

Patient Consent for Molecular Profiling

European Union and United Kingdom



Please read carefully and discuss with your physician.

If you have questions, please contact Caris at CustomerSupport@CarisLS.com or + 00 41 21 533 53 00

Email completed form to CustomerSupport@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 tumour 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. 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.

Your HCP will provide you with genetic counselling if required by the applicable law of your country. If genetic counseling is not mandated by the applicable law of your country, 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 (which is located in the United States), 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 HCP(s) either requested by your HCP, if applicable, or the distributor, if applicable, or as specified on the test requisition form). 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.

Caris makes no guarantee or warranty that its genetic test(s) detect all genetic mutations and all carriers of the purpose of testing. 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 and genetic information in accordance with applicable law. Your HCP [or distributor (where applicable)] 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 test results.

Sample/Data Retention, Use, and Sharing

UK and Europe only: A copy of Caris' privacy notice is available at the link below. This notice does not form part of the consent form. Caris may update the privacy notice from time to time. You can learn more about Caris' privacy practices, including information about how your personal data will be used, stored and shared, and your rights under data protection laws by visiting www.CarisLifeSciences.com/privacy-gdpr.

PATIENT CONSENT – EU AND UK

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).
- I understand that certain personal data may be shared with my healthcare insurer or healthcare plan provider in order for the payment and administration of payment for my test. I understand that my personal data may be used for regulatory purposes, including ensuring that the tests are safe and meet regulatory requirements.
- I understand that my results will be shared with my HCP and those specified on the test requisition form.
- 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 received an opportunity to ask questions of my HCP, and any questions I had have been answered to my satisfaction.
- I have read and understood the privacy notice.
- The collection kit may include components that have not been evaluated for clinical use in the UK.

I agree to the following:

All of the purposes described below.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Note: if you complete this box, then you do not need to complete any other box further below.		
The performance of the test by Caris and the collection, use, retention, maintenance, and disclosure of my sample(s) and genetic information as required to perform the test(s) for the purposes described in this form.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Note: if you do not provide your consent to the performance of the test, then Caris is unable to provide the genetic test to you.		
The use of my sample and personal data for the purposes of research, product development by Caris or its affiliates (and except where such use is required and/or permitted under applicable law).	<input type="checkbox"/> Yes	<input type="checkbox"/> No
The use of my sample and personal data for the purposes of research by academic researchers, universities, hospitals, laboratories, and life science, pharmaceutical, and other companies. You can read more about how your data is shared for research, and the steps we take to protect your data in the privacy policy available [here]	<input type="checkbox"/> Yes	<input type="checkbox"/> No
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.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Caris may contact me in the following ways about 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:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Email	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Phone call, including a pre-recorded or artificial voice message	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Text message	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Changing or revoking consents

- You can read more about your rights as a data subject in our privacy notice.
- I understand that I may contact Caris, including by email at Privacy@CarisLS.com, at any time to revoke any of the consents given in this form.
- I understand that any revocation will not have any effect on the following: (i) any sample, personal data or genetic information that has been anonymized; (ii) any use or sharing of samples, personal data or genetic information that has already occurred, or (iii) any sample, personal data or genetic information that Caris must use or retain in accordance with applicable law.
- 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 of Birth: _____ Date: _____

Patient or Legal Representative: _____ Date: _____