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

<table>
<thead>
<tr>
<th>Program</th>
<th>FY9</th>
<th>FY10</th>
<th>FY11</th>
<th>FY12</th>
<th>FY13</th>
<th>FY14</th>
<th>FY15</th>
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<tbody>
<tr>
<td>Biological Agent Dx</td>
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<td>Radiation Dx</td>
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<td>Chemical Agent Dx</td>
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## BARDA Biothreat Diagnostic

### Threats of Interest

<table>
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<tr>
<th>Biothreat Agent</th>
<th>PHEMCE Req'mt</th>
<th>Able to Fund</th>
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<tbody>
<tr>
<td></td>
<td>Marker Studies</td>
<td>POC</td>
</tr>
<tr>
<td>Anthrax</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Botulinum toxins</td>
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<td>✓</td>
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<tr>
<td>Glanders &amp; Meloidosis</td>
<td>i</td>
<td>✓</td>
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<td>Filoviruses</td>
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<td>Tularemia</td>
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<td>Typhus</td>
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<td>Smallpox</td>
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<td>✓</td>
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<tr>
<td>Plague</td>
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*i* = in process
Biothreat Diagnostics Development Strategy

Agreement on Needs

Approved Requirements

Ensure Small Event Response Capability in LRN

Lab Preferred Platform Selections

Marker & Disease Studies

POC Platform Development

Time

Baseline Response Capability

Lab Surge Capability

POC Surge Capability

Legend

Agent Specific

All Threats
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 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* (Melioidosis), Filoviruses (Ebola & Marburg), *Francisella tularensis* (Tularemia), *Rickettsia prowazekii* (Typhus), *Yersinia pestis* (Plague)
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<tr>
<th></th>
<th>FY13</th>
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<td>CDC Anthrax Toxin Diagnostic</td>
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<td>CDC LRN Multiple Biothreat Assays</td>
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<td>MRI Global – Anthrax Assay</td>
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<td>Future Biodiagnostics Starts</td>
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**Existing**  **FY14 new starts**
• 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**
  - Program description, information, news, announcements

- **www.medicalcountermeasures.gov**
  - Portal to BARDA
  - Register, request a meeting
  - Tech Watch

- **www.fedbizopps.gov**
  - Official announcements and detailed information about all government contract solicitations

- **Lynne.Wathen@HHS.gov**
- **Rodney.Wallace@hhs.gov**