Development of an Ebola Rapid Diagnostic Test

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For the
VIRAL HEMORRHAGIC FEVER CONSORTIUM (vhfc.org)
Lassa fever program at Kenema Government Hospital

Important site for Lassa fever research by CDC and others

1970s and 1980s

Blood Diamonds civil conflict forces suspension of Lassa program

1993

May Chu, Dan Bausch, others refurbish Lassa Laboratory

2005

Establishment of recombinant Lassa ELISA diagnostics

2008

Introduction of ReLASV lateral flow immunoassays

2010
Ebola came to us

HOW?

WHEN?

Guinea

Gabon

Congo

DRC

1976-77

1994-96

2001-05

2007-08

2014

Slide Credit: Kristian Andersen (Sabeti Lab)
Leading Insights and Response

- **Established Ebola Diagnostics at Kenema**
  - Performing Surveillance in March and April
  - Immediately identifying first case in hospital

- **Sequenced Ebola Genomes**
  - Rapidly making data public for 99 Ebola genomes
  - Publication in *Science* 2014

- **Provided Clinical Data**
  - Rapidly making data public from 100 patients
  - Publication in *NEJM* 2014

- **Developed Rapid Diagnostic Test**
  - 15-minute Ebola diagnostic test
  - First RDT to obtain WHO and FDA approval

*Sources: france 24, reuters, abcnews*
## Quantitative reverse transcriptase polymerase chain reaction versus lateral flow immunoassay

<table>
<thead>
<tr>
<th>Assay</th>
<th>qPCR</th>
<th>LFI-RDT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample collection</td>
<td>Venipuncture, Skilled</td>
<td>Fingerstick, Minimal training</td>
</tr>
<tr>
<td>Time to result</td>
<td>1-5 days</td>
<td>15 minutes</td>
</tr>
<tr>
<td>Assay performance</td>
<td>Skilled</td>
<td>Minimal training</td>
</tr>
<tr>
<td>Laboratory requirements</td>
<td>Electrical power qPCR machine, centrifuge, etc., Skilled technicians</td>
<td>No power required, No laboratory equipment required, Minimal training</td>
</tr>
</tbody>
</table>
ReEBOV™ Rapid Test

Matt Boisen
Corgenix
Tulane
Biomedical Sciences Program

Lateral flow immunoassay

Corgenix

Erica Saphire
Zach Bornholdt
Luis Branco
Bob Cross
ReEBOV Antigen Rapid Test Kit (Corgenix)

WHO Emergency Use Authorization and Listing EUAL
February 20, 2015

FDA Emergency use authorization (EUA)
February 24, 2015
ReEBOV Rapid Test Timeline

Phase II SBIR funded

Gates/Allen funded

Field testing initiated

WHO EUAL

FDA EUA

May  June  July  Aug  Sept  Oct  Nov  Dec  Jan  Feb  Mar

2014  2015
Where does the money come from?

Robert Garry PI
James Robinson PI
Tulane

Kelly Pitts, PI
Corgenix

WORLD BANK
Christian Happi PI
Re Redeemers University (Lagos)

H3Africa

Partnerships for Enhanced Engagement in Research (PEER) Health
Donald Grant PI
Robert Garry sponsor
KGH Sierra Leone

Lina Moses PI
Tulane

Erica Saphire PI
Scripps
How do you get the product on the market?

The market for the product is:
- the Federal Government (stockpile)
- Foundations (ex. Gates Foundation)

What do we need to do?
- Convince the USG of the need for stockpiling
- Convince relatively wealthy countries or foundations to buy or subsidize the product.
Can we implement “orphan drug” incentives for biothreat/emerging pathogen MCMs?