



Discover how Comprehensive Genomic Profiling can inform your unique treatment plan

Use this guide to discuss FoundationOne® with your doctor to help decide if it is right for you



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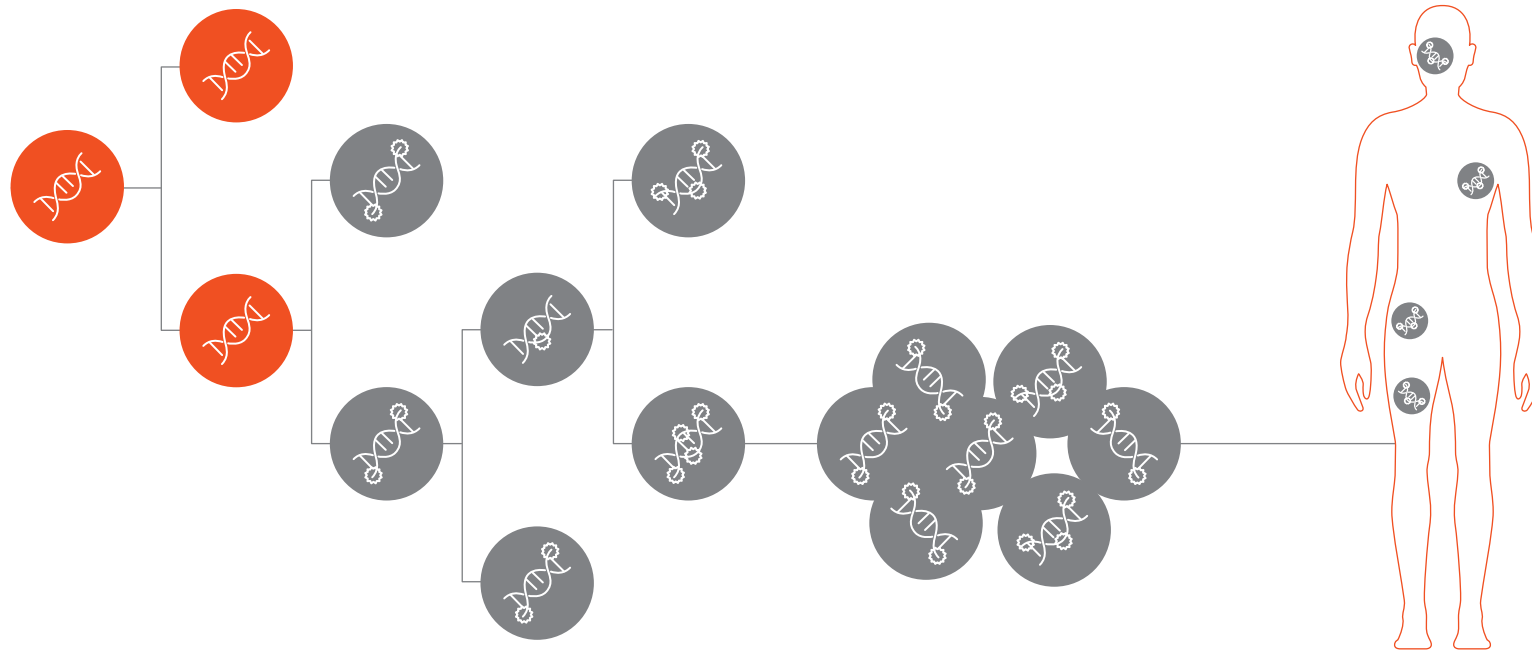


Understanding cancer, metastasis and genomic profiles

Genomic profiling is a laboratory method used to understand genes and how they interact with each other and the environment.

How cancer occurs

- > Normal cell dividing.
- > Cancer occurs when the DNA in a cell gets damaged or mutated (⊗) in a way that the body is unable to identify the problem and repair it.
- > These abnormal cells grow out of control and form tumours that invade healthy tissue and organs.
- > Tumours may become metastatic and spread throughout the body.



