



UNDERSTANDING YOUR CANCER AND PERSONAL TREATMENT PATH

FoundationOne®CDx uses a sample of your cancer tissue to provide a more complete picture of your cancer and help open up treatment possibilities for you^{1,2}

See more, do more



FOUNDATION
MEDICINE®



FoundationOne CDx searches for multiple mutations in your cancer tissue sample to increase your chances of finding a more precise treatment^{1,2}

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

If certain mutations are found in your cancer cells' DNA, your doctor may be able to give you a more precise and personalised treatment based on this finding.³⁻⁷

FoundationOne CDx searches for multiple mutations in your cancer cells' DNA and helps you and your doctor optimise and personalise your treatment plan.^{1,8,9}

What is FoundationOne CDx?

Who is it for?

FoundationOne CDx is for people with all types of solid tumours, e.g. lung or breast cancer (as opposed to blood cancers, like leukaemia*).² Your doctor can explain to you if your tumour qualifies for FoundationOne CDx testing.

What does it use?

A sample of tissue from your cancer (a tissue biopsy).² Your doctor will explain what is involved in having a biopsy.

How does it work?

Comprehensive genomic profiling searches for mutations in over 300 cancer-related genes.^{1,2}



How could it help?

It may help open up new treatment possibilities, including therapies and clinical trials^{1,2}

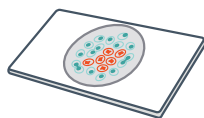
What if you've already had a test?

FoundationOne CDx can find mutations that other tests miss because it looks 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.^{1,7,10,11}

*Blood-based cancers can be tested with the Foundation Medicine test FoundationOne®Heme. Please talk to your cancer care team for more information.

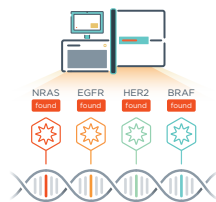
What happens to your sample?

TUMOUR SAMPLE (SURGERY OR BIOPSY)



A sample is taken from your tumour and sent to a Foundation Medicine laboratory

COMPREHENSIVE GENOMIC PROFILING



Your DNA is extracted from your sample. The DNA is searched for mutations possibly responsible for your cancer¹

DATA ANALYSIS



Mutations found are evaluated by a team of experts for treatment options, such as targeted therapies or immunotherapies, or relevant clinical trials, using a large cancer information database^{12,13}

FOUNDATION MEDICINE REPORT



Your care team will receive a comprehensive report, including the details on your tumour profile, 14 days after receipt of the sample at the laboratory¹³

The Foundation Medicine information database is continuously updated based on new research, clinical trials, and increasing amount of patient genomic profiles from clinical routine.¹² This helps ensure when a Foundation Medicine Report is created, it is based on the latest scientific data.

Please note: All patient data are anonymised, stored in a secure database and, with your consent, used to help researchers improve cancer care.

**FoundationOne CDx results are sent to your doctor
in a comprehensive report¹³**

The FoundationOne CDx report may help guide your treatment plan¹³

Page 1 of an example FoundationOne CDx report¹³

FOUNDATIONONE[®] CDx

PATIENT: Sample, Jane TUMOR TYPE: Lung adenocarcinoma REPORT DATE: 01 Jan 2018

ABOUT THE TEST: FoundationOne[®]CDx is a next-generation sequencing (NGS) based assay that identifies genomic findings within hundreds of cancer-related genes.

1 PATIENT

DISEASE: Lung adenocarcinoma
NAME: Not Given
DATE OF BIRTH: Not Given
SEX: Female
MEDICAL RECORD #: Not Given

PHYSICIAN

ORDERING PHYSICIAN: Not Given
MEDICAL FACILITY: Not Given
ADDITIONAL RECIPIENT: Not Given
MEDICAL FACILITY ID: Not Given
PATHOLOGIST: Not Given

SPECIMEN

SPECIMEN SITE: Not Given
SPECIMEN ID: Not Given
SPECIMEN TYPE: Not Given
DATE OF COLLECTION: Not Given
SPECIMEN RECEIVED: Not Given

2 Biomarker Findings

Tumor Mutational Burden - TMB-Intermediate (11 Muts/Mb)
Microsatellite status - MS-Stable

Genomic Findings

For a complete list of the genes tested, please refer to the Appendix.

EGFR amplification, L858R
PTCH1 T416S
CDKN2A/B loss
RBM10 Q494*
TP53 R267P

7 Disease relevant genes with no reportable alterations: KRAS, ALK, BRAF, MET, RET, ERBB2, ROS1

14 Therapies with Clinical Benefit
0 Therapies with Lack of Response

18 Clinical Trials

BIOMARKER FINDINGS

Tumor Mutational Burden - TMB-Intermediate (11 Muts/Mb)

9 Trials - see p. 14

Microsatellite status - MS-Stable

GENOMIC FINDINGS

EGFR - amplification, L858R

4 Trials - see p. 16

PTCH1 - T416S

5 Trials - see p. 17

THERAPIES WITH CLINICAL BENEFIT (IN PATIENT'S TUMOR TYPE)

3a

THERAPIES WITH CLINICAL BENEFIT (IN OTHER TUMOR TYPE)

3b

No therapies or clinical trials. see Biomarker Findings section

THERAPIES WITH CLINICAL BENEFIT (IN PATIENT'S TUMOR TYPE)

3a

THERAPIES WITH CLINICAL BENEFIT (IN OTHER TUMOR TYPE)

3b

Electronically Signed by Julia A. Davis, M.D., Ph.D., M.D., M.P.H., M.D., Medical Director • 30 November 2017
Foundation Medicine, Inc. • 1-888-688-3638

Sample Preparation: 161 Second St., 1st Floor, Cambridge, MA 02141 • USA • 20200701
Sample Analysis: 161 Second St., 1st Floor, Cambridge, MA 02141 • USA • 20200701

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- 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

Page 1 provides a summary of your results, while the remaining pages give more details.

