



United States Department of

**Health & Human Services**

Office of the Assistant Secretary for Preparedness and Response



# ***Biodiagnostics Program***

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**CBRN Diagnostics & Devices**

November 12, 2013

**BARDA Industry Day**

*ASPR: Resilient People. Healthy Communities. A Nation Prepared.*

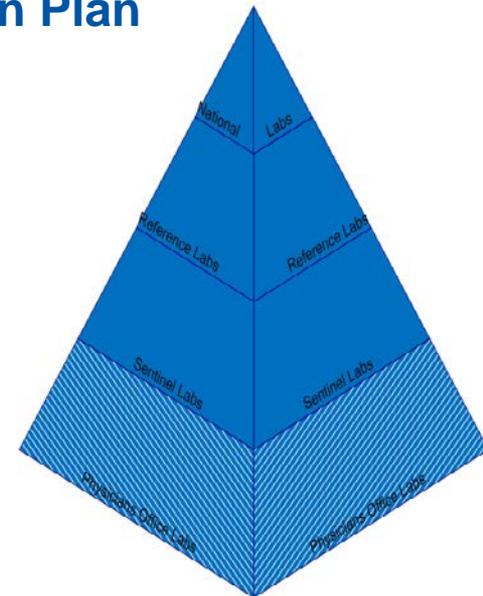


# CBRN Diagnostics & Devices Program Strategy



**Our objective is to develop tools to inform the efficient use of CBRN countermeasures, maximizing lives saved and minimizing casualties.**

- **Developing diagnostics and devices to inform CBRN countermeasure use**
  - **As identified in the PHEMCE Strategy Implementation Plan**
  - **Per PHEMCE needs assessments and requirements**
- **Key Strategies**
  - **Leverage existing clinical diagnostic laboratory infrastructure, instruments, practices, and IT**
  - **Stimulate development of Point of Care (POC) tools, moving testing closer to the casualty**
  - **Ensure appropriate capabilities at all levels**
  - **Correlate marker behavior with disease course**



**Informing Efficient Countermeasure Use,  
Empowering Healthcare Laboratory Response**



# CBRN Diagnostics(Dx) Programs

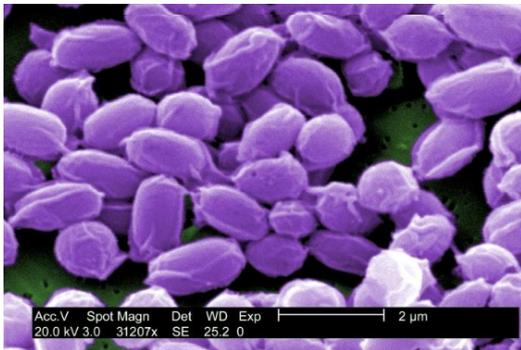


Program	FY9	FY10	FY11	FY12	FY13	FY14	FY15
Biological Agent Dx							
Radiation Dx (Biodosimetry)							
Chemical Agent Dx							

