DiaCarta RadTox™ Test Program Guidance

Test Description:

RadTox™ is a groundbreaking liquid biopsy test that directly measures cfDNA levels in plasma, bypassing the need for DNA extraction. With minimal sample requirements of just 10 µL of plasma per test, RadTox™ enables repeated clinical monitoring of this biomarker.

Test Indication:

The RadTox™ test, an advanced molecular laboratory-developed test (LDT), is designed for the quantitative detection of cell-free DNA (cfDNA) in peripheral blood plasma. Its primary purpose is to monitor cfDNA level changes during systemic therapy, including but not limited to radiation therapy, chemotherapy, immunotherapy, and other anti-cancer treatments.

RadTox™ Test Background:

Given its versatility, RadTox™ is applicable across all cancer types and stages. Key considerations include:

- Early-Stage Cancer Management: RadTox™ aids in monitoring tumor response throughout treatment phases, including pre- and post-operative stages. It provides valuable insights into surgical stress-induced inflammatory responses, helping assess prognosis and treatment efficacy.
- Adjuvant Treatments: RadTox™ monitoring offers crucial information during adjuvant therapies, allowing for treatment evaluation and surveillance.
- Radiotherapy and Chemotherapy Responses: RadTox™ testing provides insights into treatment responses, with notable observations in radiotherapy and chemotherapy settings.
- Post-Therapy Surveillance: Periodic RadTox™ testing facilitates monitoring for cancer recurrence risk, with significant increases indicating potential recurrence.

Sample Collection Guideline:

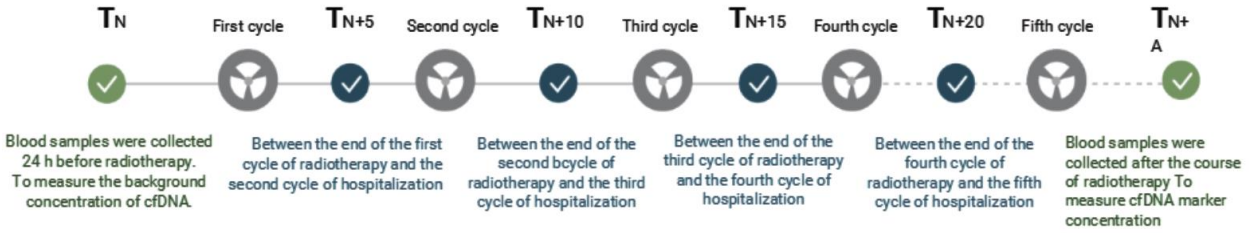
The RadTox™ program outlines a structured monitoring protocol, including:

- Weekly or biweekly RadTox™ tests are recommended for pre-surgery and continued throughout adjuvant treatments. After the treatment, monthly RadTox™ tests for monitoring are recommended.
- Synchronization of treatment schedules to ensure timely sampling before treatment changes and during imaging appointments.

Suggested Blood Sample Collection Schedule for Radiotherapy:

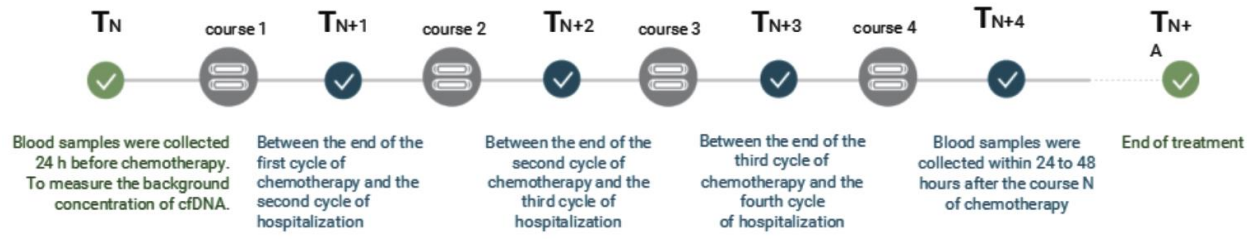
- Before radiotherapy, blood is collected from the patient to measure the background concentration of cfDNA.
- Blood is collected within 24-48 hours after the first radiotherapy session to assess the response to the treatment.
- Blood is collected again after the completion of the course of treatment.

- The timing of the blood collection process can be adjusted based on the results of cfDNA testing or the radiotherapy plan.
- Blood can be collected again if the patient experiences fluctuations in the condition or a decline in physical health during the treatment.



Suggested Blood Sample Collection Schedule for Chemotherapy:

- Blood is collected from the patient 24 hours before the start of treatment to measure the background concentration of cfDNA.
- Blood is collected within 24-48 hours after the completion of each chemotherapy session to assess the current treatment efficacy for the patient.
- After the completion of the entire treatment, blood is collected once again for testing to evaluate the overall treatment effectiveness for the patient.



Medical Benefits:

Key medical benefits of RadTox™ testing include:

- CMS Approval: RadTox™ Laboratory Developed Test (LDT) approval by CMS ensures reimbursement coverage, enhancing accessibility for eligible patients.
- Comprehensive Monitoring: Allows continuous surveillance of tumor response, optimizing treatment management across various phases.
- Personalized Clinical Information: Provides comprehensive data for informed decision-making, complementing imaging studies during treatment.

Additional Benefits:

- Superior Technology: RadTox™ is based on isobDNA technology, ensuring high accuracy and sensitivity.

- Versatility: RadTox™ has been utilized in studies involving various cancer types and stages, providing valuable insights across the spectrum of cancer care.
- Ease of Deployment: The test is easily deployable in most clinical laboratories, requiring minimal specimen processing and standard lab skills.
- Prediction of Radiation Sensitivity: RadTox™ can predict radiation sensitivity, enabling proactive management of potential toxicities, particularly in prostate cancer patients.
- Long-term Cancer Management: RadTox™ facilitates long-term monitoring and prediction of cancer recurrence, contributing to improved patient outcomes and quality of life.

For Physicians:

RadTox™ testing offers several advantages for physicians, including:

- Integrated Care: Facilitates cohesive patient management by integrating surgery, radiation therapy, and chemotherapy into a unified plan.
- Data-Driven Decision Making: Empowers physicians with comprehensive data for personalized treatment adjustments based on individual patient responses.
- Proactive Cancer Management: Early detection of significant RadTox™ number changes enable proactive intervention, potentially improving patient outcomes without relying solely on imaging.

In summary, DiaCarta's RadTox™ program offers comprehensive monitoring and personalized care for patients undergoing cancer treatments. It supports physicians in making timely, informed clinical decisions, ultimately enhancing patient care and treatment outcomes.