

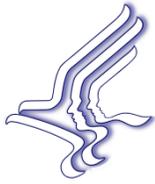
Diagnostics and Biodosimetry Programs

BARDA / CBRN Medical Countermeasures Division

**Rodney Wallace
Branch Chief, CBRN Diagnostics**

June 7, 2011

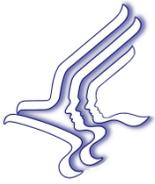
Procurement Sensitive - FOUO



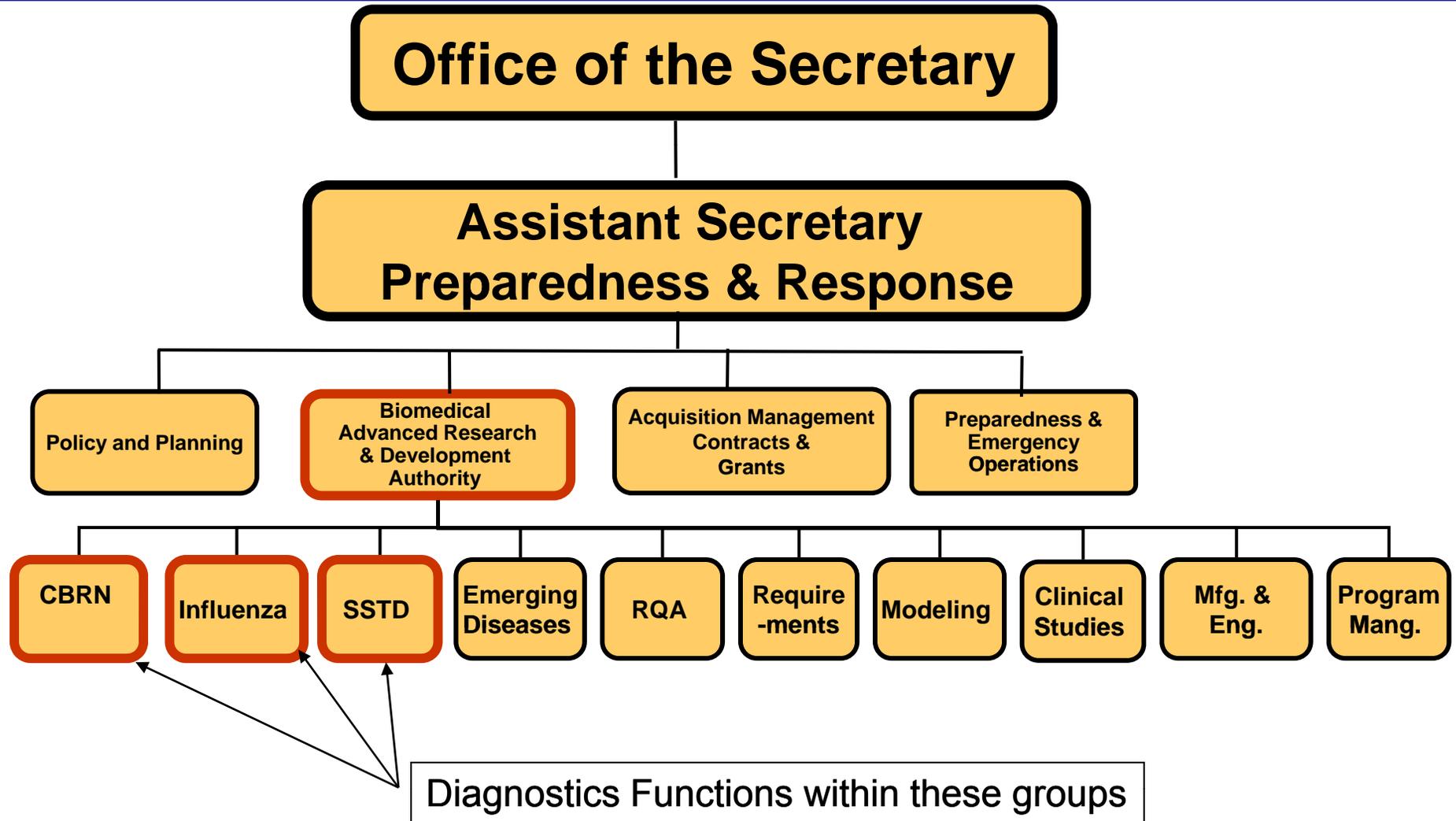
Topics

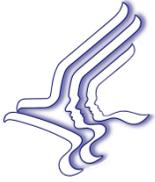


- **BARDA Diagnostics Programs**
 - Open solicitations
 - Overarching Strategy
 - Dx Usage Scenarios
- **CBRN Diagnostics Program Details**
 - Radiation Diagnostics Program
 - Biological Agent Diagnostics
 - Chemical Agent Threat Diagnostics
- **CBRN Rolling BAA**
 - Secrets to Success for Dx White Paper Submissions