What happens to your DNA

- > The unique composition of DNA is called your genomic profile.
- > Tumour cells have their own genomic profiles because the DNA in cancer contains mutations or alterations (⊗).
- > Over time, the genomic profile of your cancer can change as further genomic alterations accumulate in the DNA.

For explanations of scientific terms and abbreviations please refer to the glossary on the back cover of this booklet

Your cancer's genomic profile is unique and can change over time

Treatment has evolved to become as unique as your cancer



Now we have medicines that target the unique genomic alterations driving your cancer, so we need to find out which therapy is right for you

Before 2004, lung cancer was thought to be one disease, caused when certain genes functioned abnormally



Cancer used to be mainly categorised according to its location in the body (e.g. lung, breast, liver). Most patients with a particular tumour type were treated with the same therapy.



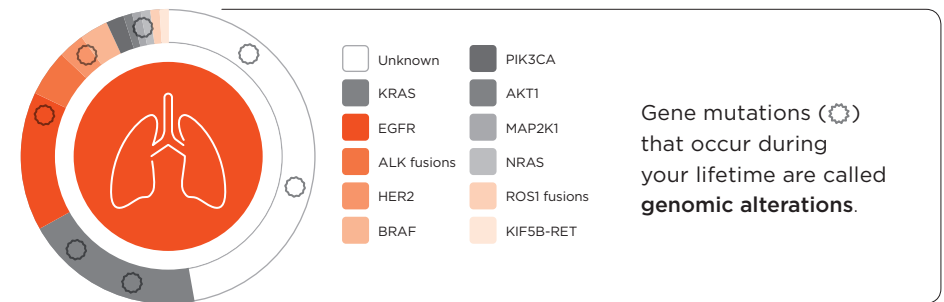
Chemotherapy

All cancers treated the same

Chemotherapies are designed to kill all fast-growing cells in the body, so not only tumour cells are killed but also healthy skin, gut and hair cells (among others) are affected.

When we thought cancer was one disease, all patients were treated the same — with chemotherapy

By 2014, more than 70% of lung cancers were known to be caused by alterations in the specific genes shown below, and our knowledge is still growing



Targeted therapy

To treat your individual cancer

Targeted therapy precisely identifies and attacks the cancer cells affected by the specific genomic alterations that are driving your cancer's growth. Therefore, they usually do far less damage to normal cells.



Immunotherapy

A treatment that helps your immune system fight cancer

The normal immune system detects and destroys abnormal cells. However, cancer can cause genomic and other alterations to cells that makes the cancer less visible to the immune system. Immunotherapies can recognise and block these signals and therefore allow immune cells to respond more strongly to your cancer.

What's the difference between all these genomic cancer tests?

Genomic testing may help to identify whether you could potentially benefit from targeted treatment



Single Marker Tests

Single Marker Tests look at mutations in single genes, or changes within single proteins, known to be associated with specific types of cancer.



Hotspot Gene Panel Tests

Hotspot Gene Panel Tests look for specific mutations in groups of genes known to be associated with cancer. Typically they focus on common genomic alterations, and they may miss less common mutations, or mutations not normally associated with specific types of cancer.



Comprehensive Genomic Profiling

Comprehensive Genomic Profiling looks for **all types of genomic alterations*** across **all of the cancer-related genes** in a single sample of tumour tissue.

*All types of genomic alterations: base substitutions, copy number alterations, rearrangements, insertions and deletions, as well as tumour mutational burden (TMB) and microsatellite instability (MSI) status.



Comprehensive Genomic Profiling enables you to be treated like an individual

How can Comprehensive Genomic Profiling help you?



Since there are hundreds of cancer genes, and many possible alterations in each gene, the type, number and combination of genomic alterations make each person's cancer unique.



Comprehensive Genomic Profiling can search for all genomic alterations that are known to drive cancer, some of which may be promoting your tumour's growth.



Your profiling results may help your doctor identify whether a targeted treatment or immunotherapy option is available for your tumour's unique genomic profile, and which treatment approach could deliver the best outcome for you.



