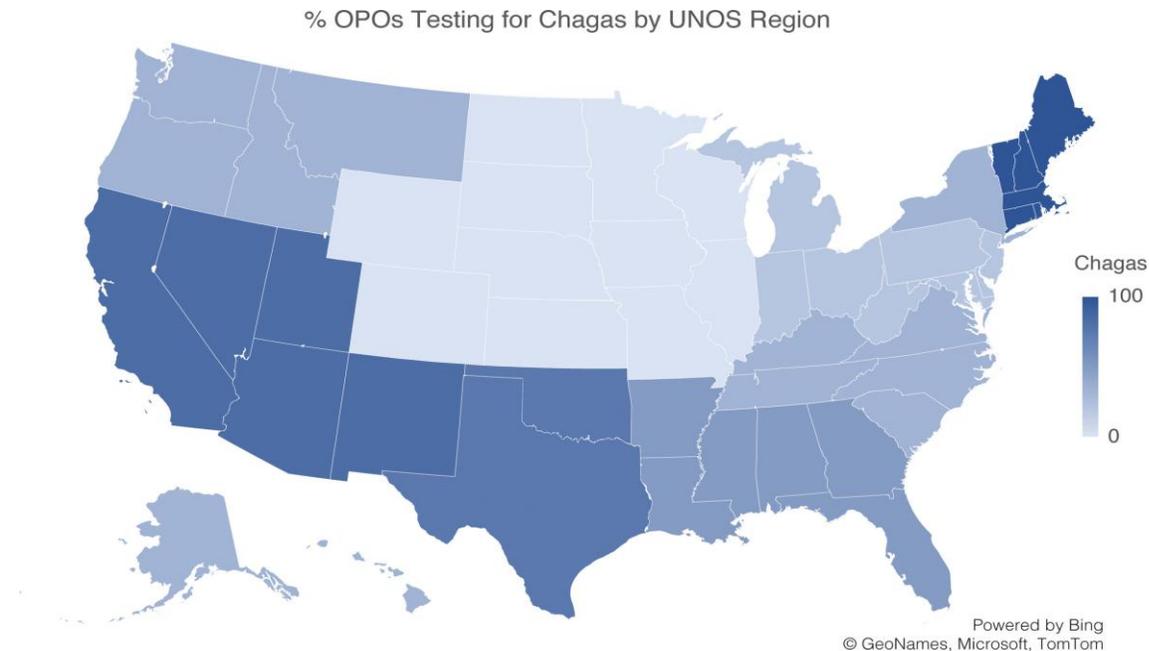


TABLE 5 (Continued)

Type	Total Reports	Total P/P Donors	Total Recipients from P/P Donors	Recipients with Transmission ÷ Exposed Recipients								Recipients with P/P Transmission ÷ Recipients from P/P Donors	Graft Loss	Total Transmission-Related Deaths ÷ Recipients with P/P Transmission	Recipients with P/P Transmission per 10,000 Transplanted Recipients During 2012-2017	Transmission-Related Deaths per 10,000 Transplanted Recipients During 2012-2017
				kidney	pancreas	kidney/panc	liver	heart	lung	heart/lung	intestine					
Total Fungal	237	35	115	18/52	0/0	0/3	11/30	6/13	15/20	0/0	0/0	41.7%	9	14.6%	2.67	0.39
Mycobacteria																
Tuberculosis	63	3	12	0/4	0/0	0/1	0/3	0/2	3/3	0/0	0/0	25.0%	0	0.0%	0.17	0.00
Parasite																
Strongyloides	52	10	29	3/12	0/0	3/3	5/9	1/3	3/3	0/1	1/1	44.8%	1	30.8%	0.72	0.22
Toxoplasmosis	18	8	30	2/12	0/1	0/1	2/7	4/6	1/3	0/0	0/0	30.0%	0	55.6%	0.50	0.28
Trypanosomiasis	7	1	5	0/2	0/1	0/0	1/1	0/0	0/1	0/0	0/0	20.0%	0	0.0%	0.06	0.00
Other	20	4	11	4/4	0/0	0/0	2/3	1/2	2/2	0/0	0/0	81.8%	2	22.2%	0.50	0.11
Total Parasite	97	23	75	9/30	0/2	3/4	10/20	6/11	6/9	0/1	1/1	42.7%	3	34.4%	1.78	0.61

