Last Modified: February 27, 2025

Patient Consent

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, genomic profiling tests such as FoundationOne®CDx, FoundationOne®Heme, FoundationOne®Liquid CDx, and FoundationOne®RNA as well as immunohistochemistry (IHC) tests.[1] Your health care provider will tell you which specific Test(s) they are ordering for you. Your health care provider may also order certain germline tests that are performed by Fulgent Genetics (Fulgent) if your provider believes these tests are clinically appropriate for you. The germline tests are described on pages 3-4 of this document.

Genomic profiling 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 IHC testing is a technique that allows a laboratory to identify specific antigens in a tissue sample. IHC tests can be used for a variety of purposes, including classification of different types of diseases, such as cancer, and to predict response to certain therapies. The results of genomic profiling 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. Some types of genomic profiling will help your health care provider monitor your response to treatment, including immunotherapies, and use those insights to make informed decisions for future care. 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 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 a sample of your tissue, blood, 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 to 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) in accordance with Foundation Medicine's standard operating procedures. This material will be analyzed and may be 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). Foundation Medicine will report the results of the Test(s) to your health care provider, who will, unless you direct otherwise, provide you with your results and discuss next steps with you. The results of your Test(s) may become a part of your permanent medical record. 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.

About the Test(s).

Foundation Medicine genomic profiling 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

[1] Descriptions of, and additional information regarding, the Tests are available at https://www.foundationmedicine.com/patient/about-the-test and https://www.foundationmedicine.com/info/detail/ihc-testing.

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 possible germline mutations in certain genes. Foundation Medicine does not provide germline testing (except through testing offered in connection with Fulgent, as described on pages 3-4 below), and the Test(s) do not distinguish between germline and somatic mutations. Therefore, a germline test from another laboratory must be performed if a possible 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 understand and have discussed with your health care provider that because the Test(s) do not distinguish between germline and somatic mutations, no level of certainty has been established that any possible germline mutations identified in the Test report are a predictor of a given disease. You also may wish to discuss with your health care provider seeking genetic counseling from a genetic counselor before pursuing 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, and if required by law in your state, will provide you with this information in written form.

Disclosure of Results.

The results of your Test(s) and other data and information generated during performance of the Test(s) will be maintained confidentially as required by the Health Insurance Portability and Accountability Act of 1996, as amended (HIPAA) and may be used and disclosed in a manner consistent with this consent and our Notice of Privacy Practices, which can be found at https://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 and/or its representatives may redact information that directly identifies you from your sample(s), Materials, 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.

For more information on how Foundation Medicine may use your health information, including your Residual Information and Materials, and your rights and choices with respect to that information (including your right to opt out of certain uses or disclosures of your health information), please visit Foundation Medicine's Privacy Page, which can be found at www.foundationmedicine.com/privacy.

Retention of Samples.

No uses other than those described in this consent will be made of your sample(s). 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 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.

Your Rights Regarding 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.

You also have certain rights with respect to genetic information generated in the performance of the Test(s), as described in our Notice of Privacy Practices, which can be found at https://www.foundationmedicine.com/resource/notice-of-privacy-practices.

Additional Information for Nevada Residents.

For additional information regarding certain rights applicable to Nevada residents, please review the information found at Nevada Administrative Code § 629.110.

Germline Testing.

Your health care provider may also want to order one or more laboratory tests offered by Foundation Medicine through Fulgent (a "**Germline Test**" or the "**Germline Tests**"). The Germline Tests include FoundationOne®Germline More and FoundationOne®Germline.

Sample Collection.

Genetic testing requires a blood sample or saliva/buccal swab. Additional samples may be needed if the sample is damaged in shipment or inaccurately submitted.

Test Description.

FoundationOne®Germline is a next-generation sequencing (NGS) panel designed for the analysis of 50 clinically validated genes associated with hereditary cancer syndromes. This test is intended to aid in the identification of pathogenic and likely pathogenic germline variants to assess cancer risk and guide clinical management. It is suitable for individuals with personal or family history indicative of hereditary cancer syndromes.

FoundationOne®Germline More is an expanded NGS panel analyzing 154 genes, including well-established cancer-related genes and candidate genes with emerging evidence of association with cancer risk. It is intended for patients with complex clinical presentations and family histories requiring broader genetic analysis.

Test Benefits and Risks.

These germline tests can be used by health care providers to understand potential underlying cancer risks in an individual and/or family. You may learn genetic information about yourself or your family members that is not related to the medical concern for which this test is ordered. This information might reveal: genetic risks for diseases that may develop later in life; diseases unrelated to the primary reason for ordering the test; and/or disorders that do not have current treatment. Learning about this information might cause anxiety and psychological stress, which include alteration of self-image, increased anxiety and guilt, altered expectation by self and others, familial stress related to identification of other at-risk family members, difficulty obtaining life and/or disability insurance, and the detection of misattributed parentage.

