BARDA BIODOSIMETRY

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Resilient People. Healthy Communities. A Nation Prepared.

BARDA Biodosimetry Desired Throughput

Point of Care Screening (1M people)

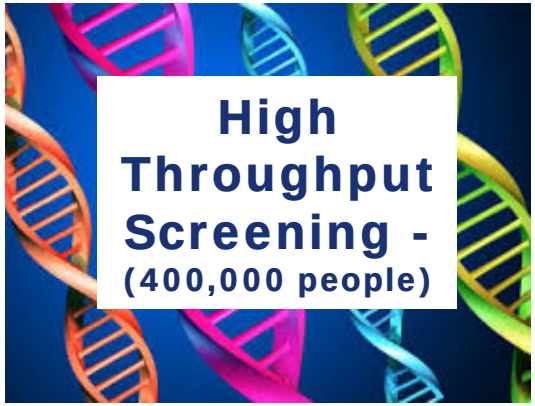
≥ 2 Gy

Plus

Follow on

Care

< 2 Gy



Target Product Profiles

	Point of Care Device (POC)	High Throughput Device (HT)
Type of result:	Qualitative	Quantitative (accuracy ± 0.5Gy)
CONOPs:	Initial Triage / Sorting	Injury Assessment / Treatment Tool
Exposure level:	2 Gy - 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 within 6 days	Up to 400,000 within 7 days (may need multiple assessments)
Time to result:	Rapid but individual sample result (15 to 30 minutes)	Up to 24 hours

Point of Care Biodosimetry Programs

Developer	Point Of Care Technology	Type	Estimated Results per Day per Instrument
	Protein Expression immunoassay	Dual Lateral Flow w/ Reader & Cell Extractor	400
	Protein Expression immunoassay	Microfluidic Cartridge & Instrument	72

ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

High Throughput Laboratory Biodosimetry Programs

Developer	HT Technology	Automation	Estimated Results per Day per Instrument
Duke/DxTerity	Gene expression	Semi-automated including ABI 3500 Dx	500
Northrop Grumman/ Applied Spectral Imaging	Cytology – micronuclei	Semi-automated including Applied Spectral Imaging Cytology Microscopes	1200
Arizona State University	Gene expression	Semi-automated including ABI 7500Dx or Life technologies QuantStudio	700

BARDA Broad Agency Announcement Number: CBRN-BAA-1X-100-SOL-0001X

Biodosimetry Diagnostic Areas of Interest (AOI)

6.1 Development of a **dosimetry self-assessment tool** in order 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 **advanced development** of a rapid **point- of-care** diagnostic assay for assessing whether an individual's absorbed dose of ionizing radiation was above or below 2 Gy, and/or a centralized **high-throughput** assay system for determining absorbed doses of ionizing radiation in the range of 0.5 Gy to 10 Gy, that have a robust detection signal from 24 hours post-exposure which persists at least one (1) week. **Minimum technology readiness: TRL-6**.

6.3. Development of an **improvement on** the current "gold standard" for assessing absorbed doses of ionizing radiation (**the dicentric chromosomal assays** (DCA)) in terms of ease of use, time for performance, statistical certainty of dose, improved dose range, and biomarker lifespan.

6.2 Advanced Biodosimetry Systems

- White papers must at a minimum include:
  - Listing of radiation responsive marker(s) and performance data in human and an animal model for each of them.
  - Evidence that a pre-submission meeting has been held with the FDA
  - Instrument and consumable definition and performance data of key components or entire system.
  - Listing of all key team members, identifying who will fill each key skill needed to develop, manufacture, and achieve regulatory approval of the product.
  - Functional prototype instrument and consumables in final form.