## Testing deceased organ donors for infections: An organ procurement organization survey

Nicole M. Theodoropoulos<sup>1</sup> | Melissa A. Greenwald<sup>2</sup> | Peter Chin-Hong<sup>3</sup> |  
Michael G. Ison<sup>4,5,6</sup>



Seventeen (37%) OPOs tested for Chagas disease (*Trypanosoma cruzi*); seven tested all donors, while 10 tested based on travel history or nation of birth

*Notice of OPTN Guidance Change***Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations during Deceased and Living Donor Evaluation**

Sponsoring Committee:

Ad Hoc Disease Transmission Advisory

Public Comment:

July 27, 2023- September 19, 2023

Board Approved:

December 4, 2023

Effective Date:

January 10, 2024

New screening policy approved in 2024, implemented as of October 1, 2025

**Who Should Be Screened****Living and Deceased Donors**

Deceased donors who were born in a country currently classified as endemic for Chagas disease by the CDC must be screened according to OPTN Policy 2.9 pending implementation of *Improve Deceased Donor Evaluation for Endemic Diseases*<sup>220</sup> and is recommended until then. Screening is recommended for living donors born in a country currently classified as endemic for Chagas CDC by the CDC as well.

Screening should also be considered for living and deceased donors in the following circumstances:

- Children of women born in endemic regions if their birth mother's serology is positive or unknown
- Donors who have resided in an endemic region for more than three months
- Donors who received a blood transfusion in endemic regions and those who have a previous diagnosis of Chagas disease
- Symptomatic donors who have chronic infection and may present with cardiomyopathy, cardiac conduction abnormalities, megaesophagus, megacolon

Countries currently classified as endemic for Chagas disease by the CDC:

ArgentinaGuyanaBelizeHondurasBoliviaMexicoBrazilNicaraguaChilePanamaColombiaParaguayCosta RicaPeruEcuadorSurinameEl SalvadorUruguayFrench GuianaVenezuelaGuatemala

# Chagas testing options (circa 2023)

Table 2: Serological Tests Available for *T. cruzi* Infection

<u>Test name, Manufacturer</u>	<u>Target Antigen</u>	<u>Test Format</u>	<u>Sample Type</u>	<u>FDA-cleared/approved use</u>
<u>Abbott Prism Chagas (T. cruzi [E. coli, recombinant] antigen)<sup>221</sup>, Abbott Laboratories, Abbott Park, IL</u>	<u>T. cruzi recombinant antigens (FP10, FP6, FP3, TcF)</u>	<u>ChLIA<sup>222</sup></u>	<u>Serum/plasma</u>	<u>Donor screening</u>
<u>ORTHO T. cruzi ELISA Test System Ortho-Clinical Diagnostics, Inc. Raritan, NJ</u>	<u>Whole cell lysate</u>	<u>EIA<sup>223</sup></u>	<u>Serum/plasma</u>	<u>Donor screening, individual diagnostics</u>
<u>Chagatest ELISA recombinant v.3.0 <sup>224</sup>Wiener Laboratories S.A.I.C., Rosario, Argentina</u>	<u>Recombinant epimastigote and trypomastigote Proteins</u>	<u>EIA</u>	<u>Serum/plasma</u>	<u>Diagnosis, NOT donor screening test</u>
<u>Hemagen Chagas' Kit, Hemagen Diagnostics, Inc., Columbia, MD</u>	<u>Purified antigens from cultured T. cruzi</u>	<u>EIA</u>	<u>Serum</u>	<u>Diagnosis, NOT donor screening test</u>
<u>Abbott ESA Chagas Assay, Abbott Laboratories, Abbott Park, IL</u>	<u>T. cruzi recombinant antigens (FP10, FP6, FP3, TcF)</u>	<u>Enzyme Strip Assay</u>	<u>Serum/plasma</u>	<u>Supplemental test in donors who test positive with first-line assays, not approved for individual diagnosis</u>

\*Serologic testing may also be available through the CDC

- “For access to testing of transplant recipients at risk for reactivation of Chagas, contact the CDC Division of Parasitic Diseases and Malaria at 404-718-4745 (business hours) or 770-488-7100 (nights and weekends) or via e-mail at [parasites@CDC.gov](mailto:parasites@CDC.gov).”