Limitations.

Genetic testing is complex and Fulgent is taking extensive measures to avoid errors and failed tests. Although the laboratory takes every precaution, technical, biological, and systematic errors may occur. You and/or your healthcare provider will be notified should such an event be discovered.

Accurate interpretation of test results is dependent upon your clinical diagnosis or family medical history, as well as the fact that any reported family relationships are true biological relationships. An erroneous clinical diagnosis can lead to an incorrect interpretation of the laboratory result.

This analysis is specific only for the test ordered, and only variants deemed to be in relation to your clinical presentation or test order will be reported. This test will not detect all variants in any evaluated gene. There are some types of DNA changes that cannot be detected by this test and there are some disease-related DNA changes which are outside the region of the genome that is queried by this test. Your physician may determine that further/other DNA testing is necessary in addition to this test.

The interpretation of the test results will be based on the laboratory's current information at the time of analysis. As medical knowledge advances and new discoveries are made, the interpretation of results may change. It is possible that re-interpretation of results could lead to new information about potential medical conditions. Such reinterpretation must be requested by a physician and will involve additional costs. However, it may not be possible to re-interpret the test data at a future date, and it may instead require retesting with a new sample. While Fulgent does not guarantee re-analysis of all detected or reported variants, if a significant change is identified the laboratory may issue an updated report or contact the original ordering healthcare provider.

All results should be interpreted in the context of the clinical findings, biochemical profile, and your family history.

Return of Results and Use of Your Information.

Fulgent, through Foundation Medicine, will report the results of the Germline Test(s) to your health care provider, who will, unless you direct otherwise, provide you with your results and discuss next steps with you. In certain instances, your health care provider may also receive the results of the Germline Test(s) from Fulgent directly. A positive test result is an indication that you may be predisposed to or have one or more of the hereditary cancer syndromes that is linked to the gene(s) that had a positive result and may wish to consider further independent testing, consult your physician or pursue genetic counseling. The results of your Germline Test(s) may become a part of your permanent medical record and may be material to your ability to obtain certain insurance benefits.

You also may wish to discuss with your health care provider seeking genetic counseling from a genetic counselor before undergoing the Germline Test(s). 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 and, if required by law in your state, will provide you with this information in written form.

No tests other than those ordered by your health care provider will be performed on your sample. Your samples submitted for the Germline Test(s) will be destroyed not more than sixty (60) days after the sample has been taken.

The information generated in the performance of the Germline Test(s) may be used and disclosed by Foundation Medicine and Fulgent for the purposes described in the earlier sections of this consent titled "Disclosure of Results" and "Secondary Data and Sample Uses," including the uses described in the Patient Opt-Out section of Foundation Medicine's Privacy Page, which can be found at https://www.foundationmedicine.com/patient-opt-out-rights, and you have the same rights with respect to information generated in performance of the Germline Test(s) as those described in the sections above titled "Secondary Data and Sample Uses," including the uses described in the Patient Opt-Out section of Foundation Medicine's Privacy Page, which can be found at https://www.foundationmedicine.com/patient-opt-out-rights," and "Your Rights Regarding Samples and Results." References to Foundation Medicine in those sections of this consent and the Patient Opt-Out section of the linked Foundation Medicine Privacy Page shall be read to mean both Foundation Medicine and Fulgent with respect to the Germline Test(s). To exercise your right to opt out, please contact Foundation Medicine at privacy@foundationmedicine.com or +1 (888) 988-3639 so that Foundation Medicine can communicate your request to Fulgent. Please review Fulgent Notice of Privacy Practices, which can be found at https://www.fulgentgenetics.com/content/EP-HIPAA_Privacy_Notice-V3.pdf, for more information on how Fulgent uses and discloses your health information.

By signing below, you (or your legally authorized representative) acknowledge receipt of information regarding the potential risks, benefits, and limitations of the Germline Test(s) and provide your consent as to the matters listed above in this consent, including with respect to (i) the collection, use, retention, maintenance, and disclosure of (a) your samples, (b) your health and demographic information provided by your health care provider, as required for your Germline Test(s) and (c) the results and other data and information generated during performance of the Germline Test(s); and (ii) your right regarding your samples and results, including the right to opt-out of disclosures of de-identified samples and data.

If you have any questions or need additional information about the Germline Test(s), please consult your health care provider before signing 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), other than those submitted for the Germline Test(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 or Fulgent, as applicable, 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