FOUNDATIONONE® CDx

Comprehensive Genomic Profiling: your questions answered

Information on the FoundationOne® CDx test

FOUNDATION MEDICINE®

Roche

This booklet provides you with useful information about the FoundationOne® CDx comprehensive genomic profiling test.

This booklet is only a brief guide to genomic testing. If you have any questions about the test, your diagnosis or treatment, please speak to your doctor.

For further information:
This booklet should supplement the advice given to you by your doctor. If there is anything you don't understand or if you have any concerns, please speak to your doctor in the first instance.

Contact Roche Foundation Medicine - Medical Information: Phone: 0800 3281 629

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What is FoundationOne® CDx comprehensive genomic profiling?

Our bodies are made up of trillions of cells. Each cell has an instruction manual called DNA, which programs all the functions of the cell, including the instructions for cell reproduction. Sometimes, the DNA in our cells gets damaged or mutated.

These changes are known as genomic alterations and can cause cancer by allowing cells to grow out of control and thus form tumours.

It is possible to look for genomic alterations that may be involved in a person's cancer. Knowing which genomic alterations are found in a tumour may help personalise cancer care by matching any available medicines or clinical trials to those genomic alterations.

FoundationOne® CDx comprehensive genomic profiling looks for all known alterations in solid tumours, irrespective of the location and may help to identify treatments or trials in helping to treat your cancer.

What are the three types of genomic tests used in cancer?

Single marker tests
Look at changes in single genes, or within single proteins, known to be associated with specific types of cancer.

Hotspot gene panel tests
Look for specific changes in groups of genes known to be associated with cancer. Typically, they focus on common genomic alterations associated with specific types of cancer.

FoundationOne® CDx comprehensive genomic profiling
Looks for all four classes of genomic alterations required to profile cancer at a molecular level, in a single sample of cancer tissue.[1]

Base substitutions
A replacement of a base pair (the building block of DNA) that alters gene function.

Copy number alterations
People have two copies of most genes. In some cases, the number of copies varies, so they can have one, three, or more copies.

Rearrangements
Structural changes caused by breakage of DNA, followed by incorrect rejoining.

Insertions and deletions
An addition or removal of a piece of DNA within a gene.

1. Data on File RXUKRFMI00065

How can treatment be personalised to me?

Cancers with certain genomic alterations may respond to some medicines better than others. These are known as targeted therapies.

Targeted therapies are designed to attack cancer cells affected by certain genomic alterations. They are therefore specific in what they do and often more effective at treating cancer than just chemotherapy alone.

Having a FoundationOne® CDx test to know which genomic alterations, if any, are present in your cancer will help your doctor to understand:

- If any currently available targeted therapies are suitable for you.
- If you may be a candidate for a clinical trial (a test of a targeted therapy that is being developed).
- If no genomic alterations are found, this may help your doctor to rule out medicines that may not work for you.

Targeted therapies work in a number of ways, including:

- Blocking or turning off the signals that tell cancer cells to grow and divide.
- Stopping new blood vessels that feed the cancer cells from developing.
- Killing the cancer cells.
- Reactivating the body's own immune system to attack the cancer cells.

What is a "targeted" therapy?

Targeted therapies are suitable for people with certain genomic alterations.

Here are four people with different genomic alterations, represented by the different shapes above their heads.

A treatment that works on the circle genomic alteration (B) would only be suitable for patient B.

A treatment that does not work on the hexagon genomic alteration (A) might be suitable for patients B, C and D, but not for patient A.

How does FoundationOne® CDx work?

Takes on average 11-14 days

1. 
   You and your doctor talk about testing options together. Your doctor orders the appropriate test. Funding is arranged either directly through you or your health insurer.

2. 
   Your doctor sends a tissue sample to Roche Foundation Medicine for testing. If an appropriate recent sample is not available your doctor may wish to arrange for another sample/specimen to ensure the most up to date information of your cancer is available.

3. 
   Roche Foundation Medicine analyses your sample to find cancer-causing genomic mutations. The initial results are extensively reviewed to ensure the quality of the results.

4. 
   Your doctor receives the results.

5. 
   You and your doctor talk about the results and next steps for you.

How long does FoundationOne® CDx take to complete?

Your doctor will typically receive the results within two weeks after the sample has been received by the Roche Foundation Medicine laboratory.

There is sometimes a need to retest certain parts to ensure the quality of the result and this may cause a slight delay.

There may also be circumstances where your DNA may not be able to be analysed, or where technical issues affect the test outcome. If this happens, your doctor will discuss this with you and there may be a need for another sample to be sent.

How will the results of FoundationOne® CDx help my doctor?

The results will show your doctor what genomic alterations, if any, were found in your sample.

It will also highlight if there are targeted therapies currently available for that genomic alteration. The listed therapies may be licensed for your tumour type or licensed for another tumour type and as such may not be approved or funded for use in the UK. It will also show if there is a clinical trial that you and your doctor may want to consider.

Your doctor will discuss the results of the test with you, so you can decide together what the next steps are for you.

Important considerations of FoundationOne® CDx

No guarantee of identifying a suitable treatment
The results may not identify a medicine or clinical trial suitable for you, or one that is currently available in the UK.

No guarantee of finding a genomic alteration
Sometimes no genomic alteration linked to a targeted treatment will be found. If this is the case your doctor will discuss alternative treatment options for you. This may mean that your cancer is not linked to any of the genes that are known today to be associated with cancer.

However, showing no genomic alterations may still help your doctor to rule out medicines that may not work for you.

No guarantee that any treatment will work for you
It is important to understand that while the FoundationOne® CDx may help you and your doctor decide on what is right for you, however there is no guarantee that the treatment will work for you.

Frequently asked questions

Does it matter what kind of cancer I have or how advanced the cancer is?
FoundationOne® CDx is designed to analyse most types of solid tumour, regardless of where it is found in the body, or how advanced it is. FoundationOne® CDx is performed on the most recent biopsied tissue.

Can FoundationOne® CDx predict if chemotherapy will work for me?
No. Comprehensive genomic profiling does not predict how a cancer will respond to chemotherapy, but does aim to provide information on targeted and immunotherapies.

Your doctor will discuss the results with you to decide together what the next steps are that are right for you.

Can FoundationOne® CDx tell me if a genomic alteration was inherited from one of my parents?
No, FoundationOne® CDx looks only for genomic alterations in the tumour and as such is not designed to identify genomic alterations that are inherited and present in every cell of your body. Certain alterations found in the tumour are however linked to inherited alterations and your doctor may want to discuss further genetic testing for you and your family.

What are my payment options for FoundationOne® CDx?
If you have private healthcare please contact your insurer - many insurers will cover the test. Alternatively, if you are a self funding or an NHS patient with approval from your doctor you may pay directly. Please contact Roche Foundation Medicine on 0800 328 1629 or medinfo.uk@roche.com.

Can I cancel a FoundationOne® CDx after it has been ordered?
The test can be cancelled at any point up until the results are issued. Please contact your doctor to cancel the test. A reason for cancellation is not required.

When do I need to pay and under what circumstances can I get a refund?
Payment is required before the Roche Foundation Medicine genomic test can be started.

If the test is cancelled, or if there are problems with the sample that prevent the test from being completed, you will receive a refund.

For further information about these services:

Visit online:
www.foundationmedicine.co.uk

To find out more contact Medinfo on:
Telephone: 0800 328 1629
Email: medinfo.uk@roche.com

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