



# CURRENT USG INVESTMENTS IN ZIKA VIRUS MEDICAL COUNTERMEASURES

October, 2016



# Diagnositics

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# HHS Zika Diagnostics Strategic Goals

- Expand testing capacity in public health/LRN and commercial laboratories.
- Advance the development of more specific and sensitive tests for use in the U.S. and elsewhere.
- Provide reagents (viruses, antigens, clinical samples) and reference panels for test development and validation.
- Develop high throughput assays to detect Zika virus in the blood supply.
- Define and communicate to developers the FDA regulatory pathways for Zika virus assays.



# NIAID Zika Diagnostics Research

- Goal: Development of rapid, specific, low-cost diagnostic tools
- Molecular tests
  - Multiplex PCR-based assays
  - On-chip assay for direct ZIKV RNA detection
  - Paper assays with CRISPR-based technology
  - Virome capture sequencing platform (VirCapSeq)

# BARDA Zika Diagnostic Activities

- Market research
- Rapid performance evaluation of early candidates
  - Collaboration with CDC
- Fund development of commercial assays via BAA
  - point-of-care and laboratory based serology assays for Zika virus
  - serologic assays to discriminate Zika, dengue and chikungunya virus infections
- Connect developers to flavivirus researchers
  - Collaboration with NIH
- Assemble specimens for test evaluation
- Identify role of diagnostics for vaccine trials

# Current Available Diagnostics for Zika

- CDC Developed Assays
  - TrioPlex Molecular Test (Zika, Dengue, Chikungunya)
  - Zika MAC-ELISA (IgM)
- BARDA-Enabled Commercial Tests
  - Laboratory Serology Tests
    - InBios International (IgM capture)
    - Diasorin, Inc. (IgM and IgG capture)
  - Point of Care Serology Tests
    - Chembio Diagnostic Systems
    - Orasure Technologies
  - Blood Screening Molecular Tests
    - Roche
    - Hologic
  - Sample Collection and Characterization

All assays operating under Emergency Use Authorization



# Zika Diagnostic Assays

Indication	Diagnostic Technology	Useful Period (Post Onset)	EUA/IND	BARDA Role
Identify persons with active Zika infection (active symptoms)	Molecular (PCR-like) tests	Up to 7 days	CDC and 6 commercial partners	Small Zika PCR positive validation panels (plasma)
Identify persons previously infected with Zika virus, particularly women infected during pregnancy.	Serologic/Antibody (IgM) tests	~3 days to >> 3months	CDC and 1 commercial partner	ARD funding, Serum panels
Ensure safety of the blood supply.	Molecular assays, high-throughput platforms	Active infection in asymptomatic individuals	2 commercial partners (IND)	ARD funding, validation panels

# BARDA Diagnostic Projects

	Serology Test name	Company	Status
Laboratory	Zika Detect™ IgM Capture ELISA	InBios International, Inc.	EUA issued Aug 17
	LIAISON Zika Virus IgM and IgG assays	Diasorin	Late stage development
POC	DPP® Zika IgM/IgG Assay	ChemBio Diagnostics, Inc.	Late stage development
	OraQuick® Zika Test	OraSure Technologies, Inc.	Mid-stage development

# Opportunities for FL Research Investments: Diagnostics

- Other serological assays (e.g. NS-1 based)
- Other multiplexed assays
- Subtractive or reductive diagnostics for flavivirus pre-exposed populations
  - Differentiate Zika from other flavivirus responses

# Vaccines

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# Vaccine Strategic Needs

- Protect at-risk population of pregnant women / women of child-bearing age
- General population protection and potential herd-immunity
- Travel-medicine or military deployment needs



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# Overview of Vaccine Platforms

Current Aim	Candidate Vaccine			
Evaluation of viable vaccine platforms and deployment to "at risk" population	<b>DNA Vaccine Candidate</b> <b>VRC</b>	<b>PIV</b> <i>ASPR, BARDA, Emergent</i>	<b>mRNA vaccine candidate</b> <i>VRC, GSK</i>	<b>mRNA</b> <i>ASPR, BARDA, Moderna</i>
Commercialization of Global, Durable Vaccine	<b>Live Attenuated Zika Chimera</b> <i>LID, Butantan</i>	<b>PIV</b> <i>WRAIR, NIAID, BARDA, Sanofi</i>	<b>PIV</b> <i>ASPR, BARDA, Takeda</i>	<b>PIV</b> <i>ASPR, BARDA, Butantan</i>
Research Understanding Only	<b>VSV Vecteded Vaccine</b> <i>NIAID, Harvard CoE</i>	<b>Chimera</b> <i>CDC</i>	<b>VLP</b> <i>CDC</i>	

\*Note: primary aim is based largely on time of availability of market data, this preliminary alignment does not preclude the ability of a candidate to achieve the other aims

\*\*Note: A vaccine designated as being for "research understanding only" indicates that a vaccine does not meet the necessary criteria for either set of aims

# Zika Virus Vaccine Landscape: September 7, 2016

Discovery and in vitro

Pre-clinical

Clinical

Technology/  
Platform

Recombinant  
or Subunit



Live  
Attenuated



Dengue/Zika  
Chimera

Whole  
Inactivated



Nucleic Acid



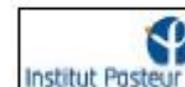
Viral Vector



VSV with  
Harvard



DNA-VRC



Other



# Opportunities for FL Research Investments: Vaccines

- Expanded Clinical Trial Network Sites for Vaccine Development



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# Therapeutics

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# Therapeutic Strategic Needs

- Treat infected pregnant women to reduce viral impact on developing fetus
- Treat individuals with residual infection for viral clearance from immune-privileged sites
- Treat moderately to severely ill patients
- Potential for non-vaccine afforded passive immunity for specialized needs



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# NIAID Biomedical Research Response: Therapeutics

- Developed Zika in vitro screening assay
  - 326 compounds with known anti-flavivirus activity tested to date
  - 29 compounds showed moderate to high activity
- Developed a mouse model for further testing
  - BCX4430 (RNA polymerase inhibitor) protected mice infected with Zika virus
  - Screened 8 compounds with 3 showing activity
- Screening approved-drug libraries (collaboration with NCATS and Gates Foundation)
- Identifying promising monoclonal antibodies

# Opportunities for FL Research Investments: Therapeutics

- Therapeutic approaches for viral clearance and treatment post infection



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# Other Efforts

- Development of novel toxicants and/or repellents with high safety profile
- Pathogen reduction technologies in blood products

# Additional Ideas for FL Research Investments

- Novel products and approaches to vector control
- Participate in clinical trial protocol for pathogen reduction in blood products

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# Current Florida-affiliated R&D Efforts for Zika

- NIAID Grant Supplement to J.G.Morris, University of Florida, study on Zika transmission



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