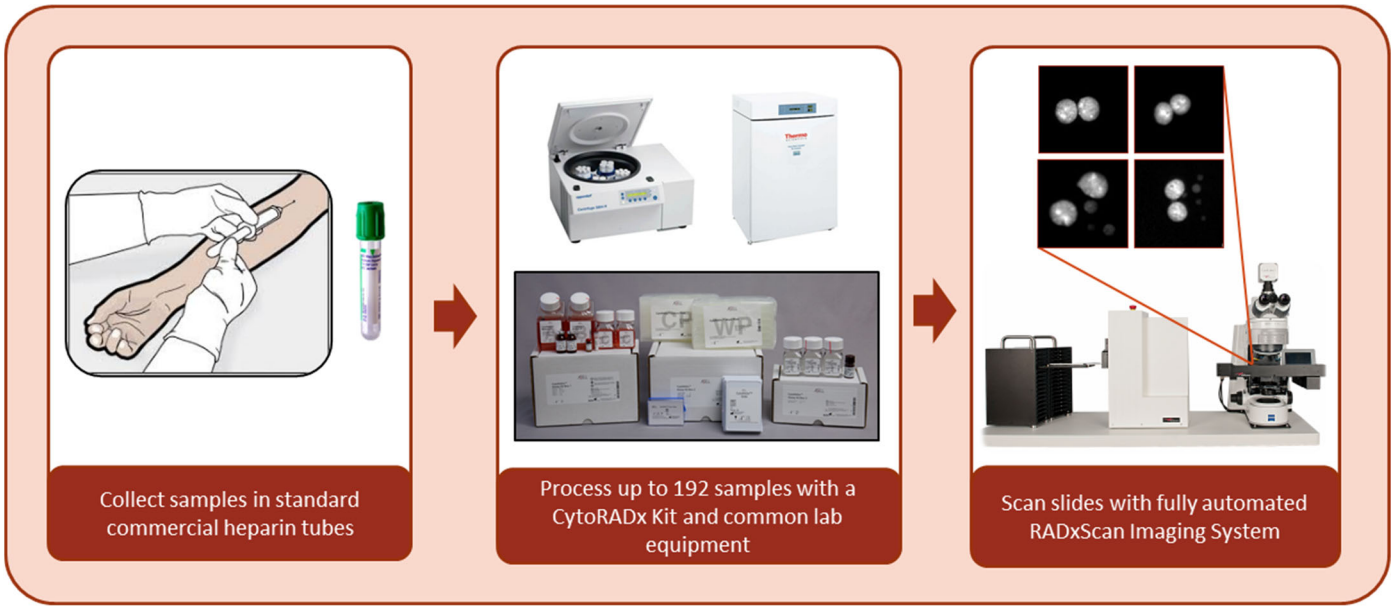
CytoRADx™

High-Throughput Biodosimetry System

CytoRADx – A High-Throughput Implementation of the CBMN Assay

ASELL and MetaSystems have co-developed the CytoRADx Biodosimetry System, a high-throughput implementation of the proven Cytokinesis Block Micronucleus (CBMN) assay. The CBMN assay has been accepted by many institutions around the world, such as the International Atomic Energy Agency (IAEA), as a standard method for performing biodosimetry[1]. The traditional CBMN assay, however, is very labor intensive, requires site-specific calibration curves, and is not feasible for high-throughput applications. CytoRADx addresses these concerns.

The US Government's Biomedical Advanced Research and Development Authority (BARDA) is currently funding ASELL and MetaSystems to perform advanced development and validation of the CytoRADx System for use in a radiological event, and to seek marketing clearance from the FDA.



The CytoRADx™ System combines existing clinical lab equipment with a low-cost assay and the Metafer-based RADxScan automated imaging system to provide high-throughput biodosimetry capability.

CytoRADx Test Overview

Each CytoRADx System can test up to 1000 blood samples per day, providing quantitative results of absorbed radiation dose to guide appropriate treatment by a medical practitioner. As shown in the figure above, blood samples are drawn into commercially-available blood collection tubes, which are transported to laboratories at room temperature. Once received by the laboratory, the CytoRADx Assay and RADxScan Imager (a variant of the MetaSystems Metafer platform) are used to test the samples in parallel. The system uses other materials and equipment widely available in clinical laboratories.

[1] International Atomic Energy Agency. (2011). Cytogenetic Dosimetry: Applications in Preparedness for and Response to Radiation Emergencies. IAEA, Vienna, Austria

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ASELL
Turning Science Into Solutions

MetaSystems

Expected Benefits for Biodosimetry

The CytoRADx System is being developed to provide several advantages for biodosimetry, including:

- Excellent accuracy and precision in the clinically relevant dose range of 0-8 Gy.
- Proprietary image analysis and dose calculation methods provide for fully automated and repeatable results across labs.
- The CytoRADx biomarkers are a direct measurement of biological damage at the cellular level. They do not require subsequent secondary events, such as gene or protein expression, to occur.
- The CytoRADx System is not confounded by other injury conditions, such as burns, trauma and severe infections.

Anticipated CytoRADx Performance	
Dose Range	0-8 Gy
Throughput	Up to 1000 samples/day per instrument
Test Window	Up to 4 weeks post-exposure
Patient Population	All individuals 2 years and older

- The system can test samples drawn up to four weeks post-exposure. The extended test window allows testing of people who may have been exposed to radiation but did not seek immediate medical attention.
- The assay kit and other consumables are low cost compared to other methods.

About Us

ASELL is a small company focused on integrating and delivering cutting edge technology solutions that strengthen the world's health security and emergency preparedness. We have a wide-range of expertise, including radiation biodosimetry, in vitro diagnostics, civilian biodefense, and CBRN defense systems. As a government prime contractor, we are interested in partnering with companies who have discriminating technology that can be applied to 21st century health security challenges. Current programs and interests include: High-throughput & point of care biodosimetry; Biodosimetry techniques for partial body and mixed field exposures; Measurement of radiation damage to specific organs or physiological systems; and Rapid diagnostic techniques for health challenges such as infectious disease & sepsis.

MetaSystems has been designing and manufacturing systems for computerized automated microscopic imaging since 1986. From the very beginning, the close relationship to the end user has been an essential part of the MetaSystems philosophy. MetaSystems established itself very early as a leading developer and manufacturer of automated chromosome analysis solutions and then expanded into other applications in cytogenetics, cytology, microbiology, pathology and toxicology. Using versatile platforms and a modular architecture, MetaSystems' solutions are easily tailored to specific requirements and adapted to any existing workflow. Currently MetaSystems has installed over 2,000 systems worldwide in 93 countries.

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