Test for Presence of Cell-Free Tumor DNA

Patient Information

You are a patient interested in a test, which utilizes a blood sample analysis which can provide an indication of the presence of a new tumor malignancy. Below we explain what such a test can deliver, so that you can make an informed decision whether to proceed with having such a test performed.

How does the test work?

In recent years many new scientific findings in cancer research have been reported which have led to new therapies, but also to new diagnostic methodologies. Today we know that in a very large number of cases a tumor is indicated by substantial changes in the genetic material of the degenerated cells. If a patient has such a tumor then the genetic material is different than that from all other normal cells of the body, and we can detect this difference with modern methodologies. Many tumors release their cellular content such as DNA into the bloodstream e.g. due to cell death. Among other indicators, many tumors exhibit gains and losses of large sections of the genetic material and this is what we test for. These tumor-specific changes, at sufficiently high concentration, allow for detection in the blood and thus give us the chance to detect a tumor before symptoms appear.

This blood analysis to determine *cell-free tumor DNA* is a new aid, which can help with the early detection of tumors. However, this test should supplement and not replace the regular screening checkups, which you should continue to undergo.

Can any other diseases be detected?

Fundamentally, current medical science accepts that the described changes occur almost exclusively with tumors. These are not necessarily malignant; several clinically benign tumors are described which exhibit similar patterns of genetic material changes. Several of these tumors can change over time and become malignant. In this process the genetic changes continuously increase. Other tumors are generally not affected and rarely degenerate, yet also lead to disease (for example, hormone-producing thyroid adenomas).

What does the test results mean?

If our cell-free tumor DNA test measured value lies within the range statistically found for healthy persons, then that means that the sample contained no indication of a tumor exhibiting the above-mentioned preconditions. Then there are no consequences from the test result. Your doctor may wish to run other tests to check for

cancer and these other medical procedures should be performed. We would recommend repeating the Chronix test at a regular interval at your own discretion.

Given a substantially elevated measured value, we will recommend to your doctor to take a second sample to verify the result (at no additional cost to you). If the initial result is confirmed, we will recommend to your doctor to initiate further diagnostic procedures. Next should be checked, for example, if a benign tumor is the cause of the elevated values. Your doctor will discuss with you which further diagnostics are recommended to detect and treat a potentially malignant tumor as soon as possible.

If the measured value is slightly elevated, we will recommend taking an additional blood sample from you (at no additional cost) after approximately 4-8 weeks to clarify the cause of the elevation. Theoretically, there are several viral diseases, which could cause a slight elevation. That is why one should wait some time before taking the second blood sample. The result will be evaluated by your doctor in consideration of all other medical findings.

In summary, it can be said that the test can detect tumors which have such specific changes in the genetic material which we test for and which release these in sufficient quantity into the blood. Many solid tumor types have these changes, several tumor types are nevertheless less often affected by them.

With this test, it is possible to detect a large proportion of tumors before they are noticed through symptoms.
A therapy can then be initiated earlier than normal. Tumors without these biological preconditions cannot be detected, thus a negative result does not rule out a tumor with certainty. Likewise, no tumor may be detected during further medical investigation by other tests despite an elevated level of the test.

What else must I know?
It is possible that in performing your test we discover inherited changes. You can decide whether we should inform you of such incidental findings. If we determine that it is a change indicative of a disease, then we will recommend a consultation with a geneticist who can explain such findings in depth to you.

I want to be informed of a finding of an inherited change in DNA:

yes / no (cross out whichever does not apply)

How will the test be performed?
A sample of your blood will be drawn for the test. The analysis report will be available within 2-3 weeks.
Our laboratory has specialized expertise in performing the test described above. The state-of-the-art procedures and methodologies we employ are subject to continuous

quality control so that we can guarantee delivering to you the best possible test quality.

I have read and understood the above information. All questions I had have been sufficiently answered. I agree to have the test performed and have been informed that this innovative test does not provide complete certainty, in particular does not cover every occurance of tumor, and that other diseases which are completely unrelated to tumors can lead to a positive test result.

Place, Date _____,_____

_____
_____

Patient

(_____)
Name in block letters

Doctor providing this information

(_____)
Name in block letters