# BARDA Biothreat Diagnostic Threats of Interest



Smallpox



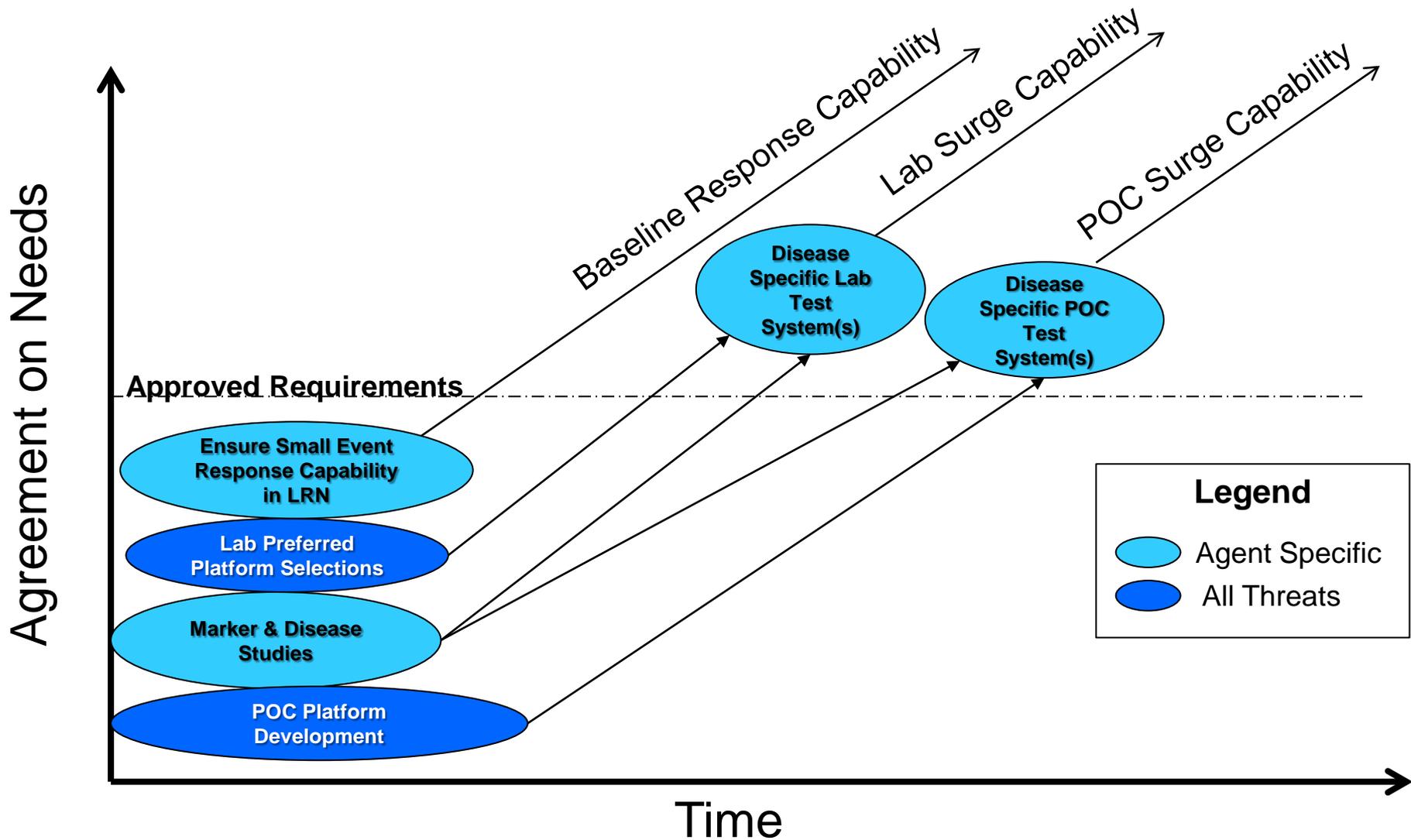
Anthrax Spore

Biothreat Agent	PHEMCE Requir'm't	Able to Fund		
		Marker Studies	POC Assay Dev	Lab Assay Dev
Anthrax	✓	✓	✓	✓
Botulinum toxins	<i>i</i>	✓		
Glanders & Meloidosis	<i>i</i>	✓		
Filoviruses	<i>i</i>	✓		
Tularemia	<i>i</i>	✓		
Typhus	<i>i</i>	✓		
Smallpox	<i>i</i>	✓		
Plague	<i>i</i>	✓		

*i* = in process



# Biothreat Diagnostics Development Strategy





# Diagnostics Instrument Strategy (All Threats)



- Laboratory

- Leverage platforms widely placed in clinical labs (at the time of the incident) to inform routine healthcare.
- Assays needed on multiple platforms for a given threat if a large Dx surge demand is expected.
- Fund adaptation, if required, to allow utilization of existing products.

- Point of Care

- Develop new platforms where existing platforms do not meet needs of ConOps.
- Improve performance of existing platforms
- Assays needed on multiple platforms for a given threat if a large Dx surge demand is expected.



# Biothreat Diagnostics Areas of Interest

## CBRN-BAA-13-100-SOL-000013



## Biothreat Dx Development

- 6.5 Anthrax Diagnostics Assay Development
- 6.6 POC Hardware Platform Development & Sample Prep System Development
- 6.7 Fundamental Knowledge Development for Biothreats\*
  - Marker Identification\*
  - Animal Studies – Time Course of Markers w/ Disease\* Progression

\* Biothreats of Interest – (listed alphabetically): *Bacillus anthracis* (Anthrax), Botulinum toxin (Botulism), *Burkholderia mallei* (Glanders) and *Burkholderia pseudomallei* (Meliodiosis), Filoviruses ( Ebola & Marburg), *Francisella tularensis* (Tularemia), *Rickettsia prowazekii* (Typhus), *Yersinia pestis* (Plague)





# CBRN Diagnostics Trajectory for the Future



- **Substantial Growth in Biothreat Diagnostics:**
  - Completion of PHEMCE requirements/Needs Assessments for the additional 7 threats of interest
  - Increase in portfolio of projects to develop assays on multiple platforms for each threat by:
    - Correlating biothreat marker behavior with disease course
    - Funding additional efforts to develop assays to detect anthrax infection for FDA clearance
    - Improvements in POC platforms



# Interfacing with BARDA



- [www.hhs.gov/aspr/barda](http://www.hhs.gov/aspr/barda)
  - Program description, information, news, announcements
- [www.medicalcountermeasures.gov](http://www.medicalcountermeasures.gov)
  - Portal to BARDA
  - Register, request a meeting
  - Tech Watch
- [www.fedbizopps.gov](http://www.fedbizopps.gov)
  - Official announcements and detailed information about all government contract solicitations
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