



BARDA Diagnostics & Medical Devices Overview

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Diagnosics & Medical Device (DMD) Division: Product Areas

Diagnosics

- Influenza Diagnosics
- Radiation Exposure Dx (Biodosimetry)
- Biothreat Agent Diagnosics
- Antimicrobial Resistance Diagnosics
- Innovation

Medical Devices

- Ventilators
- Respiratory Protection Devices





Key Initiative: Point of Care Molecular Diagnostics

- Innovation to bring diagnostics into the Physicians Office and the home
- Empower patients, reduce spread of disease, and reduce overall health care costs
- Broad Applicability to DMD Portfolio
 - Influenza
 - Biothreats
 - Antimicrobial Resistance
 - Emerging Disease
- Improved Sensitivity and Specificity
- Utility
 - Physician's Offices
 - Emergency Departments
 - Remote Settings
 - Home Use
- Current Projects
 - Abbott (Alere) - NextGen Isothermal Influenza Diagnostic
 - Roche LIAT – C. diff + MRSA assays
 - Tangen - Anthrax



 **Abbott**





Key Initiative: Simplified Sequencing

- Broad Applicability
 - Influenza Subtyping
 - Antimicrobial Resistance
 - Emerging Infectious Disease (Rapid Deployment)
 - Biothreat Diagnostics
- Rapid Identification of Dangerous Pathogens & Subtyping
- Simplified Interface Appropriate for Clinical Lab Use
- Current Projects
 - DNA Electronics PISCES





Influenza Dx

Overview

- Initiated development in 2006
- \$120M Invested
- 4 FDA clearances
- Current Projects
 - Point of Care
 - Flu A/B Molecular + Seasonal (Abbott (Alere))
 - Laboratory
 - Flu Subtyping (InDevR & DNAe)



Funding Interest

- Point of Care - Flu A/B + Seasonal
- Home -Flu A/B





Biodosimetry

Overview

- Initiated development in 2009
- \$365M Invested
- 4 Products Transitioned to Project Bioshield
- 1 Pre-EUA package submitted
- 510K filings expected 2018-2019

Funding Interest

- Self assessment tools with no specialized pre-distribution required
- Biodosimetry systems – significantly improve clinical response capability over PBS products

SRI International



ASCELL





Biodosimetry: Project BioShield

In Development

Type	Developer	Key Partners	Technology	FDA 510K Filing
Lab	DxTerity	Duke University, Thermo-Fisher	Gene expression	2018 *
Lab	MRI Global	Arizona State U, Thermo-Fisher	Gene expression	2018
Lab	ASELL, LLC	Meta Systems	Cytology – micronuclei	2019
POC	SRI International	DCN, Gener8, Web Industries	Protein Expression	2019

* Pre-EUA submitted





Anthrax Diagnostics

SRI International



Overview

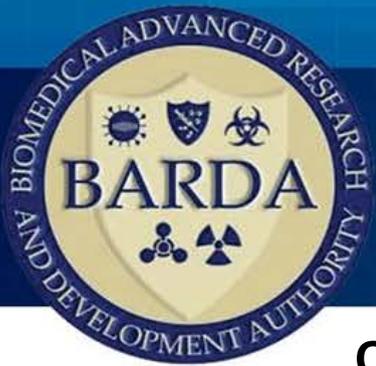
- Development initiated in 2012
- \$60M Invested to date
- 1st FDA 510K filing scheduled in 2018
- Natural history studies & antibody development @ CDC
- Point of Care Diagnostics
 - Toxin Detection (SRI, InBios)
 - Molecular (Tangen)
- Laboratory Diagnostics
 - Toxin Detection (First Light Bioscience)
 - Molecular (MRI Global)
 - Sample Concentration (DNAe)



Funding Interest

- Point of Care Diagnostics – Molecular & toxin diagnostic solutions
- Laboratory Diagnostics – High throughput diagnostic solutions





