



CytoRADx™

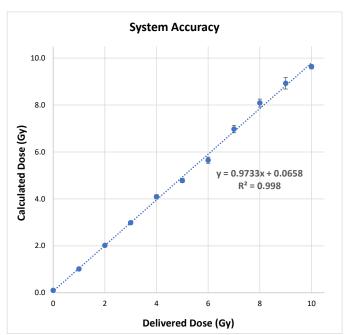
Accurate, High Throughput Biodosimetry

CytoRADx provides the strengths of cytogenetic biodosimetry in an easiser to use, high-throughput, standardized format and fully automated dose estimation. The Cytokinesis Block Micronucleus (CBMN) assay is widely accepted by the International Atomic Energy Agency and others as a standard method for performing biodosimetry and provides a direct measurement of biological damage at the cellular level. However, the traditional CBMN assay is very labor intensive, requires site and operator-specific calibration curves, and is not suitable for high-throughput applications such

as responding to a large scale radiological incident. CytoRADx is a breakthrough implementation of the CBMN assay that was developed to address these limitations.

CytoRADx will enable data-driven clinical case management

- Excellent accuracy and reproducibility across a clinically relevant dose range that is broader than other cytogenetic assays.
- Samples can be drawn for at least 2 weeks post-exposure, which allows testing of people who did not seek immediate medical attention.
- Dose estimation is fully automated with no manual cell counting or other calculations required and is not confounded by other injury conditions such as burns & trauma.



Results obtained from 376 human samples. Blood samples were irradiated *ex vivo* (Cs¹³⁷) and tested using the CytoRADx System. Data points represent mean results and error bars represent standard error.

Streamlined sample processing

CytoRADx reagents are provided in kit format, minimizing preparation time and ensuring consistent results. Kits are manufactured under GMP, eliminating the need for users to perform QC testing of reagents. Kits have at least a 12-month shelf-life.

- Whole blood samples are drawn in commercially available sodium heparin tubes. Lymphocyte isolation is not required.
- Samples are processed in microtiter plates to improve efficiency.
- Assay workflow has been simplified to drive efficiency and throughput.
- Formaldehyde fixing and dual staining are unnecessary.







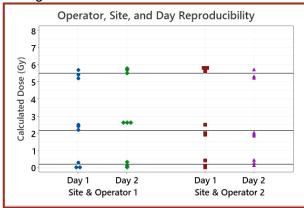


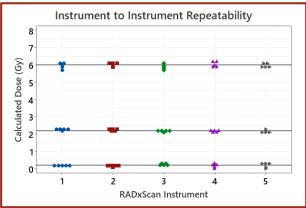
Microscopy and dose estimation are fully automated.

- A proprietary dose estimation algorithm eliminates the need to generate lab-specific calibration curves, perform manual slide review or cell counting, or execute offline dose calculations.
- Pre-qualified control slides are provided to ensure proper instrument operation. There is no need to generate reference slides.
- Each slide can be scanned and analyzed in just minutes. Each system can analyze hundreds of samples each day.

CytoRADx provides repeatable, accurate results.

Developed through robust studies that tested more than 20,000 samples, CytoRADx provides repeatable, accurate results across laboratories, operators and instruments through standardization of reagents and assay protocols, optimization of image processing, and the elimination of manual scoring.





Left: Samples were drawn from the same person on different days, irradiated *ex vivo* at 0, 2, and 6 Gy, split and sent to two different locations with different operators and instruments. Slides were scanned and analyzed 3 times. Right: 3 slides prepared from samples irradiated *ex vivo* at 0, 2 and 6 Gy were each scanned 5 times on 5 different RADxScan instruments Both: Data points shown are individual results for each scan. Horizontal lines are the mean values of each dose level.

CytoRADx: Accurate, High Throughput Biodosimetry

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