FOUNDATIONONE® CDx

FOUNDATIONONE® LIQUID CDx

UNDERSTANDING YOUR CANCER AND PERSONAL TREATMENT PATH

FoundationOne®CDx uses a sample of your cancer tissue and FoundationOne®Liquid CDx a blood sample to provide a more complete picture of your cancer and help open up treatment possibilities for you.[1-4]

See more, do more

FOUNDATION MEDICINE®

Roche

Cancer occurs due to mutations affecting the way your cells work and grow[5,6]

What causes cancer?

HEALTHY CELL WITH NORMAL DNA

DNA and RNA make up the genes within your cells and contain the genomic information needed for your body to work correctly[7,8]

CHANGED (MUTATED) DNA

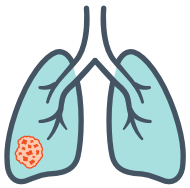
When your cells divide, the DNA is copied and translated into RNA to make proteins. Together, proteins and RNA control the activities of the cell like what it does and when it divides. Sometimes an error can occur during this process. These errors are called mutations[6,8,9]

CANCER CELL

UNCONTROLLED CELL GROWTH

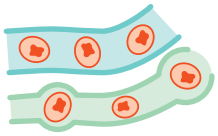
Mutations may affect the way your cells work and cause uncontrolled cell growth. These cells may become cancer cells[8]

MALIGNANT TUMOUR

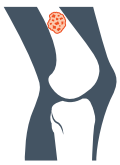


Cancer cells ultimately form a malignant tumour (a mass of cancer cells that may invade nearby tissues)[8]

CANCER CELLS ENTER BLOOD VESSELS OR LYMPHATIC SYSTEM



METASTASES: CANCER CELLS FORM SECONDARY TUMOURS IN OTHER LOCATIONS



If cancer cells enter the blood vessels or the lymphatic system, they spread to other locations within the body and can form tumours (metastases)[10,11]

Each person's cancer has unique mutations that might respond better to certain treatments[4,12,13]

Due to advances in scientific and medical research, we now understand more about the mutations causing cancer. It is now known that even if you have the same type of cancer as someone else (e.g. breast cancer), your mutations may differ and you may need different treatment. Conversely, even if your primary tumour is in a different organ, the mutations can be the same. You may then benefit from a similar treatment.[14]

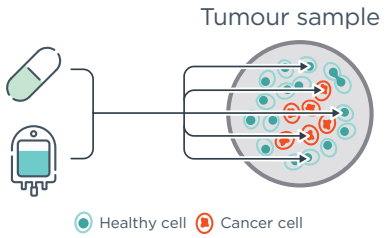
Knowing the mutations in your cancer can help you and your doctor understand your treatment options and may help to personalise your treatment[12,13,15–17]

What are targeted therapies and personalised treatments?

There are several different treatment options, including surgery, radiotherapy, chemotherapy, targeted therapy and immunotherapy.[18]

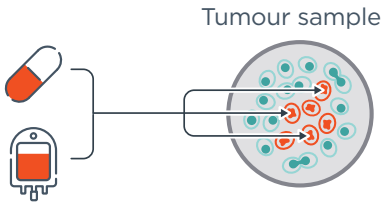
Targeted therapies are able to target cancer cell with specific mutations. These are different from non-targeted therapies, such as chemotherapies, which act on any type of fast-growing cell, whether cancerous or healthy.[19,20] Immunotherapy is a type of targeted therapy that uses the body's immune system to fight cancer.[21] A biomarker is a sign or marker of how a cell is behaving. It might indicate a type of disease or help to predict how the cell will react to certain treatments.[22] If a tumour has a specific biomarker, targeted therapies may be used against this biomarker. By testing your tumour sample, your doctor can consider this information for identifying the most appropriate treatment approach for your cancer.