Important considerations about your results

Sometimes no mutations can be found

This information will still be helpful to your doctor, as it may help to rule out giving you treatments that are unlikely to help you.

If a mutation is found, several factors affect if there will be therapies or clinical trials available

If a mutation is found there may be therapies or clinical trials available for your mutation, but this depends on whether the therapy or trial is available in your country or is appropriate for you. It is also possible that there may not yet be any therapies or trials for your mutation.

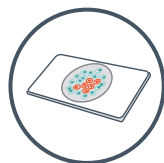
FoundationOne CDx cannot predict how your cancer will respond to a therapy

If you receive a therapy or enter a clinical trial mentioned in the report it does not mean that the therapy will work as there are many factors that influence the efficacy.

How to order?



Your doctor orders the test



Your doctor arranges to have a sample of tissue from your cancer taken (a tissue biopsy)



Your sample is sent to the Foundation Medicine laboratory



DNA is extracted from your sample and analysed



Your doctor receives the report

It takes around 14 days from receipt of your sample at the Foundation Medicine laboratory to your doctor receiving the report

Discuss the findings of your report and the next steps for your personalised treatment plan with your doctor

FoundationOne CDx helps open up treatment possibilities for your cancer^{1,2}

Where can you find more information?



For more information on comprehensive genomic profiling and FoundationOne CDx, please visit www.rochefoundationmedicine.com

Pricing and reimbursement is dependent on your country, please contact your local Foundation Medicine team for more information

<Space for local patient Medical Information contact details>

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. ¹⁴
Biopsy	The removal of cells or tissues for examination by a pathologist. ¹⁵
Cell	The basic building blocks of all living things. ¹⁶
Clinical trial	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. ¹⁷
Comprehensive genomic profiling	A type of cancer test that looks for several cancer-related DNA mutations across a broad region of the cancer cells' DNA in a single test. ¹
DNA	The genetic "blueprint" found in the nucleus (centre) of each cell. DNA holds genetic information on cell growth, division, and function. ¹⁸
Gene	A section of DNA that contains the information to control the development one or more of a person's traits. A gene can be passed from parent to offspring. ^{19,20}
Immunotherapy	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. ²²
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. ²³
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. ^{24,25}

References

1. Frampton GM *et al.* *Nat Biotechnol* 2013; 31: 1023–1031; 2. FoundationOne®CDx Technical Specifications, 2018. Available at: www.rochefoundationmedicine.com/fcdxtech (Accessed January 2019); 3. Baumgart M *et al.* *Am J Hematol Oncol* 2015; 11: 10–13; 4. Schwaederle M, Kurzrock R. *Oncoscience* 2015; 2: 779–780; 5. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines). Non-small cell lung cancer. V.2.2019, 2018. Available at: https://www.nccn.org/professionals/physician_gls/recently_updated.aspx (Accessed January 2019); 6. Ohashi K *et al.* *Clin Cancer Res* 2013; 19: 2584–2591; 7. Rozenblum AB *et al.* *J Thorac Oncol* 2017; 12: 258–268; 8. Dong L *et al.* *Curr Genomics* 2015; 16: 253–263; 9. Sicklick JK *et al.* *Nature Medicine* 2019; 25: 744–750; 10. Drilon A *et al.* *Clin Cancer Res* 2015; 21: 3631–3639; 11. Schrock AB, *et al.* *Clin Cancer Res* 2016; 22: 3281–3285; 12. Foundation Insights. Available at: <https://www.foundationmedicine.com/insights-and-trials/foundation-insights> (Accessed January 2019); 13. FoundationOne®CDx Sample Report, 2018. Available at: www.rochefoundationmedicine.com/reporting (Accessed January 2019); 14. The NCI Dictionary of Cancer Terms. Biomarker. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/biomarker> (Accessed January 2019); 15. The NCI Dictionary of Cancer Terms. Biopsy. Available at: <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/biopsy> (Accessed January 2019); 16. American Cancer Society Glossary. Cell. Available at: <https://www.cancer.org/content/cancer/en/cancer/glossary.html?term=cell> (Accessed January 2019); 17. American Cancer Society Glossary. Clinical trials. Available at: <https://www.cancer.org/content/cancer/en/cancer/glossary.html?term=clinical+trials> (Accessed January 2019); 18. American Cancer Society Glossary. Deoxyribonucleic acid. Available at: <https://www.cancer.org/content/cancer/en/cancer/glossary.html?term=deoxyribonucleic+acid> (Accessed January 2019); 19. The NCI Dictionary of Cancer Terms. Gene. Available at: <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/gene> (Accessed January 2019); 20. Merriam-Webster Dictionary. Gene. Available at: <https://www.merriam-webster.com/dictionary/gene> (Accessed June 2019); 21. American Cancer Society Glossary. Immunotherapy. Available at: <https://www.cancer.org/content/cancer/en/cancer/glossary.html?term=immunotherapy> (Accessed January 2019); 22. American Cancer Society Glossary. Mutations. Available at: <https://www.cancer.org/content/cancer/en/cancer/glossary.html?term=mutation> (Accessed January 2019); 23. The NCI Dictionary of Cancer Terms. Solid tumour. Available at: <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/solid-tumour> (Accessed January 2019); 24. American Cancer Society Glossary. Targeted therapy. Available at: <https://www.cancer.org/content/cancer/en/cancer/glossary.html?term=targeted+therapy> (Accessed January 2019); 25. American Cancer Society. What is targeted cancer therapy? Available at: <https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/targeted-therapy/what-is.html> (Accessed June 2019).

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