By using Comprehensive Genomic Profiling to determine the unique genomic alterations driving your cancer, your doctor can better tailor your treatment

What genomic profiling tests are offered by Foundation Medicine?



 FOUNDATIONONE® CDx

1. For patients with solid tumours
2. 324 genes (DNA)
3. TMB, MSI
4. LoH (F1 CDx only)

 FOUNDATIONONE® LIQUID CDx

 FOUNDATIONONE® HEME

1. For patients with haematological cancers or sarcomas
2. Covers 406 genes (DNA) and 265 genes (RNA)
3. TMB, MSI

FoundationOne CDx, FoundationOne Liquid CDx and FoundationOne Heme are Comprehensive Genomic Profiling assays that:



...use advanced technology to read your genes and **simultaneously identify** alterations in **all the genes** known to be implicated in cancer — specifically, your cancer.



...help your doctor to identify potential options for targeted therapies, immunotherapies and clinical trials that may be **best suited to the genomic alterations driving your tumour**.



...allow your doctor to see all potential genomic alterations and therefore **explore all potential targeted therapies or treatment approaches** that might benefit your individual case, including therapies that may not otherwise have been considered.



...can also inform your doctor of established therapies that may not be clinically useful in someone with your genomic profile. This is because Foundation Medicine identifies all alterations in the genes included in the profile, and hence can determine whether commonly targeted mutations have not occurred in your cancer.



FoundationOne CDx and FoundationOne Liquid CDx are approved by the US FDA.

What is the process for FoundationOne CDx, FoundationOne Liquid CDx or FoundationOne Heme

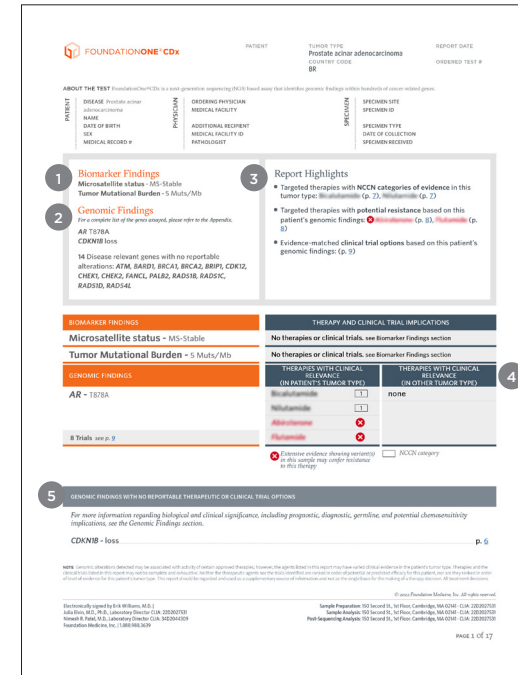
If you and your doctor decide that comprehensive genomic profiling is right for you, your doctor will order the appropriate FoundationOne profile, and send a small piece of your tumour or a blood sample to Foundation Medicine to be analysed. Your doctor will receive a detailed report containing your tumour's genomic findings in about 2-3 weeks.*

STEPS



FOUNDATIONONE® CDx
 FOUNDATIONONE® LIQUID CDx
 FOUNDATIONONE® HEME

What the results mean



- 1 Biomarker findings:** may help predict response to immunotherapy
- 2 Genomic findings:** your unique clinically-relevant genomic alterations
- 3 Report highlights:** This section provides a bulleted list of the key actionable results in the report
- 4 Therapies with clinical relevance:** These are potential treatment options based on the genomic findings in the report. The therapies listed in the left column are FDA-approved. The therapies in the right column are FDA-approved for another cancer type[#]
- 5 Clinical trial options:** Results may match with treatments that are currently being developed in clinical trials. A clinical trial could allow you to access some of the newest treatments in development*

*These therapies may or may not be registered in New Zealand by Medsafe, the New Zealand health authority responsible for assessing the safety and efficacy of medicines.

