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DxTerity Diagnostics Receives CE Mark for the REDI-Dx® Test

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REDI-Dx® blood test to estimate absorbed radiation after a nuclear event

DxTerity Diagnostics has declared conformity with the requirements of the European In Vitro Diagnostic Directive (98/79/EC) and has applied the CE mark to the REDI-Dx® Radiation Biodosimetry Test for the quantitative estimation of the absorbed ionizing radiation dose after a nuclear event.

A radiological event, from the use of a nuclear weapon or improvised nuclear device, could potentially expose thousands of individuals to high or moderate levels of radiation that would require immediate medical intervention.

REDI-Dx measures the biological response to radiation and provides individualized estimates of absorbed radiation from a peripheral blood sample. Physicians can use the estimate, in conjunction with radiation dispersal monitoring and clinical signs and symptoms, to prioritize the highly and moderately exposed individuals from the concerned public for medical treatment.

According to Bob Terbrueggen, CEO and Founder of DxTerity, "REDI-Dx fulfills a critical unmet need for responding to a mass scale nuclear event. It is the first CE-IVD assay for radiation biodosimetry and is designed to integrate into existing clinical testing infrastructure and read-out on the installed base of ABI 3500 Dx CE instruments."

The dicentric chromosome assay is the current "gold standard" in Europe and Asia; however, the limited testing capacity, lack of standardization, and 72-hour time to result limits its practicality. REDI-Dx overcomes these limitations with ambient sample shipping, 6-hour assay processing time, and a standardized CE-IVD kit for high throughput testing.

REDI-Dx is the result of a multi-year collaboration between DxTerity, Duke University, the University of Arizona, and Thermo Fisher Scientific; as well as patients and researchers from City of Hope Cancer Center and University of California Los Angeles.