Global view of diagnostic testing for Chagas Disease

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Conventional methodology

- **Methodology and advantages**
  - Total and recombinant or synthetic antigens
  - Most used techniques: HAI, ELISA, IFAT.
  - Sensitivity
  - Specificity
  - Validated
  - Quantifiable results (titers)

- **Applications**
  - Clinical diagnosis
  - Blood, Serum, other fluids
  - Restricted to large urban centers with hospitals, equipped laboratories and trained human resources
  - Usually used for the evaluation and follow up of treatment
Conclusions Meeting Rio janeiro MSF 2007

Accelerate development of reliable rapid diagnostic tests to reinforce the diagnostic capacity in limited lab settings and simplify the algorithms and facilitate access to treatment

Accelerate development of new generation tests with high sensitivity and specificity for diagnosis of *Trypanosoma cruzi* infection, follow-up of patients after treatment and cure verification

Bolivia and Chile Example

**Bolivia**
- Use test Stat Pack CHEMBIO
- Confirmation in blood by HAI and IFAT
- Treatment
- Follow-up with conventional serology
- Price Stat Pack: more than $ USA 3 dollars

**Chile**
- Use test Dipstik INBIOS
- Confirmation in blood by IFAT and ELISA
- Treatment
- Follow-up with conventional serology
- Price INBIOS Dipstick $ USA 2 dollars
**Collection of blood in filter paper**

- Filter paper Whatman
- Fill-up of a standardized area
- Dry and send to Laboratory
- IgG stable in the paper, 4 °C for a year
- IgM stable only for 6 months

**Obtained Sample**

- Eluate
- Stable for 24 to 48 hours at 4°C
- Contains IgG and IgM
- Test using IFAT, ELISA and HAI
Recombinant antigens and / or Synthetic peptides utilized

**TRYPANOSOMA DETECT**
- Inbios
  - Tcf
  - SAPA
  - Peptide 30
  - Peptide 36
  - Kmp 11
  - Peptide 1

**STAT PAK**
- Chembio
  - B13
  - 1F8
  - H49/JL7

Comparison in the field Stat pack CHEMBIO vs conventional serology

<table>
<thead>
<tr>
<th>Stat Pak</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>80</td>
<td>7</td>
<td>87</td>
</tr>
<tr>
<td>Negative</td>
<td>2</td>
<td>699</td>
<td>701</td>
</tr>
<tr>
<td></td>
<td>82</td>
<td>706</td>
<td>788</td>
</tr>
</tbody>
</table>

Total Agreement: 98.8%, Disagreement: 1.2%
False Negative: 0.25%
False positive: 1.25%  
- Bolivia (Sucre: Municipios Padilla y Alcalá, 2009)
Comparison in the field Trypanosoma Dipstik INBIOS vs conventional serology

### CONVENTIONAL SEROLOGY

<table>
<thead>
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<th>Dipstik Inbios</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>82</td>
<td>14</td>
<td>96</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>692</td>
<td>692</td>
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### Proposal

**New algorithm?**

- Screening in the field with: INBIOS and Statpack.
- One sample of filter paper is sent to central laboratories.
- Treatment
- Follow-up with the screening test and blood collected in filter paper.
- Meantime a cure test is developed.
- Samples of sera and urine must be collected for a cure test evaluation.
**Algorithm for Blood Banks**

**LOW PREVALENCE AREAS**
- Screening with the conventional serology
- Patient counseling in positive cases
- Clinical management and treatment

**HIGH PREVALENCE AREAS**
- Screening with rapid test
- Discard of the positive patients
- Blood collection for rapid test of negative donors
- Testing with conventional serology

**Algorithm for Recent Chronic Chagas (1-15 years old)**

Screening with two rapid tests
- Patient counseling in positive cases
- Clinical management and treatment
- Evaluation of the cure with conventional serology obtained in filter paper
- URGENT NEED: DEVELOPMENT OF A CURE TEST
Algorithm for Chronic Chagas patients over 15 years old

Screening with two rapid tests
- Patient counseling in positive cases
- Clinical management and treatment
- Evaluation of the cure with conventional serology obtained in filter paper
- URGENT NEED: DEVELOPMENT OF A CURE TEST

Algorithm for Congenital Chagas disease

Maternal Screening with two rapid tests
- Maternal counseling in positive cases
- Counseling of the mother on the importance of the study in newborn at birth
- Screening of the child at birth
- Microhematocrit
- Rapid test confirmation in the baby
- Control with rapid test at 6 or 1 year old
- If positive: Clinical management and treatment
- Evaluation of the cure with conventional serology obtained in filter paper
- URGENT NEED: DEVELOPMENT OF CURE TEST
Policies to be implemented or strengthened

- The conclusions of the 2007 Meeting are still valid and must be completed.
- In the near future despite we have not yet the needed tools, we which need adapt all the possibilities to achieve full patient care.
- Primary care and the IEC component is very important.
- It is necessary to propose a policy for stable prices for diagnostic tests and drugs.

- Thank you