



BARDA INDUSTRY DAY

Biodosimetry and Other CBRN Diagnostics

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and Devices Infrastructure (DDDI)

October 29, 2018

October 29-30, 2018 | Grand Hyatt • Washington, D.C.



DDDI Addresses Diagnostic Needs Across BARDA's Portfolio



- For CBRN
 - Biodosimetry
 - Biothreat Diagnostics
 - Antimicrobial Resistance
- Key Strategies
 - Point of Care Diagnostics
 - Diagnostics Infrastructure (Future)
 - Sample Banking (Future)



The Radiation Biodosimetry Revolution: Targeted Diagnostics to Save Lives



Point of Care
Patient Sorting



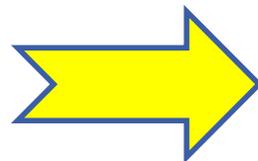
High-Throughput
Radiation Dose
Assessment



Biodosimetry **Revolution** Endpoints



Point of Care and High-Throughput
Biodosimetry Tests



Preparedness

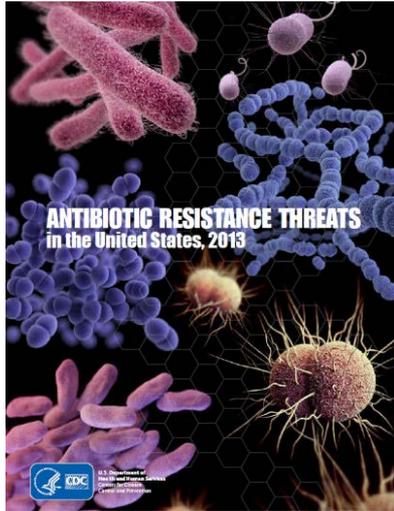
Four Products Transitioned to Project BioShield Funding

Type	Developer	Key Partners	Technology	FDA 510K Filing
Lab	DxTerity	Duke University, Thermo-Fisher	Gene expression	2019
Lab	MRIGlobal	Arizona State U, Thermo-Fisher	Gene expression	2020
Lab	ASELL, LLC	Meta Systems, Thermo- Fisher	Cytology – micronuclei	2020
Point of Care	SRI International	DCN, Gener8, Web Industries	Protein Expression	2020



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Combating Antibiotic Resistant Bacteria (CARB) and Biothreat Diagnostics



Point of Care Limited Resource Laboratory



Point of Care Limited Resource Laboratory

BARDA CARB Diagnostics



- BARDA Diagnostics Portfolio (5 products & growing)
 - Viral Vs. Bacterial for Point of Care (POC)
 - ✓ Eliminate Antibiotic Prescriptions for viral infections
 - Rapid Bacterial Identification (POC & Lab)
 - ✓ Identify bacteria to treat
 - Rapid Antibiotic Susceptibility Tests (Lab & POC)
 - ✓ If resistant bacteria, identify antibiotics that work



Roche



- First BARDA Portfolio FDA 510K clearance
 - Clostridium difficile on Roche LIAT



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NIH & BARDA Antimicrobial Resistance Rapid, Point-of-Need Diagnostic Challenge

Alternative Approach to stimulate Antimicrobial Resistance Diagnostics Development

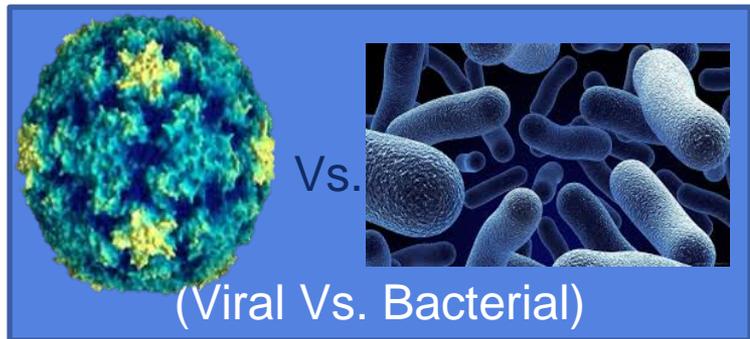
- Total Prize \$20M
- 3 Step process initiated **September 2016**
 - Step 1: Completed 10 semifinalists named **March 2017**



Now

- Step 2: In Process - 19 submissions received **September 2018**
 - Semifinalists (≤ 10) to be named **December 2018**
- Step 3: Submissions due **January 2020**
 - Winners (≤ 3) to be Named: **July 31, 2020**

Combating Antibiotic Resistant Bacteria by Developing Viral vs. Bacterial Diagnostics



Point of Care



Limited Resource

BARDA Diagnostics Industry Partners



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How to contact BARDA



Medical
Countermeasures.gov

[medicalcountermeasures.gov/home.aspx](https://www.mediccountermeasures.gov/home.aspx)

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



www.fbo.gov/
("FedBizOpps")

Official announcements and info for all government contract solicitations



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

Program description, information, news, announcements



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