*The trials listed may or may not be available in your location.

Payment You will most likely receive an invoice for payment via email. Please pay immediately. Some private cancer treatment providers offer FoundationOne genomic profiling as part of their service and will request payment from you directly.

*Allow up to 7 days for your sample to be obtained and prepared for shipment to Foundation Medicine. Once the sample has arrived, it takes approximately 12 days to generate the report for FoundationOne CDx or FoundationOne Liquid CDx, and up to 21 days for the FoundationOne Heme report.

You and your doctor can use these results to discuss possible treatment options – either Medsafe-registered therapies, or unregistered treatments still under development in clinical trials

Frequently asked questions

1 What are the chances that Foundation Medicine will find a relevant genomic alteration?

It is impossible to predict which tumours will have a genomic alteration. That is why Foundation Medicine's comprehensive profiling includes all types of alterations in all the genes known to be involved in cancer, to make sure nothing is missed. Depending on the type of mutation and our currently available knowledge, the report may highlight approved therapies, therapy approved in another tumour type, or a clinical trial. However, not all of the genomic alterations that have been identified to date have potential treatments available.

In some cases, treatments may not be available for your specific disease, or trials targeting your type of cancer may not be available in your location.

Also your doctor may recommend alternative treatment based on other factors which the report does not look at. For example, side effects of some treatments may mean they are not suitable for you.

2 Does it matter what kind of cancer I have or how advanced the cancer is?

FoundationOne CDx, FoundationOne Liquid CDx and FoundationOne Heme are designed to analyse any type of solid tumour regardless of where the cancer is found in your body or how advanced it is. FoundationOne Heme is also designed to analyse cancers of the blood.

3 What if my report shows no alterations?

There are cases where no genomic alterations can be found. This means that your cancer is not caused by any of the genomic alterations that have already been discovered and known to be associated with your cancer type. The underlying genomic cause of your cancer may still be uncharacterised, or not yet published in the scientific literature. However, this information is still useful because it tells your doctor that the use of certain targeted therapies may not be beneficial for you.

4 Will I need to have another biopsy taken for the genomic profiling?

Comprehensive Genomic Profiling with Foundation Medicine can be run on a tissue sample from an earlier biopsy of either the primary tumour, or cancer cells that have spread to other parts of your body (metastases). If there is not enough tissue left from an earlier biopsy to run the analysis, a new biopsy may need to be taken. Your doctor may also recommend a new biopsy to obtain a more recent sample. If obtaining a new biopsy is not possible or appropriate at this time then your doctor may suggest a blood sample is taken and a FoundationOne Liquid CDx test is ordered.

5 How can a blood test provide information about my tumour?

Tumour cells often release DNA that circulates freely in the blood. With a simple blood test, it is possible to detect traces of this free-floating cancer DNA, also known as circulating tumour DNA (ctDNA). While the ctDNA is present in the blood in very small quantities it still contains important information about genomic alterations that may be causing your cancer to grow. Using advanced technologies available only in specialist laboratories the ctDNA can be detected and analysed.

6 Will my genomic profile identify the best treatment for me?

Only you and your doctor can identify the best treatment for you. However, because Foundation Medicine profiles look for all types of alterations in all genes known to be involved in cancer, you can be confident that if an alteration is present in your tissue sample, there is a strong chance that Foundation Medicine will detect it. Your genomic profile may identify potential avenues of treatment you can explore with your doctor. It is important to understand that the profile may not identify a currently available therapy or trial in New Zealand.

7 Can a Foundation Medicine genomic profile predict if chemotherapy will work for me?

No. Comprehensive Genomic Profiling is not designed to predict how your cancer will respond to chemotherapy. However, Foundation Medicine profiling can help your doctor to potentially match the genomic alterations present in your cancer with other treatments that can specifically target your cancer type. These can be either registered treatments or those being investigated in clinical trials.

Response to a particular therapy is determined by a number of factors such as previous treatments, performance status, and your ability to tolerate cancer medication. Therefore, this decision is best made by your physician.