BARDA Diagnostics Programs





Open Diagnostics Solicitations



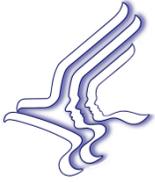
- **Influenza Division**
 - BAA-BARDA-11-100-SOL-00013 (Announcement)
- **Strategic Science and Technology (SSTD)**
 - BARDA_BAA_11-100-SOL-00001
- **CBRN Division**
 - BARDA-CBRN-BAA-11-100-SOL-00009



Overarching Strategy

- **Purpose - discrimination of disease resulting from exposure to CBRN agents, pandemic influenza, or other emerging threats during an outbreak or CBRN incident**
 - **Informed treatment decisions for use of medical countermeasures:**
 - **Vaccines, antibiotics**
 - **Therapeutics**
 - **Targeted U.S. population:**
 - **General population, pediatrics, geriatrics**
 - **Special populations (pre-existing conditions, underlying diseases)**
 - **Sample types:**
 - **Clinical specimens (blood, swabs, urine,....)**
 - **Regulatory authority: FDA**

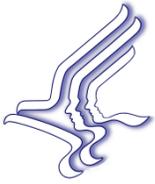
- **Product Development Phases**
 - **Advanced Development (Initiation of Design Control to FDA filing)**
 - **Potential Acquisition**



Diagnostic Use Scenarios

- **Point of Care Diagnostics**
 - Limited availability of diagnostic platforms
 - Fund development:
 - Assays
 - Diagnostic platforms
 - New/advanced diagnostic approaches
 - Intended settings for use:
 - Physician's office/labs, rural & public health clinics
 - Community hospitals
 - Emergency rooms
 - First responders in temporary facilities (tents, shelters, schools, RTR*, etc.)

*RTR = Radiation Triage, Treatment, and Transport



Diagnostic Use Scenarios (continued)



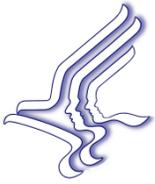
- **High Throughput Laboratory Diagnostics**
 - Wide availability of diagnostic platforms in clinical diagnostic labs
 - Fund development:
 - Assays for use on existing diagnostic platforms
 - Platform development only if technology not compatible with existing platforms
 - Intended settings for use:
 - Clinical diagnostic laboratories (LRN, commercial hospital labs, commercial reference labs, expert federal, state and local government labs)



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CBRN Diagnostic Programs



CBRN Diagnostics Programs



| Program | FY09 | FY10 | FY11 | FY12 |
|-----------------------|------|------|------|------|
| Radiation Diagnostics | I | A | E | E |
| Biological Agent Dx | | I | A | E |
| Chemical Agent Dx | | | I | A? |

I = Program Initiation

A = Initial Program Awards

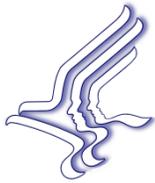
E = Program Execution



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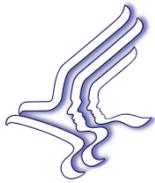
Radiation Diagnostics



Radiation Diagnostics Programs of Interest



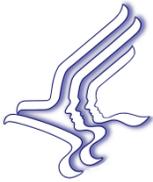
- **Active:**
 - Biodosimetry – 10 Awards, 7 Active Programs
 - Interested in additional promising technologies
- **Additional Development Interests**
 - Self Assessment tool
 - Device to be carried by interested parties to detect the quantity of radiation received.
 - Improvements to “Gold Standard” Dicentric Chromosome Assay
 - Automation
 - Image Processing
 - RadioBioassay
 - Measurement of inhaled or ingested fallout



BARDA Biodosimetry Program (Active Programs)



| Active | Contract | POC or HT | TECHNOLOGY | | | | | |
|--------|-------------------------------|--------------|----------------|---------------|-------------|------|--------|-----|
| | | | Protein Exp | DNA Damage | Gene Exp | VOCS | Ocular | EPR |
| ✓ | MesoScale Diagnostics, LLC | Both | ✓ | | | | | |
| ✓ | SRI International | POC | ✓ | | | | | |
| ✓ | Northrop Grumman | HT | | ✓ | | | | |
| ✓ | Duke University | HT | | | ✓ | | | |
| ✓ | Arizona State Univ | HT | | | ✓ | | | |
| ✓ | ChromoLogic, LLC | POC | | | | | ✓ | |
| ✓ | Messana, Inc. | POC | | | | ✓ | | |



