

FOUNDATIONONE® LIQUID

Patient information: frequently asked questions

How does cancer develop and what are the genetic characteristics of a tumour?

THE DIAGNOSIS is often completely unexpected and shocking: cancer. What actually is cancer? Over time there have been lots of different definitions and attempts to explain cancer. However, according to scientific consensus it is now clear: the starting point of cancer is usually a change in one or more genes in the body's cells.

Currently, hundreds of different mutations in cancer-relevant genes are known about, and these are divided into four main groups.



Determining which mutations a tumour has is essential for further treatment and a key element of personalised medicine.

There are thus various methods for determining the mutations (Page 6).

What is a genetic tumour profile?



We are learning more and more about how diseases develop - down to the level of the smallest particles, the molecules, from which our cells are built. Cancer develops when particular genes in the genetic material of the cells have changed. The genetic changes are like a fingerprint: this is also called a "genetic tumour profile". The genetic tumour profile shows all of the mutations in currently known cancer-relevant genes. This knowledge is a key element of personalised medicine.

What is personalised medicine and what are targeted therapies?

THE APPROACH OF PERSONALISED MEDICINE is to identify patient groups who possess certain characteristics, such as the same genetic changes, and who could therefore benefit in particular from a medication tailored to said characteristics. The doctors then decide on the basis of the located genetic characteristics, among other things, whether or not the therapy is suitable for you. They also take into account your general health status.

TARGETED THERAPIES are part of personalised medicine. The treatment is aimed directly at the cancer cells and can impede or slow down the growth of the tumour. This means: scientists are already looking into developing new medications according to the altered characteristics of cancer cells, which play a central role in tumour growth. Unlike healthy body cells, cancer cells exhibit a multitude of genetic changes. However, the mutations are not always the same - even when the type of cancer is the same, for example lung cancer. Whether targeted therapy is suitable - and if so, which therapy - therefore depends on whether there are corresponding changes in the tumour DNA.

Which different test methods are there?

SINGLE-MARKER TEST

The so-called single-marker tests are currently the most common approach in diagnostics. These tests look for one or two classes of genetic changes in a particular gene. Namely changes that have a direct connection with cancer or that indicate whether a targeted therapy is effective.

MULTIGENE "HOTSPOT" TEST

In this test, predefined, known mutations or genetic changes are analysed in particular genes. Other important genetic changes for cancer, which do not belong to the predefined changes, therefore cannot be analysed in hotspot tests. Therefore, these tests do not detect all genetic changes in a gene, but only changes that were specifically looked for.

COMPREHENSIVE GENETIC TUMOUR PROFILE

In a comprehensive genetic tumour profile, all four classes of cancer-related changes are analysed in hundreds of genes using Next Generation Sequencing*. Hence these tests are often described as "cross-indication" or applicable for all types of cancer. In lung cancer, for example, the test can simultaneously identify mutations in EGFR, RAS, ALK, ROS etc. as well as all other clinically-relevant genes (e.g. MET or mTOR) in a single test.

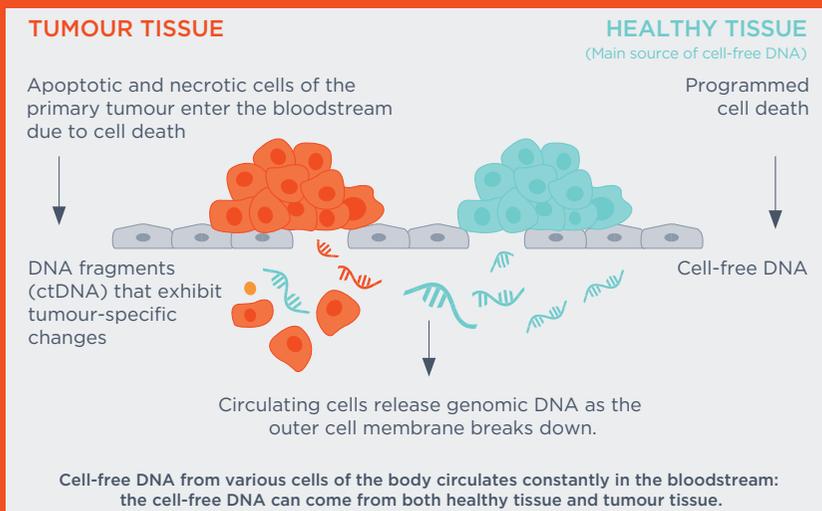
*The name Next Generation Sequencing (NGS) encompasses several methods of genetic analysis, which can simultaneously identify (sequence) a very large number of DNA molecules.

