



# ENHANCING NATIONAL PREPAREDNESS THROUGH BIODOSIMETRY

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# Radiation Biodosimetry Program

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

Two types of biodosimetry tests are under development:

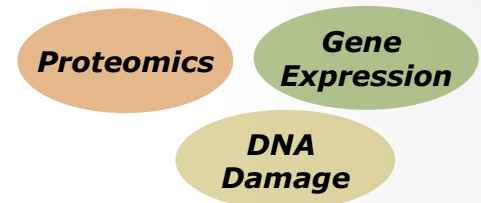
- **Point of Care Triage Screening Tests** to discern individuals needing medical evaluations from those who can evacuate
- **High Throughput Laboratory Screening Tests** to report the absorbed dose an individual received and inform further care



# BARDA Biodosimetry Program Overview

- Awarded 11 projects in 2009 – 2010
- Via In Process Reviews of progress, some contracts were down-selected
- 5 projects are currently funded
- The projects are on the cusp of starting test verification procedures to prepare for pre-Emergency Use Authorization requests, clinical validation, and seeking FDA clearance.

## Current Technologies



Clinical Diagnostic Test Development Stages



# Target Product Profiles

	<b>Point of Care Device (POC)</b>	<b>High Throughput Device (HT)</b>
<b>Type of result:</b>	Screening/Qualitative	Quantitative
<b>CONOPs:</b>	Initial Triage / Sorting	Injury Assessment / Treatment Tool
<b>Exposure level:</b>	2 Gray (Gy) threshold	Range: 0 – 10 Gy
<b>Ease of operation:</b>	Easy to operate, minimal complexity, requires minimal training, CLIA waived	Laboratory instrument—more labor intensive, requires training
<b>Device Characteristics:</b>	Integrated components—no separate sample preparation	May include separate components as needed. High automation desired.
<b>Intended use:</b>	Tents, shelters, open settings	Labs, hospitals, fixed facilities
<b># Patients / Event</b>	Up to 1,000,000 within 7 days	Up to 400,000 within 7 days
<b>Time to result:</b>	Rapid (15 to 30 minutes)	Up to 24 hours



# High Throughput Laboratory Advanced Research & Development (AR&D) Biodosimetry Projects

- Active Projects:

Developer	HT Technology	Type
Arizona State University	Gene expression	Semi-automated including ABI 7500Dx or QuantStudio Dx
Northrop Grumman	Cytology - <i>micronuclei</i>	Semi-automated including Cytology Microscopes
Duke University/ DxTerity	Gene expression	Semi-automated including ABI 3500 Dx



- All Entering Verification / Analytical Testing Phase

# High Throughput Laboratory Project Bio-Shield Contracts

- Solicitation published on June 6, 2016
  - Product Validation / Clinical Testing
  - Acquisition of Initial Test Stockpile
  - Maintenance of Stockpile through 2026
- Proposals received by July 23, 2016
- Contract awards made in September, 2016



# Point of Care Biodosimetry AR&D Projects

- Active Projects

Developer	Point Of Care Technology	Type
SRI International	Protein Expression immunoassay	Dual Lateral Flow w/ Reader & Cell Extractor
MesoScale Diagnostics	Protein Expression immunoassay	Microfluidic Cartridge & Instrument



- Project Bio-Shield Solicitation Envisioned later in FY2017

# Conclusions

BARDA is advancing high-throughput and point of care biodosimetry tests toward:

- Attaining Pre-Emergency Use status to begin preparing the nation for a radiological incident
- Seeking FDA clearance for at least one high-throughput and one point of care biodosimetry test to enhance our preparedness position
- Developing a test implementation strategy with CDC and other key stakeholders to help inform patient management, improve health and psychosocial outcomes, and save lives





# Continuing Biodosimetry Interests

## BAA 16-100-SOL-0001 Area of Interest Six:

- **6.1 Self Assessment Tool:**  
Development of a dosimetry self-assessment tool to determine if an individual has been exposed to ionizing radiation at a dose equal to or greater than 2 Gy.
- **6.2 Biodosimetry Systems:**  
BARDA is interested in more advanced development of rapid point- of-care diagnostic assays and/or a centralized high-throughput assay systems
- **6.3. Dicentric Chromosome Assay:**  
Development of an improvement on the current dicentric chromosome assay (DCA) in terms of ease of use, time for performance, statistical certainty of dose, improved dose range, and biomarker lifespan.

See [FedBizOpps.gov](http://FedBizOpps.gov) for further details.

