

Patient Consent for Molecular Profiling – Nevada

Please read carefully and discuss with your physician.

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

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



TEST INFORMATION

Test Purpose, Sample Collection, and Results

Molecular profiling from Caris Life Sciences® (Caris) assesses cancer markers found in your tumor or blood to help your health care team develop a treatment plan that is specific to you. As part of your testing, your blood sample(s) and/or tumor sample(s) will be sent to Caris, where your sample, and DNA and RNA extracted from your sample, will be analyzed, producing genomic information. Caris will report your test results to the physician who ordered your test and to other health care providers requested by your treatment team. Test results may indicate that the markers 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 physician, or from Caris upon written request as allowed by law.

For blood-based profiling (Caris Assure), you and your doctor each have the opportunity to opt-out from receiving reports of heritable (from your family) genetic information. Your doctor may have opted-out of this reporting as part of your test order. If you would like to opt-out of heritable reporting of genetic information, please check the following box:

I opt-out (do not want to receive) reporting of heritable genetic testing.

Blood Profiling Only: Unless you or your physician have opted-out of receiving reports of heritable genetic information, Caris Assure includes reporting of heritable (from your family) genetic information, which can provide information about whether your cancer is driven by an inherited DNA variant and your risk of developing other types of cancer. These results may reveal additional information about you or your family that is unexpected, and your testing results may have implications for your family members. In some cases, your physician may recommend further testing to clarify those results. You may wish to obtain genetic counseling before consenting to the test. If you provide a blood sample for your test, and you or your physician have not opted-out of receiving reports of heritable genetic information, your 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 physician or a genetic counselor. You or your family members may be referred by your physician 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 physician.

Benefits, Risks, and Limitations of Genomic Testing

Benefits of the test may include: (i) more information to make healthcare decisions for yourself and your family members; and (ii) potential enrollment in research studies. Risks of the test may include: (i) anxiety about the testing; (ii) mild discomfort when providing your tissue or blood sample; (iii) discrimination based on your test results (while certain federal and state laws provide some protections against genetic discrimination, these laws do not apply in all situations. You can visit www.genome.gov/10002328 for information about the Genetic Nondiscrimination Act, a federal law that protects genetic information); and (iv) loss of confidentiality due to unauthorized access to your personal information (Caris implements reasonable safeguards to protect your personal information but cannot guarantee the confidentiality of this information). Limitations: Caris makes no guarantee or warranty that its genomic test(s) detect all genomic mutations and all carriers of a condition. Genetic variation that are not associated with the purpose of testing may not be reported with your test results.

Confidentiality, Sample/Data Retention, Use, and Sharing

You have the right to confidential treatment of your sample(s), genomic information, and other health data in accordance with applicable law. The physician who ordered your test, their staff and affiliates, and third parties as your physician requests may have access to your sample and test results. Caris personnel and others working for Caris may receive your sample, perform testing or have access to your health data and test results. Caris may store, use, and disclose your sample(s), genomic information, and other health data, both internally and to third parties, as permitted by law 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 and data will be stored indefinitely. Caris will de-identify or anonymize the sample(s), genomic information, and other health data to the extent required by law. Third parties that may receive your sample(s), genomic 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), genomic information, and other health data are used. You can learn more about Caris's privacy practices, including information about how de-identified sample(s), genomic 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.

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PATIENT CONSENT

By signing below:

I acknowledge that I have read and understand the information provided in this form, discussed the reliability of positive or negative test results and the level of certainty that a positive test result for a disease or condition serves as a predictor of such disease or condition with my physician, and received an opportunity to ask questions, which 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), genomic information, and other health data as described in this form, including to contact me about potential research opportunities for which I may be eligible. I understand and authorize Caris to obtain payment for testing, authorize Caris to act on my behalf regarding the determination, denial and/or any necessary appeal relating to coverage of the services provided by Caris, and I assign all health insurance benefits and reimbursement under my health insurance plan (including Medicare and Medicaid) to Caris. I authorize Caris and third-party payors to release any of my protected health information for the purpose of resolving my claim and/or appeal. I understand that may contact Caris at any time to revoke my consent to the retention of my sample(s), genomic information, and other health data. However, my revocation will not have any effect on the following: (i) any sample(s), genomic 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), genomic information, and other health data that has already occurred, or (iii) to the extent Caris must retain the sample(s), genomic 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 physician provide to Caris. If I am signing on behalf of the patient, I further certify that I have legal authority to consent on behalf of the patient.

