

Patient Consent for Molecular Profiling – Massachusetts/Minnesota/Wyoming



Please read carefully and discuss with your physician.

If you have questions, please contact Caris at PatientNavigator@CarisLS.com or (888) 979-8669.

Email completed form to PatientNavigator@CarisLS.com, or fax to 866-479-4925.

TEST INFORMATION

Purpose of Molecular Profiling

Comprehensive molecular profiling from Caris Life Sciences® (Caris) assesses the biomarkers found in your tumor or blood, revealing a molecular blueprint to help your health care provider (HCP) make more informed and individualized treatment decisions specific to your cancer.

Blood Profiling Only: Caris' molecular profiling of blood sample(s) includes genetic (germline/hereditary) testing, which can provide information about whether your cancer is driven by an inherited DNA variant and your risk of developing other types of cancer or other health problems. Test results may reveal additional information about you or your family that is unexpected, and your testing results may have implications for your family members. You may wish to obtain genetic counseling before consenting to the test. If you provide a blood sample for your test, germline/hereditary test results may include:

Positive: A positive result may indicate that you are a carrier of, predisposed to, or have the specific disease or condition being tested for. If you receive a positive result, you may wish to talk to your HCP or a genetic counselor. You or your family members may be referred for additional or confirmatory testing.

Negative: A negative result indicates that no disease-causing variant was identified in the test performed. However, a negative result does not guarantee that you and your family are free from genetic disorders or other medical conditions, and additional information may become available in the future that could impact the interpretation of your test results. However, Caris is not obligated to update, revisit or later re-evaluate the results of the tests after those results have been made available to your HCP.

Sample Collection

If you consent to testing, your blood and/or tissue sample(s) will be sent to Caris, where DNA and RNA will be extracted from your sample and analyzed.

Test Results

Caris will report your test results to the HCP identified on the test requisition form (and to other HCPs requested by your treatment team, if applicable). Biomarker test results may indicate that the biomarkers being tested for are, or are not, present in your sample and may identify other characteristics of your cancer. Your test results are available from your HCP, or from Caris upon written request in accordance with applicable law.

Benefits, Risks, and Limitations of Genetic Testing

Benefits of the test may include: (i) more information to make healthcare decisions for yourself and your family members, including creating a management or treatment plan; (ii) potential enrollment in research studies; and (iii) important health information for your family members.

You may experience anxiety about the testing, and you may have brief and mild discomfort when providing your tissue or blood sample. In addition, while certain federal and state laws provide some protections against genetic discrimination by employers and health insurers, these laws do not apply in all situations. You can visit www.genome.gov/10002328 for information about the Genetic Information Nondiscrimination Act, a federal law that protects genetic information.

Caris makes no guarantee or warranty that its genetic test(s) detect all genetic mutations and all carriers of a condition. Variations that are not associated with a clinical condition may not be reported to your HCP.

Confidentiality

You have the right to confidential treatment of your sample(s), genetic information, and other health data in accordance with applicable law. Your HCP identified on the test requisition form and their related practice or facility personnel and affiliates may have access to your sample and test results. Caris may also be directed by your HCP to provide results to third parties. Caris personnel and others working for Caris may receive your sample, perform testing or have access to your health data and test results.

Sample/Data Retention, Use, and Sharing

To the extent permitted by applicable laws, Caris may store, use, and disclose your sample(s), genetic information, and other health data, both internally and to third parties, for regulatory compliance purposes, reimbursement purposes, quality assurance or improvement, operational activities, validation studies, research, product development, or in publications. Caris may also use your information to identify and contact you about clinical trials or other research opportunities that may be of interest to you. Your samples will be stored indefinitely. Caris will de-identify or anonymize the sample(s), genetic information, and other health data to the extent required by applicable laws. Third parties that may receive your sample(s), genetic information, and other health data may include non-profit, commercial, or governmental entities such as academic researchers, universities, hospitals, laboratories, and life science, insurance, pharmaceutical, and other companies. If these activities result in commercial products or compensation of any sort, proceeds will not be shared with you or your family, even if your sample(s), genetic information, and other health data are used. You can learn more about Caris privacy practices, including information about how de-identified sample(s), genetic information, and other health data may be commercially used and shared in or out of the United States by visiting www.CarisLifeSciences.com/privacy-us.