What is FoundationOne® Liquid?

FOUNDATIONONE®LIQUID is a blood-based test procedure. The test can identify clinically-relevant genetic changes that may be responsible for cancer growth in a particular patient. In this test, 70 cancer-relevant genes are examined in the blood sample with regard to genetic changes as well as the MSI status of the circulating tumour DNA. FOUNDATIONONE®LIQUID also provides an overview of the therapies and clinical studies that may be pertinent based on the identified gene changes. The results of this test procedure can help your oncologist find a therapy that is optimally tailored to your tumour profile.

FOUNDATIONONE®LIQUID can be used in particular if in the case of solid tumours:

- there is no longer sufficient tumour tissue for analysis
- the tumour has relapsed and the metastases are spread throughout the body
- the tumour is in a location where a biopsy is impossible



Liquid biopsy refers, among other things, to the analysis of circulating tumour DNA in the blood. It may differ from normal blood cells through particular characteristics. The blood also carries DNA from healthy cells. The tumour DNA is detected by examining the entire cell-free DNA from the blood sample for changes (mutations).

How likely is it that FoundationOne[®] Liquid will find a relevant genetic change?

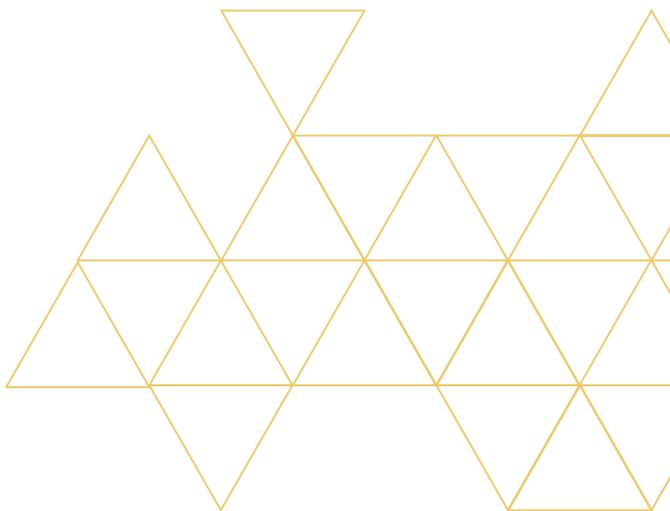
It is not possible to predict which tumour will exhibit which genetic change. It is precisely for this reason that FOUNDATIONONE[®] LIQUID examines 70 potential cancer-relevant genes with regard to genetic changes as well as the MSI status of the circulating tumour DNA of solid tumours. The DNA in your blood may contain information regarding which gene changes play a role in the growth of your tumour.

Which therapy options are presented in the results report from FOUNDATIONONE[®] LIQUID depends on which mutation was found. Moreover, the treatment options depend on the current status of research into this mutation with regard to potential targeted medications. In addition, it is possible that studies are mentioned in the report that are investigating new active ingredients for your identified mutation. However, a corresponding choice of therapy is not yet available for each genetic change identified using the test.

In general: the treating doctor weighs up the information on the therapy options in the report with various other factors such as your general condition and any possible side effects. This information is not included in the FOUNDATIONONE[®] LIQUID results report. For this reason, it may be the case that your doctor also recommends an alternative therapy to you or decides that you are not suited to a particular therapy.

Does the type of cancer I have or how advanced my cancer is make a difference?

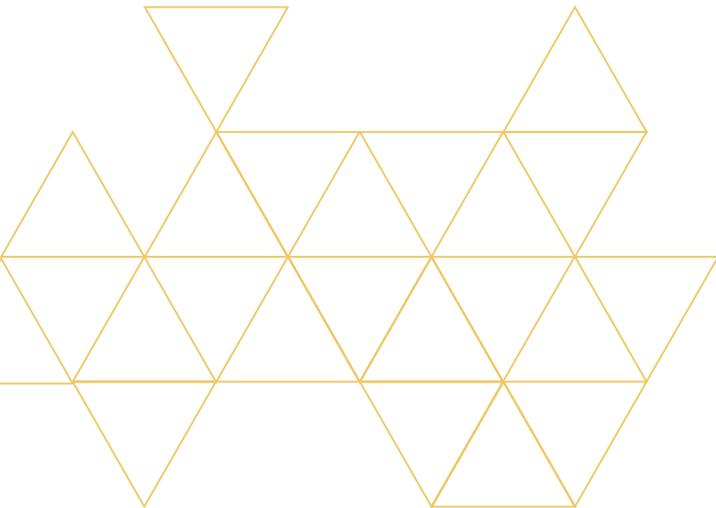
FOUNDATIONONE®LIQUID was developed in such a way that in late-stage, solid tumours, the test can provide information on the genetic changes of the tumour by means of a blood sample.

