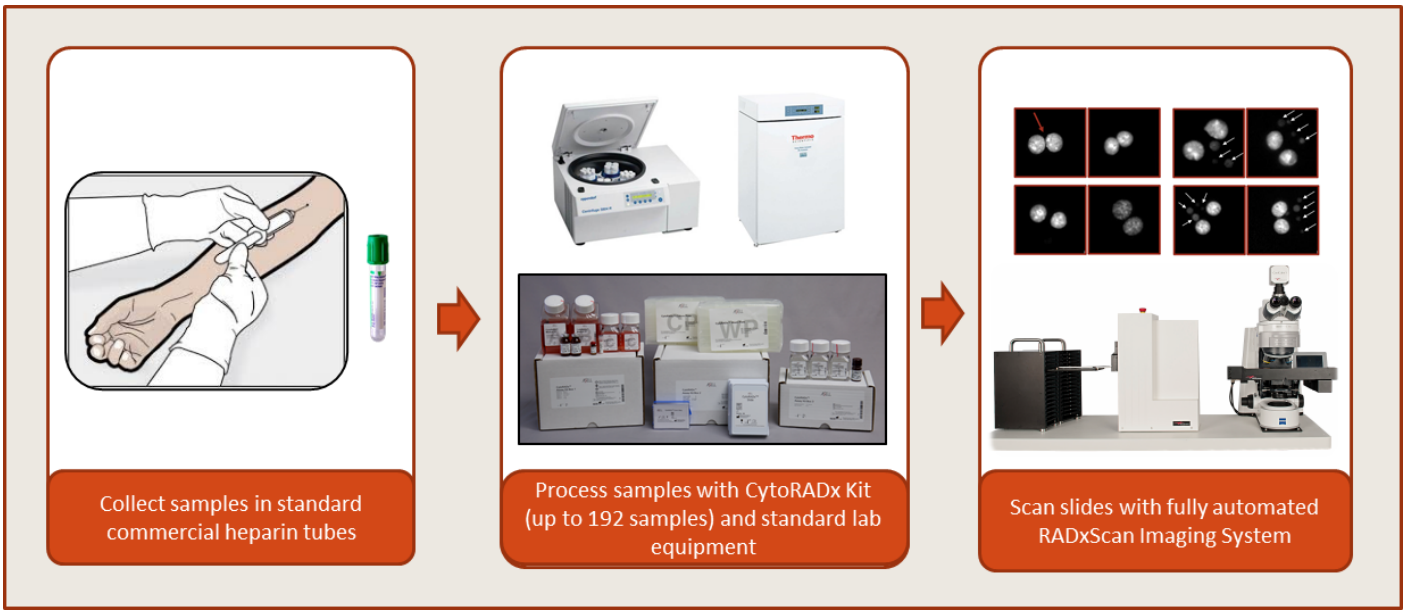
CytoRADx – A High-Throughput Implementation of the CBMN Assay

The CytoRADx Biodosimetry System is a high-throughput implementation of the proven Cytokinesis Block Micronucleus (CBMN) assay. The CBMN assay was developed in 1984 and first used for biodosimetry in 1994. The 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 and not feasible for high-throughput applications.

The US Government's Biomedical Advanced Research and Development Authority (BARDA) is currently funding ASELL 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 an automated imaging system to provide high throughput biodosimetry capability.

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

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

CytoRADx™

High-Throughput Biodosimetry System

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 0-10 Gy. Over 90% of CytoRADx results are within 1 Gy of the actual dose between 0 and 8 Gy.
- 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.
- 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.

Anticipated CytoRADx Performance	
Dose Range	0-10 Gy
Accuracy & Precision	90% of results within 1 Gy between 0 and 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

Other Potential Applications

The CytoRADx System offers outstanding performance and has been tested in many studies using both human and non-human primate samples. Although the original mission of the system is to provide a biodosimetry capability, there are many other potential applications of the core technology being considered, including:

- Radiation Sensitivity Assessment: Studies have shown that people respond differently to radiation exposure[2]. The CytoRADx System could be used to assess an individual's sensitivity prior to radiation treatment. With this additional information, the patient's treatment scheme can be tailored to maximize effectiveness and minimize harmful side effects.
- Early Stage Cancer Detection: The biomarkers produced by the CBMN Assay have been shown to correlate with the presence of early stage cancers of various types (e.g., lung, bladder)[3]. The CytoRADx System could be used to assess individuals for early stage cancer before they are symptomatic.
- Individual Cancer Risk Assessment: Prior studies suggest that the biomarkers produced by the CBMN Assay correlate with the likelihood of an individual's susceptibility to develop cancer in the future[4]. The CytoRADx System could be used to identify individuals with this higher risk of developing cancer, increasing the chances of diagnosing their cancer early and increasing the probability of a positive outcome.

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[2] Lee, WH, Nguyen, PK, Fleischmann, D., Wu, JC: DNA damage-associated biomarkers in studying individual sensitivity to low-dose radiation from cardiovascular imaging. European Heart Journal 37:3075-3080 (2016)

[3] Baeyens A, Thierens H, Claes K, Poppe B, Messiaen L, De Ridder L, Vral A: Chromosomal radiosensitivity in breast cancer patients with a known or putative genetic predisposition. Br J Cancer 87:1379–1385 (2002)

[4] El-Zein R, Vral A, Etzel C; Cytokinesis-blocked micronucleus assay and cancer risk assessment; Mutagenesis; 26:101-106 (2011)