PATIENT CONSENT

By signing below:

- I acknowledge that I have read and understand the information provided in this form, including regarding the purpose and potential benefits, risks, and limitations of the test(s) and how my sample(s), genetic information, and other health data may be used, retained, and disclosed. I have discussed with the HCP ordering my test the reliability of positive or negative test results and the level of certainty that a positive test result for that disease or condition serves as a predictor of such disease.
- I acknowledge that I received an opportunity to ask questions, and any questions I had have been answered to my satisfaction.
- I voluntarily consent to performance of the test by Caris and to the collection, use, retention, maintenance, and disclosure of my sample(s), genetic information, and other health data as required to perform the test(s) and for the other purposes described in this form, including research, product development, and publication, to the extent permitted by, and in compliance with, applicable law. MINNESOTA PATIENTS ONLY: I understand that the foregoing consent to disclose my genetic information is valid for a period of one year from the date of my signature below.
- I understand and authorize Caris to obtain payment for services, and I assign all health insurance benefits and reimbursement under my health insurance plan (including Medicare and Medicaid) to Caris. I appoint Caris as an authorized representative with the power to file medical claims, appeals, and/or grievances with the health plan agency or governmental body governing such plans. This appointment includes all rights in connection with any claim, right, or cause of action (litigation) that I may have against my health plan.
- I authorize Caris to act on my behalf regarding the determination, denial and/or any necessary appeal relating to coverage of laboratory services provided by Caris, as well as authorize Caris and third-party payors to release any of my protected health information for the purpose of resolving my claim and/or appeal.
- Caris may contact me in the future about potential research opportunities for which I may be eligible. I understand that I am not under any obligation to participate in any research about which I am contacted, and I can notify Caris by email at PatientNavigator@CarisLS.com if I no longer agree to be contacted in the future about research opportunities.
- I may contact Caris, including by email at PatientNavigator@CarisLS.com, at any time to revoke my consent to the retention of my sample(s), genetic information, and other health data. However, my revocation will not have any effect on the following: (i) any sample(s), genetic information, and other health data that has been de-identified and cannot be readily traced back to me; (ii) any use or sharing of sample(s), genetic information, and other health data that has already occurred, or (iii) to the extent Caris must retain the sample(s), genetic information, and other health data to comply with applicable law.
- I consent and authorize Caris (and its agents, contractors and others acting on its behalf) to place calls or send text messages to me, including those involving a pre-recorded or artificial voice, or placed using any kind of automatic telephone dialing system or other automated system for placing calls or sending texts, to any of the numbers I (or my HCP on my behalf) provide to Caris. These calls or texts may relate to tests that were ordered by my HCP, patient account statements, products or services Caris thinks may be of interest to me, or requests for patient feedback. I understand that call and text message frequency may vary, there is no limit on the number of calls or texts Caris may send to me, and I may incur a charge from my telephone carrier for these calls or texts and Caris is not responsible for the charges. I consent to such calls or texts sent or made without regard to any time-of-day limitations, and even if my telephone number is registered on any state or federal Do Not Call list. I understand that text messages may be unencrypted and carry some risk that the information in the messages could be read by an unauthorized person. I understand that Caris cannot guarantee the security and confidentiality of the text messages it sends to me. I agree that Caris is not responsible for any unauthorized access that occurs during or after the transmission of the text messages to me. I further understand that to opt-out of text messages, I may reply STOP to any text message I receive. To opt-out of telephone calls or voicemail transmission, you may contact Customer Support at 1-888-979-8669.
- WYOMING PATIENTS ONLY: I understand that I have the right to inspect, correct, and obtain my genetic information and request destruction of my genetic information under certain circumstances in accordance with Wyoming Statutes § 35-32-103. For example, Caris may deny my request to destroy my genetic information if retaining my information is necessary for one of the purposes described in this Patient Consent for Molecular Profiling.
- If I am signing on behalf of the patient, I further certify that I have legal authority to consent on behalf of the patient.

Patient Name (print): _____ Date: _____

Patient or Authorized Signatory: _____ Date: _____