

# Informed Consent Form for Testing

THIS DOCUMENT SHOULD BE READ WITH THE UNDERSTANDING THAT MENTIONS OF “YOUR HEALTH CARE PROVIDER,” “YOUR SAMPLE(S),” “YOUR TEST RESULTS,” AND SIMILAR REFERENCES REFER TO THE PATIENT BEING TESTED. IF THE PATIENT IS A MINOR, A PARENT OR GUARDIAN WILL PROVIDE CONSENT ON THE MINOR’S BEHALF.

Your health care provider wishes to order one or more laboratory tests offered by Foundation Medicine (a “**Test**” or the “**Tests**”). The Tests include, for example, comprehensive genomic profiling (CGP) tests such as FoundationOne®CDx, FoundationOne Heme and FoundationOne Liquid CDx, as well as PD-L1 immunohistochemistry (IHC) tests.<sup>1</sup> Your health care provider will tell you which specific Test(s) they are ordering for you. CGP is a type of cancer testing that can find mutations and biomarkers in your DNA or RNA that may be causing your cancer to grow, and PD-L1 IHC testing is an optional add-on to CGP testing. The results of CGP combined with IHC can help your health care provider choose a treatment plan that is right for you, which may include a targeted therapy, immunotherapy or clinical trial. By signing below, you (or your legally authorized representative) acknowledge receipt of information regarding the potential risks, benefits, and limitations of the Test(s) and provide your consent as to the matters listed in this consent, including collection, use, retention, maintenance, and disclosure of (i) your biological sample(s), as required for your Test(s), which together with any residual or derivative materials maintained or created from your sample(s) are referred to in this consent as your “**sample**” or “**samples**,” (ii) health and demographic information provided by your health care provider, as required for your Test(s) and (iii) the results of any Test(s) performed on your sample(s) and other data and information generated during performance of the Test(s). If you have any questions or need additional information about the Test(s), please consult your health care provider before signing this consent.

## Sample Collection

The Test(s) require either a sample of your tissue, blood or bone marrow aspirate, or extracted nucleic acid. Foundation Medicine will work with your health care provider to request and obtain your sample(s) (as required for your Test(s)) and obtain from your health care provider information related to you or your cancer that is relevant for the Test(s). Please be aware that performing the requested Test(s) may exhaust the tissue that is sent to Foundation Medicine and that, depending on how much tissue remains from your biopsy, additional tests/studies requiring tissue from this biopsy may not be possible in the future.

## Testing Process

Genetic material, including nucleic acid (e.g., DNA and/or RNA), will be extracted and/or obtained from your sample(s). This material will be analyzed and stored. You authorize the release of the original pathology slides/blocks/clinical sample(s) and other materials, including extracted nucleic acid, that are requested by Foundation Medicine (“**Materials**”) to conduct the Test(s), and hereby direct any pathology lab receiving a request for your Materials from Foundation Medicine to release and provide all such Materials to Foundation Medicine or a third party with which Foundation Medicine is contracted.

Foundation Medicine, or a third party with which Foundation Medicine is contracted, will perform the requested Test(s) using genetic material, including nucleic acid, extracted and/or obtained from your sample(s). The Test(s) look at cancer-related genes to see if there are mutations, or changes, that may be relevant to your cancer. Foundation Medicine will report the results of the Test(s) to your health care provider, who will discuss your results and next steps with you. The testing process also generates additional data, information, and genetic and other material that may be retained and used for future testing ordered by your health care provider or to improve tests and testing technologies.

1. Descriptions of, and additional information regarding, the Tests are available at <https://www.foundationmedicine.com/info/detail/for-patients> and <https://www.foundationmedicine.com/info/detail/ihc-testing>.

## About the Test(s)

Foundation Medicine CGP Test(s) are next-generation sequencing based tests. Some of these Tests are companion diagnostic tests used to identify patients who may benefit from treatment with specific therapies in accordance with the approved therapeutic product labeling. Other reported genomic findings are not prescriptive or conclusive for labeled use of any specific therapeutic product. Use of the Test(s) does not guarantee that you will be matched to a treatment or clinical trial or that all relevant mutations will be found. Mutations reported may include somatic (not inherited) or germline (inherited) mutations; however, the Test(s) do not distinguish between germline and somatic mutations. The Test(s) do not provide information about susceptibility to developing disease in the future. A negative result does not rule out the presence of a mutation below the limits of detection of the Test(s). Some patients may require a biopsy, which poses certain risks. Foundation Medicine is under no ongoing obligation to update, revisit, or later re-evaluate the results of the Test(s) after those results have been made available to your health care provider through the Test reports described above.

