DIACARTA®

TRANSFORMING CANCER CARE WITH

SPOT ON

PRECISION DIAGNOSTICS

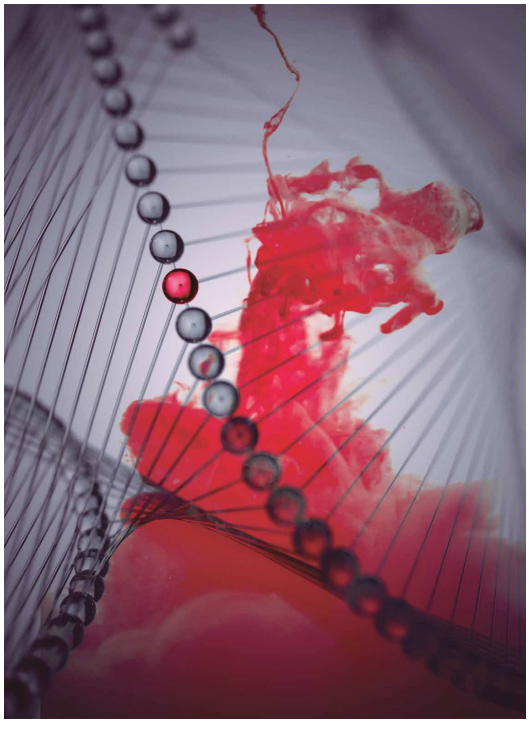
RadTox™ Test

A simple blood test to monitor tumor response & progression after treatment

The DiaCarta RadTox™ Test is intended to offer an early assessment of patient response to treatment. It is a simple blood test to monitor tumor response & progression after treatment by monitoring changes in cell-free circulating DNA (cfDNA) levels. To ensure effective patient care, it is necessary for doctors to know early on whether a patient is responding to treatment to mitigate adverse events.

The RadTox™ Test is based on DiaCarta's proprietary QuantiDNA™ Direct cfDNA Test technology. It directly measures the concentration of circulating cfDNA in blood sample, and is used to monitor the cfDNA levels during treatment, such as radiation therapy (radiotherapy), chemotherapy, immunotherapy, and other anti-cancer therapies.

Why is Blood cfDNA Useful?



The discovery of cell-free DNA (cfDNA) dates back to 1948, when Mandel and Metais found it in blood samples of cancer patients. It was later demonstrated that the level of cfDNA is significantly higher in cancer patients than healthy individuals (Leon et al., 1977)[1]. The cfDNA are typically small fragments of DNA that are released during the process of cell death (apoptosis and necrosis). In healthy individuals, the concentration for the cfDNA in blood is very low, average ranging from 0 to a few nanograms per milliliter. The blood cfDNA levels are significantly higher in patients with cancer and in patients with cardiovascular, infectious and autoimmune diseases.

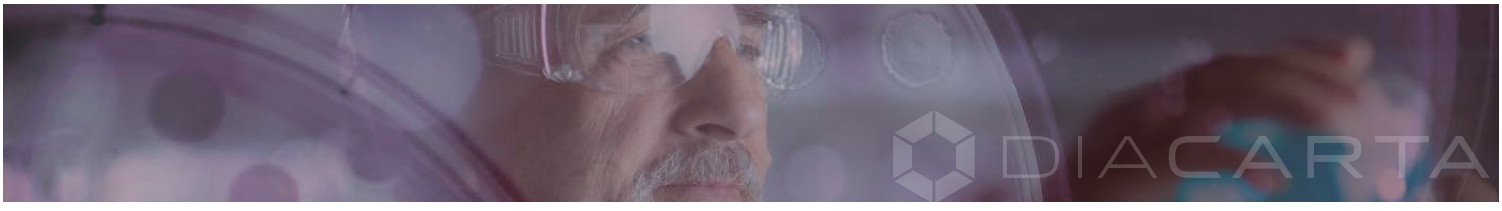
For cancer patients, tumor burden in the body is traditionally determined by advanced imaging technologies. The blood cfDNA level is a surrogate marker tumor burden and aggressiveness of cancer. It has been shown to be useful as a predictive and prognostic biomarker in overall survival[2,3].

About the RadTox™ Test

The RadTox™ Test was developed to measure the blood cfDNA level in assessment of radiotherapy (RT)-induced tissue damage in prostate cancer patients, in a clinical trial funded by National Cancer Institute (NCI). It was shown that the cfDNA level not only correlated with the integral dose, but also correctly predicted which patients receive proton versus photon RT[4].

In Clinical studies, it has been demonstrated that the RadTox™ Test can predict treatment response earlier than current standard-of-care assessment in other cancer types and anticancer therapies. Zhou et al[5], showed that the kinetics of plasma cfDNA during chemotherapy can function as a prognostic biomarker and efficacy predictor for non-small cell lung cancer (NSCLC) patients. Zhong et al[6], explored the clinical utility of using it as a tumor biomarker to monitor the efficacy of chemotherapy for gastric cancer.

The test results can be used by your doctors develop a more precise and personalized treatment plan. It help doctors to determine if you should remain on current treatment, or receive the treatment with adjusted dose and/or frequency, or switch to a different treatment.



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Disclaimer

RadTox™ Test is performed at DiaCarta laboratory as a laboratory developed Test (LDT). It was developed, and its performance characteristics were determined by DiaCarta, based on the clinical studies on radiation toxicity assessment on prostate cancer patients. The test is not cleared or approved by the U.S. Food and Drug Administration (FDA). This test has been validated at DiaCarta clinical laboratory pursuant to the CLIA regulations and can be used for clinical purposes. The test may be used on other therapies and cancer types, but the result interpretation has not validated by clinical trial. DiaCarta is not responsible for the decision made based on the RadTox™ Test result. The DiaCarta laboratory is regulated under CLIA as qualified to perform high-complexity testing.