

Patient Authorization/Consent Form

Individual states may have additional informed consent requirements for this type of testing - please review your own state law requirements prior to use

Patient Information

Last Name	First Name	MI
Date of Birth		
Foundation Medicine Account Number		
Referring Physician	Date	

Please read carefully and discuss with your ordering physician/person obtaining consent before signing. This form must be completely filled out and signed by you, your parent/legal guardian or legally authorized representative.

Purpose

FoundationOne testing is designed to look at the genetic profile of your tumor and to look for specific genomic alterations (mutations or variants) that may be affecting its growth. This information may help your physician determine what targeted therapies may be available to treat your cancer or clinical trials in which you may be able to participate. Additional information about the test is available at www.foundationone.com.

Process

A sample of your tumor, usually one removed in connection with a biopsy or completed surgery, will be sent to Foundation Medicine, Inc.'s laboratory where it can be examined for genomic alterations. Foundation Medicine, Inc. will then send your physician a detailed report with information about your tumor's genomic makeup and potential treatment options and clinical trials. You and your doctor can then evaluate the test results along with other information (e.g., your medical history, other tests) to determine what next steps are right for you.

Potential Benefits and Risks

It is possible that the test results will show one or more genomic alterations that are "actionable" meaning that there may be FDA-approved therapies available that target your specific type of cancer or clinical trials that are studying investigational therapies for your type of cancer.



Knowledge about the impact of genetic changes is constantly changing. As a result, 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 test results mean and what treatment should be provided in light of the test results. This test does 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 testing 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. It is possible that the test will not reveal the cause of your disease or help identify possible treatments. Because genetic information is involved, it is possible that the results of this test could impact your ability to obtain life, disability or long-term care insurance. _____

I certify that my physician or the person ordering this test has explained the purpose, benefits and risks of Foundation One testing and also has provided the following information to me:

1. The results of the FoundationOne test will become part of my medical record. They will also be retained by my physician and Foundation Medicine, Inc. as required by law and may be retained for an indefinite period and used by my physician and/or Foundation Medicine, Inc. for internal quality assurance or other operations purposes. They may be made available to individuals/organizations with legal access to my medical records including, but not limited to the physicians and nursing staff directly involved in my care, employees of Foundation Medicine, Inc., my current and future insurance carriers, others authorized by law or a court order, and others specifically authorized by me or my authorized representative to gain access to my medical records. No other person or entity may have access to or retain my FoundationOne Test results without my written authorization. I may request removal or destruction of identifiable genetic information from my medical record to the extent permitted by law.
2. Foundation Medicine, Inc. shall return any unused sample tissue to my treating physician or the pathology laboratory once testing is completed. If I am in New York, I understand that Foundation Medicine, Inc. must discard any remaining sample tissue in its possession within 60 days after analysis in the lab.
3. To the extent my consent is required by state law, I authorize Foundation Medicine, Inc. to de-identify my genetic information and test results and use or disclose that de-identified information/results for future unspecified genetic research or other purposes. I agree that Foundation Medicine, Inc. 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 Health Information Portability and Accountability Act (HIPAA). If state law requires my consent for de-identification for research or other purposes, I understand that I am not required to consent to de-identification of my genetic information/test results as a condition of receiving the FoundationOne test.



4. I understand that once my genetic information and test results have been de-identified, Foundation Medicine, Inc. will not be able to determine which genetic information and test results relate to me and therefore I will no longer be able to withdraw my consent to its future use or disclosure.
5. I have been asked if I have questions about or want a more detailed explanation of the risks and benefits of the FoundationOne Test. I am satisfied with the explanation provided to me and do not need more information.

<input type="checkbox"/> I consent to the retention of my genetic information and test results by Foundation Medicine, Inc. and the use of de-identified information/ results for future de-identified research or other purposes as described above.	<input type="checkbox"/> I do not consent to retention of my genetic information and test results by Foundation Medicine other than as may be required by law and specifically decline to permit Foundation Medicine, Inc. to use my de-identified information or test results for future research or other purposes.
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Patient Name (Print)	Patient Name (Signature)	Date
Personal Representative	(Relationship to Patient)	Date

In accordance with State Law, the following has been discussed with the patient/legal guardian and informed consent obtained. The following was signed in my presence.

Name of Physician or Person Obtaining Consent:	
Signature (MD/NP/Genetic Counselor)	Date

