

Application of oncoMonitor liquid biopsy assay for monitoring of therapy and minimal residual disease in various solid cancers

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Background: The detection and quantification of somatic aberrations in circulating tumor DNA (ctDNA), generally referred to as "liquid biopsy", has gradually evolved from its early technological development to routine clinical use. In its initial application, plasma-derived ctDNA serves as an alternative source to tissue. This, in particular, where tissue is available or when DNA yield is insufficient. In addition to predictive testing, ctDNA may also serve as a negative prognostic biomarker as ctDNA has been associated with poor outcome across various treatment types. ctDNA positive patients exhibit reduced times to progression as well as shorter overall survival. Finally, there is a growing interest in utility of ctDNA dynamics for continuous monitoring of ongoing therapy. For the latter, so-called „tumor informed“ approach is most appropriate in which somatic mutations found in tumor tissue are subsequently targeted in ctDNA.

Methods: Our accredited tumor-informed oncoMonitor[®] ctDNA test utilizes a simple PCR-based mutant heteroduplexes assay capable of detecting mutants at fractions as low as 0.5%. Initially, tissue mutation profiling is done by Illumina NGS sequencing using a rapid AmoyDX HANDLE panel NGS technology. A simple PCR is then designed for detection and quantification of mutants in ctDNA by heteroduplex separation on capillary electrophoresis (SeqStudio genetic analyzer).

Results: We employ the approach for longitudinal monitoring of ctDNA in patients treated in advanced stages of colorectal, lung and breast cancer. Our data shows correlation with the clinical course of the treatment including decrease in ctDNA levels at tumor regression or reappearance or increase in levels at disease recurrence or progression. In cases of surgical treatment we have detected residual disease suggesting R1 resection with a need of subsequent adjuvant therapy.

Conclusion: The oncoMonitor[®] ctDNA assay shows very promising results when applied for monitoring of ongoing therapy.

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