8 Can Foundation Medicine genomic profiling predict if a mutation was genetically inherited (germline)? Can germline mutations be detected for family members?

While Foundation Medicine profiling can detect many genetic alterations, it cannot determine whether any specific genomic alteration was inherited (germline) or acquired over time. Foundation Medicine profiling is designed to search for all known genomic mutations associated with human cancer regardless of whether they have been inherited or not. Your Foundation Medicine report will indicate whether your genomic alteration has been associated with germline cancer-predisposition syndromes.

If you and your family would like to determine whether your specific cancer type is inherited, you will need to talk to your doctor about having a separate germline test.

9 What is Foundation Medicine?

Foundation Medicine is a world-leading molecular insights company, connecting physicians and their patients to the latest cancer treatment approaches and making precision medicine a reality for thousands.

In New Zealand, Roche's pharmaceutical division is the licensed distributor of FoundationOne CDx, FoundationOne Liquid CDx and FoundationOne Heme, offering Comprehensive Genomic Profiling services and decision support tools that may inform cancer treatment decisions.

Understanding your patient consent form



Patient Information and Consent Form

To be completed by the patient and retained by the requesting doctor



PATIENT INFORMATION:

Please read carefully and discuss this information and any questions you have with your doctor or healthcare professional (HCP) ordering this genomic profile.

Who is Foundation Medicine?

Foundation Medicine, Inc. ('Foundation Medicine') provides genetic profiling services from its laboratory in the United States of America. It analyses acquired alterations or variants in genes known to drive tumour growth of most cancers. Foundation Medicine products and services are distributed in New Zealand by Roche Products New Zealand Ltd. ('Roche').

What is the purpose of genomic profiling?

Foundation Medicine profiles are designed to look at the genetic profile of your tumour and to look for specific genomic alterations (mutations or variations in the tumour makeup) that may be affecting its growth. This information may help your doctor determine what targeted therapies may be available to treat your cancer (treatment that targets the mutations in the tumour) or clinical trials in which you may be able to participate. Additional information about the profiles are available at www.foundationmedicine.co.nz

What is the process in obtaining a Foundation Medicine profile?

A blood sample or a sample of your tumour (usually one removed in connection with a biopsy or surgery you have had) will be sent to Foundation Medicine's laboratory, 150 Second Street Cambridge, MA 02141, USA, where it can be examined for genomic alterations. The sourcing and preparation of your sample may be managed by IGENZ Ltd ('IGENZ'), a medical testing laboratory located in Auckland. Foundation Medicine will then send IGENZ and your doctor a detailed report with information about your tumour's genomic makeup and potential treatment options and clinical trials. You and your doctor can then evaluate the results along with other information (e.g. your medical history, other tests, availability of medicines in NZ) to determine what next steps are right for you.

Potential benefits and risks

Cancers are caused by alterations in the DNA within a few hundred specific genes. Alterations in one or more of these genes can lead to abnormal cell growth and the formation of cancer tumours. With many possible alterations in each gene, the number and combination of these alterations make each person's cancer unique.

DNA alterations can be inherited from our parents or acquired during a person's lifetime. These acquired alterations are thought to cause the majority of cancers. Foundation Medicine profiling provides information about acquired genetic alterations in your tissue sample.

Foundation Medicine profiling does not provide information about inherited genetic alterations which can be passed down from generation to generation in families.

It is possible that the results will show one or more genomic alterations that are "actionable" meaning that there may be therapies available that target your specific type of cancer or clinical trials that are studying investigational therapies for your type of cancer. It is also possible that the profiles will not reveal the cause of your disease or help identify possible treatments.

Knowledge about the impact of genetic changes is constantly changing. We may not yet understand the significance of certain mutations or variations we observe or whether anything can be done to address those mutations or variations. As a result, physicians may have different opinions about what the results mean and what treatment should be provided in light of the results. These profiles do not examine every possible mutation or variant that may exist and our technology also may not identify all mutations related to your cancer. There is also a small possibility of errors.