NEVADA CONSENT FOR OBTAINING, RETAINING OR DISCLOSING GENETIC INFORMATION

As used in this document, "genetic information" means any information that is obtained from a genetic test.

1. I understand that no insurer or corporation that provides health insurance, carrier serving small employers or health maintenance organization may: (a) require me or any member of my family to take a genetic test; (b) require me to disclose whether I or any member of my family has taken a genetic test; (c) request my genetic information or the genetic information of a member of my family; or (d) determine the rates or any other aspect of the coverage or benefits for health care for me or my family based on whether I or any member of my family has taken a genetic test or based on my genetic information or the genetic information of any member of my family.
2. I also understand that:
 - (a) I have the right to receive the results of a genetic test, in writing, within 10 working days after the person conducting the test has received the results. The written results must indicate that, except as otherwise provided in Chapter 629 of the Nevada Revised Statutes, my genetic information may not be obtained, retained or disclosed without first obtaining my informed consent.
 - (b) It is unlawful for a person or entity to obtain my genetic information without my informed consent, unless the information is obtained: (1) by a federal, state, county or city law enforcement agency to establish the identity of a person or a dead human body; (2) to determine the parentage or identity of a person in certain circumstances; (3) to determine the paternity of a person in certain circumstances; (4) for use in a study where the identities of the persons from whom the genetic information is obtained are not disclosed to the person conducting the study; (5) to determine the presence of certain inheritable disorders in an infant in certain circumstances; or (6) Pursuant to an order of a court of competent jurisdiction.
 - (c) It is unlawful for a person to retain genetic information that identifies me without first obtaining my informed consent, unless retention of the genetic information is: (1) necessary to conduct a criminal investigation, an investigation concerning the death of a person or a criminal or juvenile proceeding; (2) authorized pursuant to an order of a court of competent jurisdiction; or (3) necessary for certain medical facilities to maintain my medical records.
 - (d) If I have authorized a person to retain my genetic information, I may request that the person destroy the genetic information. Such a person shall destroy the information, unless retention of the information is: (1) necessary to conduct a criminal investigation, an investigation concerning the death of a person or a criminal or juvenile proceeding; (2) authorized by an order of a court of competent jurisdiction; (3) necessary for certain medical facilities to maintain my medical records; or (4) authorized or required by state or federal law.
 - (e) Except as otherwise provided by federal law or regulation, a person who obtains my genetic information for use in a study shall destroy the information upon completion of the study or my withdrawal from the study, whichever occurs first, unless I authorize the person conducting the study to retain my genetic information after the study is completed or upon my withdrawal from the study.

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(f) It is unlawful for a person to disclose or to compel another person to disclose my identity if I was the subject of a genetic test or to disclose to another person genetic information that allows the other person to identify me without first obtaining my informed consent, unless the information is disclosed: (1) to conduct a criminal investigation, an investigation concerning the death of a person or a criminal or juvenile proceeding; (2) to determine the parentage or identity of a person in certain circumstances; (3) to determine the paternity of a person in certain circumstances; (4) pursuant to an order of a court of competent jurisdiction; (5) by a physician after I am deceased and my genetic information will assist in the medical diagnosis of persons related to me by blood; (6) to a federal, state, county or city law enforcement agency to establish the identity of a person or dead human body; (7) to determine the presence of certain inheritable preventable disorders in an infant in certain circumstances; or (8) by an agency of criminal justice in certain circumstances.

I, _____ (name of person giving consent), hereby give my consent to Caris to obtain my genetic information;

I, _____ (name of person giving consent), hereby give my consent to Caris to retain my genetic information; and

I, _____ (name of person giving consent), hereby give my consent to Caris to disclose my genetic information to the health care provider who ordered my test at the address identified on the test requisition and to my health plan/insurance carrier and its authorized representatives as necessary for reimbursement purposes.

By signing below, I also acknowledge that I have read, understand, and agree to each statement on the preceding page of this form.

This consent document is valid until _____ (date of expiration). If no date is provided, this consent document will not expire.

If the person tested is unable to sign, please indicate the reason here: _____

Signature of consenting person or his or her legal representative: _____ Date: _____