# Chagas testing options - updated

Test name	Methodology/target(s)	Diagnostic vs donor screening
<ul style="list-style-type: none"> <li>• Lab(s)</li> </ul>		
<b>Abbott Alinity s Chagas</b>	<ul style="list-style-type: none"> <li>• Chemiluminescent microparticle immunoassay (CMIA)</li> <li>• T cruzi recombinant antigens (FP10, FP6, FP3, TcF)</li> </ul>	Donor screening
<b>Roche cobas Elecsys Chagas</b>	<ul style="list-style-type: none"> <li>• Electrochemiluminescent assay (ECLIA)</li> <li>• T cruzi recombinant antigens derived from FCaBP, FRA and Cruzipain</li> </ul>	Donor screening
<ul style="list-style-type: none"> <li>• Eurofins Viracor, etc.</li> </ul>		
<b>Abbott ESA Chagas</b>	<ul style="list-style-type: none"> <li>• Nitrocellulose strip confirmatory assay</li> <li>• T cruzi recombinant antigens (FP10, FP6, FP3, TcF)</li> </ul>	Supplemental test in donors who test positive with first-line assays, not approved for individual diagnosis
<b>Hemagen Chagas' Kit</b>	<ul style="list-style-type: none"> <li>• EIA</li> <li>• Purified antigens from cultured T cruzi</li> </ul>	Diagnostic
<ul style="list-style-type: none"> <li>• ARUP, LabCorp, UCSF, NYS PHL, etc.</li> </ul>		
<b>Chagatest ELISA recombinant v 3.0, Wiener Laboratories</b>	<ul style="list-style-type: none"> <li>• EIA</li> <li>• Recombinant epimastigote and trypomastigote proteins</li> </ul>	Diagnostic
<ul style="list-style-type: none"> <li>• ARUP, Kephera, LabCorp, Mayo, Quest, UCSF, NYS PHL, etc.</li> </ul>		
<b>Chagas Detect Plus Rapid Test (RDT), InBios</b>	<ul style="list-style-type: none"> <li>• Immunochromatographic strip assay</li> <li>• ITC8.2, recombinant multi-epitope fusion antigen</li> </ul>	Diagnostic
<ul style="list-style-type: none"> <li>• Mayo, Quest, UCSF, NYS PHL</li> </ul>		
<b>Chagas serology - TESA immunoblot</b>	<ul style="list-style-type: none"> <li>• Western</li> <li>• T cruzi trypomastigote excretory secretory antigens</li> </ul>	Diagnostic, confirmatory
<ul style="list-style-type: none"> <li>• CDC, Kephera</li> </ul>		

Gratitude to Sue Montgomery, CDC parasitology branch, for collaboration on this table

# Donor-derived transmission: mitigation

- Screening of living donors & deceased donors with epidemiological risk
- Non-cardiac organs from *T cruzi* infected donors can be utilized after obtaining consent from the intended recipient
- PCR monitoring with preemptive treatment (after a single positive PCR) in the recipient

# Summary points

- The evolving epidemiology of *T cruzi* infection has implications for screening, and specifically for management of patients with anticipated immune suppression.
- Heart transplant is a viable approach for management of heart failure in patients with chronic Chagas cardiomyopathy, provided care includes consultation with experts and access to preemptive monitoring by PCR.
- Donor-derived Chagas disease has been reported. Current screening guidelines are designed to mitigate risk for donor-derived disease.