You may learn medical information about yourself that you did not expect, including learning of additional diagnoses or a change in your condition, which may or may not be treatable and may make you upset or cause distress. You may wish to discuss with your doctor whether you would like this information to be communicated to you.

It is important for you to know that because genetic information is involved, it is possible that the results of these profiles could impact your ability to obtain life, disability or long-term care insurance.

PATIENT DECLARATION OF CONSENT:

This form must be completely filled out and signed by you, your parent/legal guardian or legally authorised representative.

I (*insert name*) _____ certify that my doctor or healthcare professional has explained the purpose, benefits and risks of Foundation Medicine profile and also has provided the following information to me:

General information on Foundation Medicine profiles:

1. The results of the Foundation Medicine profile will be provided to IGENZ and my doctor (or the healthcare professional ordering the Foundation Medicine profile) and become part of my medical record. They will also be retained by Foundation Medicine in accordance with applicable law and accessed by Roche at the direction of Foundation Medicine or my doctor for purposes directly related to the delivery and interpretation of the Foundation Medicine profile. They may be made available to individuals/organisations with authorised access to my medical records including, but not limited to the doctors and nursing staff directly involved in my care, employees of Foundation Medicine, my current and future insurance carriers, others authorised by law or a court order, and others specifically authorised by me or my authorised representative to gain access to my medical records. No other person or entity may have access to or retain my Foundation Medicine results without my written authorisation.

✓ Foundation Medicine genomic profiling purpose:

Foundation Medicine genomic profiles are designed to look for specific genomic alterations in your tumour or blood cancer to help your doctor identify whether there is a targeted treatment, immunotherapy or clinical trial available for your unique cancer.

✓ Foundation Medicine genomic profiling process:

A tissue sample from a biopsy of your tumour or blood sample will be sent to the Foundation Medicine laboratories to be tested for genomic alterations. The results will be sent to your doctor in a detailed clinical report. Together, you and your doctor can use these results to determine the next steps in your treatment.

✓ Potential benefits and risks of Foundation Medicine:

Your Foundation Medicine report may indicate whether targeted therapies, immunotherapies or clinical trials are available to target your unique cancer.

However, because knowledge of genomic alterations associated with cancer is constantly evolving, Foundation Medicine may not identify all mutations relating to your cancer, or understand the significance of some of the mutations that are found.

You may learn unexpected information about yourself (including additional diagnoses or changes in your disease status) that could cause you distress.

It is possible that your report will not reveal the cause of your disease or help identify possible treatments.

Your report reveals genetic information. Therefore, it is important to consider the possibility that Foundation Medicine results could impact your ability to obtain life, disability or long-term care insurance.

✓ Option to permit the additional use of results:

You can choose whether to allow your de-identified genetic information to be used by Foundation Medicine for future genetic research by checking the first box. Checking the second box allows Foundation Medicine to conduct your requested profile but not use your de-identified genetic information for future research.

2. Foundation Medicine shall return any unused sample tissue to my treating doctor or the pathology laboratory once testing is completed.
3. Results will be retained by Foundation Medicine for the minimum retention period of 10 years and thereafter as required for internal quality assurance/operations purposes.
4. Roche Products New Zealand Ltd., its affiliates or distributors, may receive Personal Data as part of its role in the sourcing and sending of tissue or blood samples to Foundation Medicine. Roche may also receive Personal Data information from PayPal related to credit card payments.
5. I understand that:
 - a) the Foundation Medicine privacy policy describes how I may access or request an amendment to my personal information and how I may complain about any use or disclosure of my personal information in breach of any applicable privacy laws;
 - b) the Foundation Medicine privacy policy is available to download at <https://www.foundationmedicine.com/pages/legal/> and I can also request a copy using the contact details below; and
 - c) I should contact Foundation Medicine if I have any privacy related queries at +1-888-988-3639, by emailing privacy@foundationmedicine.com or by writing to the Privacy Officer, Foundation Medicine, Inc at 150 Second Street, Cambridge MA 02141 USA

