



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



Bio-threat Agent Diagnostics Program

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BIO-THREAT AGENT DIAGNOSTICS PROGRAM

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Diagnostics

Resilient People. Healthy Communities. A Nation Prepared.

Bio-threat Agent Diagnostics Program Objectives

Objective: Develop rapid, accurate FDA-cleared bio-threat agent diagnostic assays/systems to inform patient management, improve health outcomes, and save lives.

For use in:

Laboratory settings

- Develop assays for high-throughput instruments to meet large diagnostics surge demand – e.g. 4.4M anthrax tests
- Leverage COTS platforms*

Point of Care settings

- Develop new or adapted platform/assay systems where existing platforms do not meet end user needs
- Greater benefit if has routine healthcare applicability*

** PHEMCE Strategy 2012: “Ensure a ... product pipeline for MCM that emphasizes multi-functional capabilities ... and includes consideration of viable commercial markets and/or routine public health applicability.”*

www.medicalcountermeasures.gov

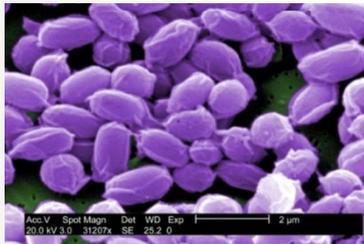


Bio-threat Agent Diagnostics

Number of Projects by Threat



Smallpox



Anthrax Spores

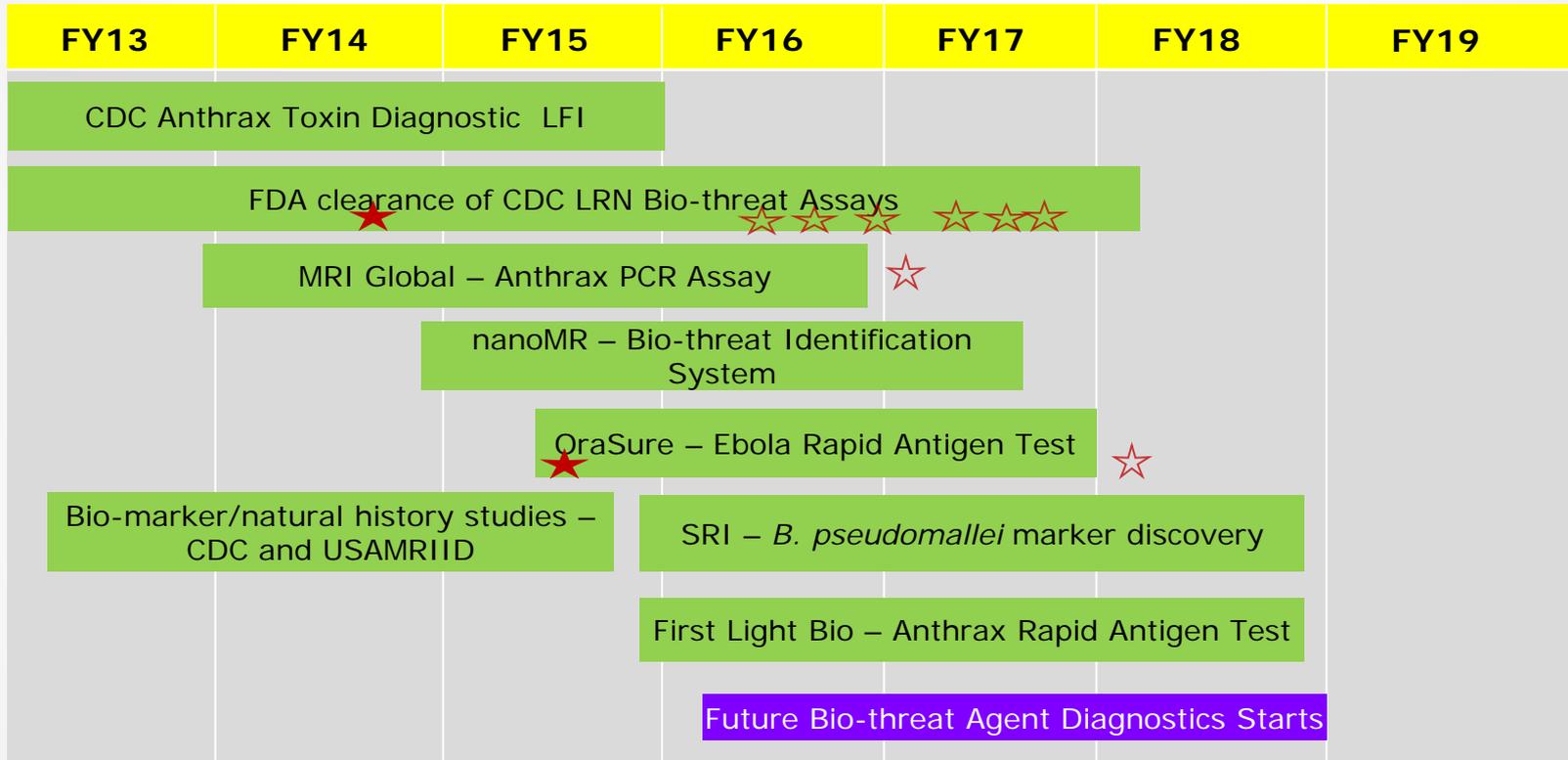


Ebola virus

Biothreat Agent	PHEMCE Rqmt	Marker Study	POC Assay	Lab Assay	Antimicrobial Resistance
Anthrax	✓	1	1	2	1
Botulinum toxins				1	
Burkholderia		1			
Filoviruses	✓ ^a	1	1		
Tularemia					
Typhus					
Smallpox					
Plague					

^aNot approved

Bio-threat Agent Diagnostics Projects



■ Existing ■ FY16 > new starts

- ★ FDA cleared (LRN anthrax PCR assay cleared May 2014)) (Orasure Ebola RAT EUA'd July 2015)
- ★ Anticipated clearance



Bio-threat Diagnostics

BAA AOI 6

- Anthrax diagnostics
 - Point of care (CLIA-waivable)
 - Systems
 - Lateral flow (with USG provided antibodies) – *new*
 - Laboratory-based (widely placed platforms)
- Hardware platform development
 - POC (CLIA-waivable)
 - Sample collection and sample preparation methods
- Biothreat knowledge development
 - Marker identification
 - Marker characterization with disease progression



Bio-threat Diagnostics

BAA AOI 6

- Examples:
 - Add antimicrobial resistance detection to existing or new assay development efforts
 - Develop multi-agent syndromic panels such that a single patient sample could yield results for multiple suspected disease-causing agents with similar sequelae (for example, an upper respiratory panel, GI panel, bio-threat panel, etc.)
 - Targeted sequencing methods for agnostic detection rather than relying on assay-specific reagents



Bio-threat Agent Diagnostics Development Strategy