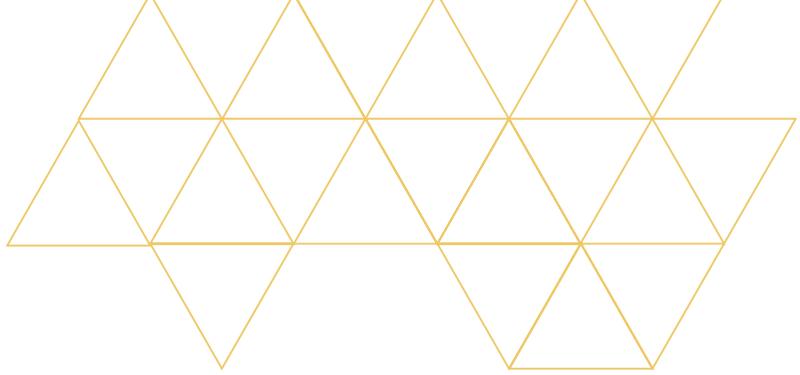


Will FoundationOne[®] Liquid indicate the best treatment for me?

You can only find your best treatment together with your doctor. This is because many more factors play a role in the decision for or against a therapy than are analysed in the test. For example, your personal situation, your age, your general health status and how you want to live your life.

The results of the test, i.e. your personal tumour profile, may present options to you and your doctor in terms of how your individual mutation profile can be treated.



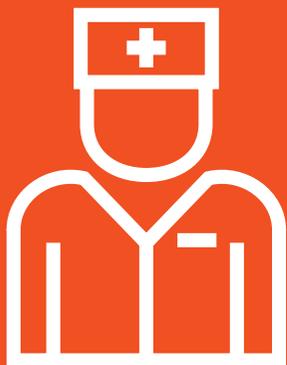


Can FoundationOne[®] Liquid predict whether or not chemotherapy will work?

No. The comprehensive genetic profiling was not developed to predict if and how an individual mutation profile will respond to a particular chemotherapy. However, FOUNDATIONONE[®]LIQUID may show whether there is a genetic change in the tumour that can be treated with so-called targeted therapies.

Does FoundationOne[®] Liquid show whether a mutation was inherited genetically?

Although FOUNDATIONONE[®]LIQUID shows which genetic changes are present in a type of cancer, it cannot explain which factors are causally responsible for the changes. For example, the test can detect that your tumour exhibits a rare genetic mutation, but it cannot determine whether this was inherited or developed due to external influencing factors.



How does
FOUNDATIONONE®LIQUID
work?

5 SIMPLE STEPS:



1 Firstly, discuss with your doctor whether you are a suitable candidate for FOUNDATIONONE® LIQUID.

2 Your doctor will subsequently request the analysis with FOUNDATIONONE® LIQUID.

3 Two blood samples (2 x 8.5 ml), which are collected by your doctor, are required for the analysis.

4 The blood samples are analysed in the Foundation Medicine laboratory in Cambridge, USA.*

5 Following a careful analysis, a results report that can be easily understood by your treating doctor is created, in which the identified gene changes are listed and potential targeted therapy options and clinical studies are specified. The molecular tumour profile created in this way can help you and your treating doctor make the right decisions to adapt the treatment to your personal needs.

* generally in between 10 and 14 days



How long does it take to receive the test results?

It takes between 10 and 14 days to analyse and evaluate the tumour sample and create the results report. Your doctor will subsequently receive the report. You can then discuss the results together.

Will my health insurance cover the costs?

The costs for FOUNDATIONONE®LIQUID are generally not covered by health insurance and will have to be paid by you yourself.



MORE INFORMATION ON
FOUNDATIONONE®LIQUID CAN BE FOUND

ONLINE AT
www.foundationmedicine.de

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