Additional use of the results:

6. To the extent my consent is required by law (including the *United States Health Information Portability and Accountability Act of 1996* (HIPAA) and the *New Zealand Privacy Act 2020* ("Act"), I **authorize** Foundation Medicine to de-identify my genetic information and results and use or disclose such de-identified genetic information/results for a range of future purposes, including research and commercial purposes.
7. I **agree** that Foundation Medicine may retain this de-identified information for as long as it believes it is useful. I understand that this information will be de-identified in a manner that meets de-identification standards under the HIPAA.
8. I **understand** that I am not required to consent to de-identification of my genetic information/results as a condition of receiving the Foundation Medicine profile.
9. I **understand** that once my genetic information and results have been de-identified such that Foundation Medicine will not be able to determine which genetic information and results relate to me, I will no longer be able to withdraw my consent to Foundation Medicine's future use or disclosure of such de-identified data.
10. I **have been asked** if I have questions about or want a more detailed explanation of the scope and limitations, risks and benefits of the Foundation Medicine profiles. I have had enough time to consider the information I have been given and discuss it with my whanau/family if desired. I am satisfied with the explanation provided to me and do not need more information.

I **consent** to Foundation Medicine conducting the requested profile (points 1-5, 10), as well as de-identifying my results and using them for research as described above (points 6-9).

OR

I **consent** to Foundation Medicine conducting the requested profile (points 1-5, 10) only.

Patient Name (Signature) Patient Name (Print) Date

Personal Representative (if applicable) (Relationship to Patient) Date

**The above has been discussed with the patient or the legal guardian and informed consent obtained.
The above was signed in my presence.**

Name of Doctor or HCP Signature Date



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More information can be found at www.mycancerisunique.co.nz



FoundationOne® CDx, FoundationOne® Liquid CDx and FoundationOne® Heme Consumer Information Summary

Description

FoundationOne® CDx, FoundationOne® Liquid CDx and FoundationOne® Heme are genomic tests that help you and your doctor understand the changes in your cancer's genes which may be promoting your cancer's growth. These tests are known as Comprehensive Genomic Profiles.

- FoundationOne® CDx and FoundationOne® Liquid CDx are profiles used for solid tumours like lung cancer or skin cancer.
- FoundationOne® Heme is the profile used for blood and lymph cancers like leukaemias, lymphomas, and myelomas; and sarcomas.

Use

A sample of your tumour or blood is sent to the Foundation Medicine® laboratory in the US. After two to three weeks, your doctor will receive a report containing the profiling results for your tumour sample. The report contains a summary of possible targeted treatments, treatment approaches or available clinical trials. You and your doctor can then consider the treatment options that suit you best.

Warnings and Precautions

FoundationOne® CDx, FoundationOne® Liquid CDx and FoundationOne® Heme profiling provide information about changes to your cancer's genes.

- FoundationOne® profiles do not provide information about your inherited genetic alterations (passed down from generation to generation in families).
- Results may show one or more genomic alterations that are "actionable". This means that there may be treatments available that target your specific type of cancer. There may also be clinical trials that are investigating therapies that target your specific type of cancer. However, it is also possible that the profiles will not reveal the cause of your disease or help identify possible treatments.
- These profiles do not explore every possible change or alteration that may exist and the technology may not identify all changes related to your individual cancer.
- There is a small possibility of errors.
- You may learn medical information about yourself that you did not expect, including learning of additional diagnoses or a change in your condition, which may or may not be treatable and may cause you distress.
- **It is important for you to know that because genetic information is involved, it is possible that the results of your profile could impact your ability to obtain life, disability or long-term care insurance.**

Speak to your oncologist about FoundationOne CDx, FoundationOne® Liquid CDx and FoundationOne® Heme and whether comprehensive genomic profiling may be able to help you. More information about Foundation Medicine® comprehensive genomic profiles can be found at www.mycancerisunique.co.nz.

mycancerisunique.co.nz