Biodosimetry Preferred Attributes



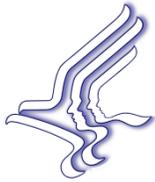
| | Point of Care Device (POC) | High Throughput Device (HT) |
|--------------------------------|--|---|
| Type of result: | Qualitative | Quantitative (accuracy $\pm 0.5\text{Gy}$) |
| CONOPs: | Initial Triage / Sorting | Injury Assessment / Treatment |
| Exposure level: | 2 Gy (200 rad) (threshold) | Range: 0.5 – 10 Gy |
| Ease of operation: | Easy to operate, minimal complexity (requires minimal training ;CLIA waived) | Laboratory instrument—more labor intensive, requires training |
| Device characteristics: | Integrated components—no separate sample preparation | May include separate components as needed. High automation desired. |
| Intended use: | Tents, shelters, open settings | Labs, hospitals, fixed facilities |
| # Patients / Event | Up to 1,000,000 in 6 days | Up to 400,000 (may need multiple assessments) |
| Time to result: | Rapid but individual sample result (< 30 minutes) | Up to 24 hours |



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Biologic Agent Diagnostics



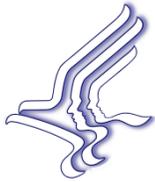
Biological Agents of Interest

(In Clinical Samples)



| Threat Agents – PHEMCE Implementation Strategy | PHEMCE | CDC |
|--|--------|-----|
| <i>Bacillus anthracis</i> (Anthrax) | ✓ | A |
| Botulinum neurotoxin (Botulism) | ✓ | A |
| <i>Burkholderia mallei</i> & <i>pseudomallei</i> (Glanders & Meloidosis) | ✓ | B |
| Filoviruses (Ebola & Marburg) | ✓ | A |
| <i>Francisella tularensis</i> (Tularemia) | ✓ | A |
| Junin virus (Argentine Hemorrhagic Fever) | ✓ | A |
| <i>Rickettsia prowazekii</i> (Typhus) | ✓ | B |
| Variola virus (Smallpox) ^{***} | ✓ | A |
| <i>Yersinia pestis</i> (Plague) | ✓ | A |

*** Future Needs in Review



Biological Agent Additional Topics of Interest



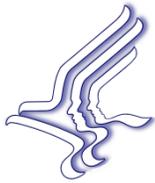
- **High Throughput : Candidate clinical reagents for use on existing, fielded high throughput platforms**
- **Point of Care: Platforms and Assays for diagnosis of diseases from threats of interest**



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Chemical Agent Diagnostics



Chemical Agents of Interest



- **Agents where Dx in clinical samples could inform treatment following low level exposure**
- **Candidates – Draft**
 - Phosgene
 - VX
 - Sulfur Mustard

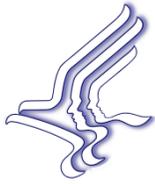


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Secrets to Success

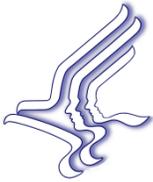
**Diagnostic white papers submitted under
BARDA-CBRN-BAA-11-100-SOL-00009**



Advanced Research And Development Funds

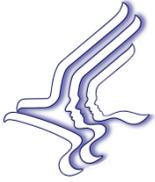


- **Funding may be used to further the development and maturity of Diagnostic Systems toward FDA clearance/approval**
- **These funds should not be used beyond the FDA clearance/approval milestone.**
- **Development of Manufacturing Capabilities, beyond those needed to manufacture materials for clinical studies, are not appropriate with these funds.**



Secrets to Success

- 1. Propose development of a product, not just a technology**
- 2. Provide data to establish current TRL of the product**
 - Both Hardware and Biologics / Assay
 - TRL 4 or greater (Defined in Attachment 1)
 - Specific data for threats proposed to address
- 3. Describe Entire Path from Current State to FDA submission**
 - Address Team Members and Capabilities
 - Include a well thought-out regulatory plan
 - Address technical improvements and challenges
- 4. Manufacturing & Commercialization Plan**
 - Volume manufacturing is not covered with AR&D funds, but describe your plan for production and commercialization
- 5. Review Biodosimetry information in Attachment 8**
 - Provides insight into USG's envisioned ConOps for a large scale event



Point of Contract



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