Additional Biothreat Diagnostics

Overview

- Initiated Development in 2012
- \$20M Invested to date
- 2 FDA Emergency Use Authorizations (EUA)
- BoNT MS assay for LRN Labs
- Ebola Lateral flow with OraSure
- Burkholderia & Plague Marker Studies with SRI

Funding Interests

- Extensive Investment Needed
 - Marker Characterization
 - Point of Care Diagnostics
 - Lab Diagnostics

Threats

- *Botulinum toxin* (botulism)
- *Burkholderia mallei* (glanders) & *pseudomallei* (melioidosis)
- Ebola and Marburg viruses
- *Francisella tularensis* (tularemia)
- *Rickettsia prowazekii* (typhus)
- *Yersinia pestis* (plague)
- Smallpox (orthopox genus virus assays acceptable)



SRI International



Antimicrobial Resistance (AMR) Diagnostics

Overview

- Development initiated in 2016
- \$38 M Invested to date
- 1 FDA Clearance
 - Roche LIAT C. difficile & MRSA
- Laboratory Diagnostics
 - ID & AST with First Light Biosciences (Anthrax + UTI)
 - Molecular (Targeted Sequencing) with DNAe

Funding Interests

- Extensive Investment Needed
 - Laboratory & POC
 - Viral vs. Bacterial
 - ID & AST
 - Molecular
 - Phenotypic Susceptibility
 - Speed up clinical Trials





AMR Diagnostics Challenge

- BARDA & NIH Funded - \$20M total of all Prizes
- 3 Tiered System
 - Stage 1 Semifinalists named in March 2017
 - 3 years to deliver prototype diagnostics
- Managed by Capital Consulting Group

Semifinalists

- *Richard Anderson, Becton, Dickinson and Company*
- *Sophia Koo, Brigham and Women's Hospital*
- *Don Straus, First Light Biosciences, Inc*
- *Ephraim Tsalik, Duke University,*
- *Joe Frassica, Philips North America,*
- *Gregory Loney, Click Diagnostics, Inc*
- *Ravi Kant Verma, Spectral Platforms, Monrovia, California*
- *Ken Babock, Affinity Biosensor*
- *Ann Falsey, University of Rochester*
- *Ellen Foxman of Yale University*





Emerging Disease: Zika Dx + Blood Screen

Overview

- Initiated Development in 2016
- \$ 39M Invested to date
- 4 EUA's, 1 FDA Approval, 2 INDs
- Laboratory Dx
 - InBios International (EUA ✓)
 - DiaSorin Inc. (EUA ✓)
 - Siemens (EUA ✓)
- Point of Care Dx
 - ChemBio Diagnostics (EUA ✓)
 - OraSure Technologies
 - InBios International
- Blood Screening
 - Roche (FDA Approved ✓)
 - Grifols (IND ✓)



OraSure Technologies, Inc.



GRIFOLS





Diagnosics Innovation

Overview:

- **New For FY2018 BAA**
- **Less Mature Technologies**
- **Needed to enable the next generation of diagnostics**

Funding Interests:

- **Innovative Sample Collection Devices**
- **Host & Pathogen Markers**
- **Wearable Sensors**
- **Novel Device Technology**
- **Improved Assay Chemistries**





Respiratory Support

PHILIPS



Overview

- Initiated Development in 2010
- \$31M Invested to date
- 1 FDA cleared product
- Current Projects
 - Ventilators
 - Next generation stockpile ventilator(Philips)
 - Respiratory Protective Devices (RPDs)
 - Reusable Mask (ARA)
 - High Speed Mask Production Line (Halyard)



Funding Interests

- Ventilators & RPD technologies that substantially reduce the cost of preparedness for these devices - purchase, storage, and /or distribution cost





Questions?

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Online Resources

<https://www.medicalcountermeasures.gov/home.aspx>

- Portal to BARDA: Register to request a **TechWatch** meeting

<https://www.fbo.gov/> (“FedBizOpps”)

- Official announcements and info for all government contract solicitations

<https://www.usajobs.gov/>

- Join the team!

<https://www.phe.gov/about/BARDA/Pages/default.aspx>

- Program description, information, news, announcements