Your Test(s) may identify suspected germline mutations in certain genes. Foundation Medicine does not provide germline testing, and the Test(s) do not distinguish between germline and somatic mutations. Therefore, a germline test from another laboratory must be performed if a suspected germline variant identified by your Test(s) is to be confirmed. Your health care provider will consider whether follow up confirmatory germline testing is appropriate, taking into consideration all applicable information concerning your condition, such as your clinical family history information. You also may wish to discuss with your health care provider seeking genetic counseling from a genetic counselor before confirmatory germline testing. Genetic counselors are clinicians who specialize in genetics and cancers that tend to occur more often in members of a family compared to the general population. Your health care provider will be able to suggest possible genetic counselors in your area.

## Disclosure of Results

The results of your Test(s) and other data and information generated during performance of the Test(s) may be used and disclosed in a manner consistent with our Notice of Privacy Practices, which can be found at [www.foundationmedicine.com/resource/notice-of-privacy-practices](http://www.foundationmedicine.com/resource/notice-of-privacy-practices). This includes disclosure to your health care provider(s) (or their designated representative(s)), your health insurance company(ies), researchers and for certain secondary uses described below.

## Secondary Data and Sample Uses

Foundation Medicine or its representatives may redact information that directly identifies you from your sample(s), the results of your Test(s), other data and information generated during performance of the Test(s), and other health or demographic information that Foundation Medicine receives about you to create what this consent calls the “**Residual Information and Materials.**” Foundation Medicine may maintain and use the Residual Information and Materials for various purposes described below. The Residual Information and Materials may also be shared with third parties, including, but not limited to, pharmaceutical and medical device companies, hospitals and universities, and other entities.

Foundation Medicine and/or other entities that receive the Residual Information and Materials may use the Residual Information and Materials for any purpose permitted by law, including but not limited to:

- Conduct commercial development and research, including performing additional analyses, such as statistical analysis, using the Residual Information and Materials for scientific and/or research purposes.
- Perform quality assurance, test validation, and other operations purposes.
- Inform you and/or your health care provider about treatments, products and services from Foundation Medicine or other companies that are relevant to the results of your Test(s) or data or information generated during performance of the Test(s), or about clinical trials for which you may be eligible.
- Aggregate the Residual Information and Materials with similar residual information from other individuals, which may be used to create, or be disclosed to, databases or datasets that are solely or jointly owned by Foundation Medicine or be submitted by Foundation Medicine to public databases to advance medical research.

You are not entitled to compensation for the use of the Residual Information and Materials or rights to any products or discoveries resulting from use of the Residual Information and Materials.

### Retention of Samples

Unless sample return is requested by your health care provider on the test requisition form (for tissue samples only), Foundation Medicine may choose to destroy or return the sample(s) at the end of the testing process or retain the sample(s) indefinitely for the secondary uses described above or for future Test(s) ordered by your health care provider. If you do not want your leftover sample(s) to be retained or used in the manner described in this consent, you may request that your sample(s) be destroyed or returned by contacting the Foundation Medicine Client Services Team at [client.services@foundationmedicine.com](mailto:client.services@foundationmedicine.com) or by calling +1 (888) 988-3639. Any such request will only be effective with respect to the storage of your sample(s) after the date such request is received by Foundation Medicine.

### Ownership of Samples and Results

You may have ownership rights in the sample(s) tested by Foundation Medicine and in the results of the testing, including any results of a Test performed on your sample(s) and other data and information generated during performance of the Test(s). By agreeing to undergo the Test(s), you nevertheless consent to the use of your sample(s), results, and other data and information generated during performance of the Test(s) for the purposes described in this consent.

### Patient Signature

By signing below, you confirm that you have read this consent and have talked with your health care provider about the Test(s), including the purpose, risks, benefits, and alternatives of this testing. You have discussed your questions with your health care provider, and you understand that if you have any future questions or concerns related to this testing, you will speak with your health care provider. You hereby agree to take part in this testing and authorize your sample(s) to be released for this testing. You understand that your leftover sample(s) may be retained indefinitely by Foundation Medicine. You understand that the results of your Test(s), other data and information generated during performance of the Test(s), and other health or demographic information that Foundation Medicine receives about you will be used for the purposes described in this consent. You further understand that the Residual Information and Materials may be used and shared for certain secondary purposes as described in this consent.

**Printed Name**

**Patient Date of Birth**

**Patient/Representative Signature**

**Relationship to Patient** (if applicable)

**Date**