NON-TARGETED THERAPIES



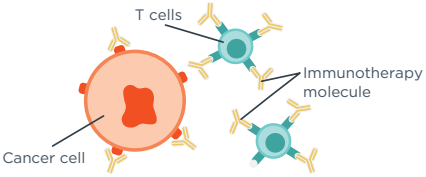
Target any fast-growing cells like cancer, but also cells such as those in your bone marrow, reproductive system, mouth lining and hair follicles.[19,23]

TARGETED THERAPIES



Target cancer cells that only contain specific cancer-related mutations.[20]

IMMUNOTHERAPIES

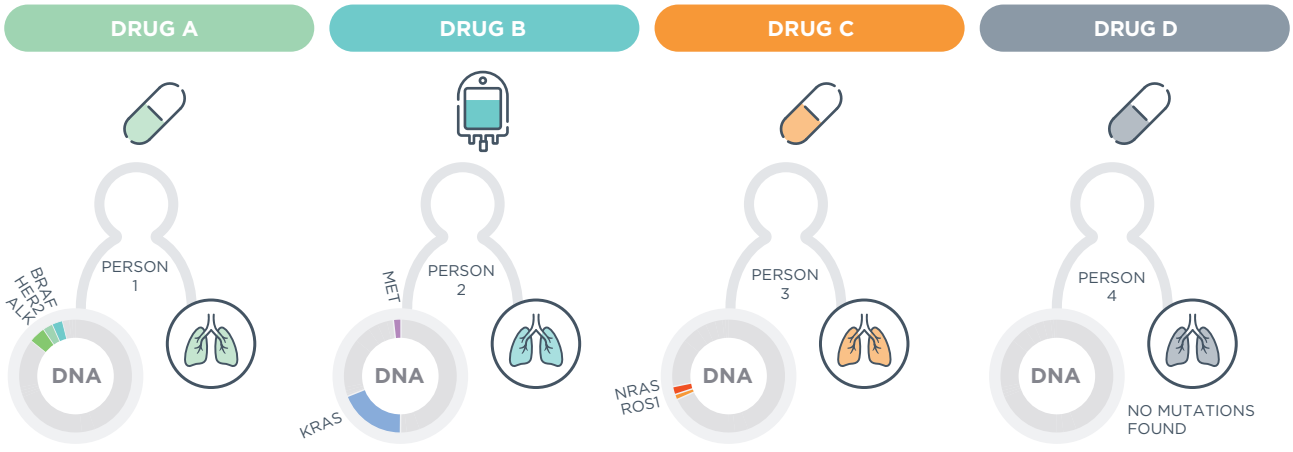


Activate or imitate your immune system to target cancer cells.[21]

How can knowing your cancer's mutations help your treatment plan?

If certain mutations are found in your cancer cells, your doctor may be able to give you a more precise treatment, such as a targeted therapy or immunotherapy, based on this finding. There might be cases where either no relevant mutation is found or no targeted treatment option is available for the mutation that has been identified. This is also valuable information to support further treatment planning.[12,13,15–17]

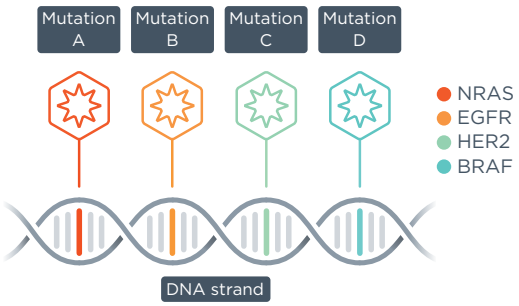
Precision medicine increases the likelihood you will find a targeted therapy, which improves your chance of responding well.[4]



There are several cancer testing methods available, which search for mutations in your cancer cells

Genomic testing encompasses single biomarker testing, hotspot testing and comprehensive genomic profiling. They all test your cancer sample for mutations.

