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MRD ASSAY: Tumor-informed MRD assay for solid tumors using liquid biopsy

In order to offer the most sensitive MRD diagnostics possible for solid tumors, we use a highly sensitive MRD assay. The MRD test is a tumor-informed ctDNA test that was developed specifically for postoperative MRD applications. The technology used is an improved version of the method used in the entire DYNAMIC clinical trials, which enables the detection of ctDNA at the lowest levels of residual disease.

For this purpose, a whole genome sequencing (WGS) is performed on tumor DNA from a paraffin block (at least 30% tumor cell content) in comparison to normal DNA from a blood sample to identify as many somatic (tumor-specific) mutations as possible. Based on this initial tumor profile, a patient-specific, individualized test is then developed and the tumor load is determined in an initial blood sample (the so-called ID report). With the patient-specific, individualized test, tumor development can then be measured as often as desired in the further course of the disease (further MRD reports).

The DYNAMIC study is the first prospective, randomized, interventional study to demonstrate the clinical utility of MRD testing to guide adjuvant therapy.
(Tie J, Cohen JD, Lahouel K, et al. Circulating tumor DNA analysis guiding adjuvant therapy in stage II colon cancer. N Engl J Med. 2022;386(24):2261-2272. doi:10.1056/NEJMoa2200075)

Prior to the DYNAMIC study, a wealth of observational data showed that ctDNA has high predictive value for disease recurrence. While these studies were important in establishing the prognostic value of ctDNA, the clinical utility of ctDNA testing to inform patient management in real time was only definitively demonstrated in the DYNAMIC study. Other studies are investigating the utility of ctDNA to guide clinical decisions in other indications beyond Stage II colon cancer:

- In Stage III CRC, it is generally accepted that all patients should receive adjuvant therapy; however, the appropriate treatment intensity and duration may be suboptimal when based on clinicopathologic risk factors alone. The DYNAMIC-III study is currently evaluating the utility of ctDNA to guide de-escalation and escalation of therapy to reduce overtreatment and undertreatment in stage III CRC patients.
- Ovarian cancer patients may receive neoadjuvant therapy followed by debulking surgery and adjuvant therapy. The DYNAMIC Ovary trial is investigating ctDNA as a prognostic marker when analyzed before, during and at the end of treatment in both the neoadjuvant and adjuvant setting.
- Further studies are investigating the validity and benefits of ctDNA testing in patients with rectal and pancreatic cancer.

To perform the initial analysis (ID-report), we require:
- initial tumor material (FFPE),
- 3x 9 ml peripheral venous blood (Streck tube)

For all further measurement points (MRD-report), we require:
- 3 x 9 ml peripheral venous blood (Streck tube)

If you have any questions, please contact us on 040-707085-311.