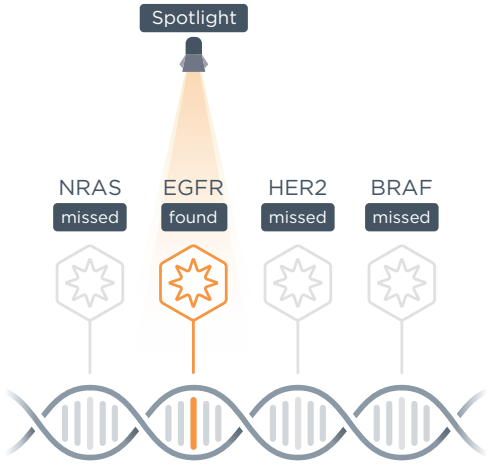
For example, this cancer cell DNA has four mutations.



How do single biomarker tests or hotspot tests work?

Single biomarker testing or hotspot testing only looks for predefined individual mutations within limited regions on your cancer cells' DNA. These mutations are always chosen before testing starts. **So, if you do not choose to look for a mutation, you will not find it.**[24,25]

Single biomarker testing or hotspot testing



Compared with other tests, comprehensive genomic profiling can find more cancer-driving mutations important for your treatment plan.[1–4]

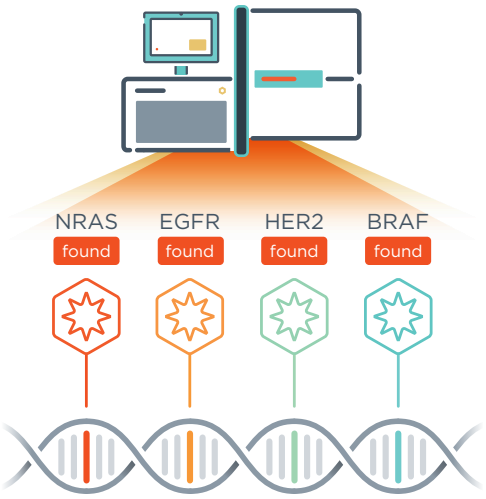
What makes comprehensive genomic profiling different?

Comprehensive genomic profiling provides a more complete picture of your cancer by searching for multiple mutations across a broad region of your cancer cells' DNA.

Comprehensive genomic profiling looks at **all potential mutations** that may drive your cancer, even if these are very rare, in a single test.

This **increases your chances of finding important mutations right away.** This may also increase the chance of finding a more precise treatment for you.[1–4]

Comprehensive genomic profiling



Foundation Medicine®'s comprehensive genomic profiling may improve your chance of finding a personalised treatment.

Which Roche Foundation Medicine service may be suitable for you?

Foundation Medicine offers a high-quality portfolio of comprehensive genomic profiling services[1,2,26,27]

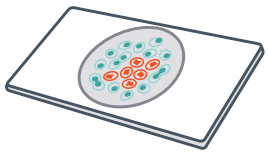
Foundation Medicine offers comprehensive genomic profiling services that can help you and your doctor better understand your treatment options. There are different Foundation Medicine tests available for patients with different types of cancer. FoundationOne CDx and FoundationOne Liquid CDx are for patients with all types of solid tumour, e.g. lung, prostate or breast cancer.[26,27] FoundationOne®Heme is for patients with sarcomas and blood cancers, such as leukaemia.[28]

Discuss with your doctor whether a tissue-based test or blood-based test is recommended for your cancer

FOUNDATIONONE®CDx

Uses a tissue sample (tissue biopsy)
Tests over 300 genes

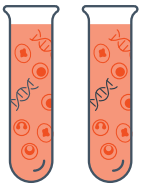
Tissue biopsy
Your doctor will take a small sample of tissue from your cancer site using a needle, surgery or endoscopy. They will preserve this sample and will use it to run the comprehensive genomic profiling test.[29,30]



FOUNDATIONONE®LIQUID CDx

Uses a blood sample (liquid biopsy)
Tests over 300 genes

Liquid biopsy
Your doctor will take a blood sample from a vein, usually in your arm or hand.[31] They will collect two tubes of blood to send off for the test. The test will then analyse DNA that is circulating in your blood.[2,27]



Why is it important to search for mutations in your cancer?

If certain mutations are found in your cancer cells, your doctor may be able to give you a more precise and personalised treatment based on this finding.[12,13,15–17]

Foundation Medicine tests search for multiple mutations in your cancer cells and help you and your doctor optimise and personalise your treatment plan.[1–4]

It may help open up new treatment possibilities, including therapies and clinical trials.[26,27]

What if you've already had a test?

FoundationOne CDx and FoundationOne Liquid CDx can find mutations that other tests miss because they look broadly and deeply into your cancer DNA and may cover genes that have not previously been tested. So even if you've already had a test, or already received some treatment, it might be beneficial to test your cancer again.[1–3,17,25–27,32–35]

In what situations might FoundationOne Liquid CDx be beneficial?

QUICK TREATMENT DECISION

FoundationOne Liquid CDx enables quicker treatment decision making by avoiding potential delays associated with tissue biopsy and delivering your report in less than **2 weeks** after receipt of your blood sample at the laboratory.[2,27]

TISSUE BIOPSY NOT POSSIBLE

FoundationOne Liquid CDx can be beneficial when an invasive tissue biopsy is not recommended for your cancer, the tissue sample that has already been taken is not suitable for analysis or to complement a tissue-based test. It can also be an alternative to tissue-based testing when access to healthcare infrastructure for tissue biopsy is limited.[2,27]

EVALUATE TREATMENT RESPONSE

FoundationOne Liquid CDx might provide an 'update' on how your cancer is responding to treatment without having to take a tissue sample and provide genomic information for potential treatment adaptation.*[2,27]

ASSESS GENES IN METASTASES

FoundationOne Liquid CDx will test for mutations in your blood which mainly contains circulating DNA from your primary tumour but also from metastases if the cancer has spread.[2,27]

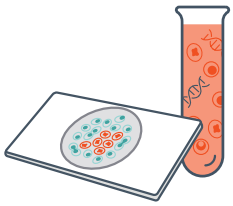
*Availability of report features in your country may vary depending on local regulations.

Your care team will send your tissue or blood sample to Foundation Medicine where it undergoes thorough analysis

A team of experts analyses your sample and creates a comprehensive report based on your cancer's mutations

What happens to your sample?

TUMOUR SAMPLE (TISSUE SAMPLE OR BLOOD WITHDRAWAL)



Your care team will send your tissue or blood sample to Foundation Medicine where it undergoes thorough analysis.

COMPREHENSIVE GENOMIC PROFILING

Your DNA is extracted from your sample and searched for mutations possibly responsible for your cancer.[1,2,26,27]

DATA ANALYSIS

Mutations found are evaluated by cancer experts and an analytical algorithm process that is being constantly updated for treatment options, such as targeted therapies or immunotherapies or relevant clinical trials, using a large cancer information database.[36–38]

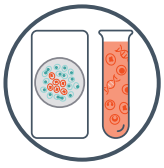
FOUNDATION MEDICINE REPORT

Your care team will receive a comprehensive report, including the details of your tumour profile, a target of less than **14 days** after receipt of the sample at the laboratory for FoundationOne Liquid CDx and **14 days** after receipt for FoundationOne CDx.[36,37]

The Foundation Medicine information database is continuously updated based on new research, clinical trials and increasing numbers of patient genomic profiles from clinical routine (depending on your consent).[38] This helps to ensure that when a Foundation Medicine report is created, it is based on the latest scientific data.

How to order?

Your doctor orders the test.



Your doctor arranges to have a sample of blood or tissue from your cancer taken.

Your sample is sent to the Foundation Medicine laboratory.

DNA is extracted from your sample and analysed.

Your doctor receives the report.

Please note: All patient data are pseudonymized, stored securely and may be used to help researchers improve cancer care provided you have given your consent for the processing of your personal data for research and scientific purposes. Access to your data processed for research or clinical purposes will depend on your consent and applicable data protection laws. For more information about data privacy, please see the Patient Consent Form or contact your local Foundation Medicine team.

The Foundation Medicine report may help guide your treatment plan[36,37]

Page 1 of an example FoundationOne Liquid CDx report*[37]

Page 1 provides a summary of your results, while the remaining pages give more details.
*The FoundationOne CDx report is similar to the FoundationOne Liquid CDx report shown here. To see an example, please ask your care team for the FoundationOne CDx brochure.

1. Your details, your doctor's details and information about your specimen (the cancer tissue sample that was analysed)
2. Biomarker findings and genomic findings: A summary of mutations and other characteristics found in your cancer to help understand which targeted therapies, immunotherapies or clinical trials may be relevant to you
3. Depending on current scientific knowledge and your cancer's mutations, the Foundation Medicine report may indicate:
   - a. Approved therapies according to the respective tumour type
   - b. Therapies approved in another tumour type
   - c. Clinical trials for you and your doctor to discuss together
4. If your cancer has progressed, the FoundationOne Liquid CDx report will help your doctor understand what has changed and may help guide further treatment plans

Availability of report features in your country may vary depending on local regulations.

Important considerations about your results

- Sometimes the test can't be performed due to inadequate sample
- Sometimes no mutations can be found
- If a mutation is found, several factors affect if there will be therapies or clinical trials available
- If no mutations were identified with FoundationOne Liquid CDx, your doctor may use FoundationOne CDx as an additional test
- The test cannot predict how your cancer will respond to therapy

Discuss the next steps for your personalised treatment plan with your doctor.

For more information on cancer testing and Foundation Medicine's comprehensive genomic profiling services, please ask your care team or contact your local Foundation Medicine team.

Pricing and reimbursement are dependent on your country. Please contact your local Foundation Medicine team for more information.

For local patient support, please contact your local Foundation Medicine team for more information.

Molecular insights leader Foundation Medicine has joined the Roche Group as part of our long-standing commitment to pioneering progress in precision medicine[39]

About Roche and Foundation Medicine

Roche and Foundation Medicine are collaborating to bring Foundation Medicine comprehensive genomic profiling services to cancer patients around the world.

Foundation Medicine is a world-leading molecular insights company and innovator in the field of comprehensive genomic profiling.

As part of a long-standing commitment to pioneering progress in precision medicine, Foundation Medicine has joined the Roche Group, a global healthcare company leading in cancer treatments and personalised healthcare.[39]

Glossary

Biomarker	A molecule that is a sign of a normal or abnormal process, or of a condition or disease. A biomarker may be used to see how well the body responds to a treatment for a disease or condition.[22]
Biopsy	The removal of cells or tissues for examination by a pathologist.[40]
Cells	The basic building blocks of all living things.[41]
Clinical trials	Research studies that use human volunteers to test new drugs or other treatments to find out whether they are better than the current, standard treatment. Before giving the treatment to people, it is studied by scientists. If these studies suggest it will work, the next step is to test it in patients.[42]
Comprehensive genomic profiling	A next-generation sequencing approach, able to detect many mutations to help you and your doctor to make treatment decisions personalised to you.[1]
DNA	The genetic 'blueprint' found in the nucleus (centre) of each cell. DNA holds genetic information on cell growth, division and function.[7]
Gene	A section of DNA that contains the information to control the development of one or more of a person's traits. A gene can be passed from parent to offspring.[43,44]
Immunotherapies	Treatments that use the body's immune system to fight cancer.[21]
Mutation	A change in the DNA of a cell. All types of cancer are thought to be due to mutations that damage a cell's DNA.[6]
Solid tumour	An abnormal mass of tissue that usually does not contain cysts or liquid areas e.g. lung or breast cancer. Cancers of the blood (leukaemias) generally do not form solid cancers.[45]
Targeted therapy	Treatment that attacks some part of cancer cells that makes them different from normal cells. Targeted therapies tend to have different side effects to chemotherapy drugs with broader action.[46,47]

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M-XX-00001287
Date of preparation: October 2020

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