



Informed Consent for Hereditary Cancer Genetic Testing

If you do not have legal authority and capacity to sign this consent under law, a legal representative who has the legal authority and capacity to do so must sign this consent and authorization on your behalf.

I hereby request the genetic testing ordered by my health care provider, which may include molecular, cytogenetic, and/or biochemical analyses of my sample(s). I have received information from my physician or from a genetic counselor that described, in words that I understand, the nature of the genetic testing that I am about to undergo (please see www.sema4.com/testcatalog for test-specific information sheet).

I understand that specimen(s), such as a peripheral blood, saliva, cheek swab, and/or skin biopsy sample, will be taken from me. I understand that these samples will be used for determining if I have a genetic disease, am a carrier of a genetic disease, or am more likely to develop a genetic disease or condition.

The nature of the genetic test(s) ordered in connection with this consent has been explained to me, and the accuracy of the test and its risks and limitations have been detailed. I understand that infrequent errors may occur, even though the likelihood of an incorrect diagnosis or a misinterpretation of the result is extremely small.

I understand that this test will include exome sequencing, which generates data on the portion of my DNA selected by Sema4 that is comprised of key genes that carry instructions for the body's development and function. However, only the information from the test(s) ordered in connection with this consent will be reported back to me.

I understand that there are several types of genetic test results, including:

- **Positive**, meaning that a pathogenic/likely pathogenic variant that may be associated with an increased risk to develop cancer has been identified. The specific type(s) of these risks can vary depending on the gene in which the variant is found. A positive result may have medical management implications. For certain genes/variants, the cancer risks are not well established at this time, and more data and specific medical management recommendations related to these genes may evolve over time.
- **Negative**, meaning that no pathogenic/likely pathogenic variant(s) were identified. A negative result reduces, but does not eliminate, the possibility that I carry a variant(s) in the gene(s) analyzed. It does not change the possibility that I carry a variant(s) in other genes that are not included in the test. I may still have the general population's risk for developing cancer and may also be at a higher risk to develop cancer based on personal/family history.
- **Inconclusive**, meaning that a technically ambiguous finding(s) has been identified. Additional analysis may be able to resolve this uncertainty.
- **Variant of Uncertain Significance**, meaning that an alteration was identified in the genes tested where there is insufficient information at the current time to determine if such alteration is associated with increased cancer risks.

I will discuss any appropriate medical intervention with my healthcare provider before taking any action based on my results, and I will provide my genetic test result and personal/family history to my healthcare providers so that they can make an appropriate recommendation. Knowledge of genetic information will improve over time and new information may become available in the future that could impact the interpretation of my results. In some cases, parental or other relative's specimens may also be tested to determine whether a specific finding was inherited. I understand that test results may reveal incidental, unsought information, such as discovering an undiagnosed disorder. This testing may reveal cases of adoption or demonstrate that a person is not the biological father or mother of the patient. An error in the diagnosis may occur if the true biological relationships of the family members involved are not as I have described.

For a test that requires Sema4 to evaluate my results in the context of clinical information from one or more of my family members and/or my reproductive partner, I understand that Sema4 may disclose my and each of my family members' and/or reproductive partner's clinical information to all tested individuals and our healthcare providers, including in a single comprehensive report, in genetic counseling sessions (if applicable), and consult notes from these sessions, for treatment purposes. I confirm that each person being tested or receiving counseling is aware of the potential for these disclosures.

I understand that my healthcare provider may have ordered a personalized cancer risk score calculation that will compare my risk of developing a certain cancer(s) to the general population risk, and that if ordered, this risk score will be included in my clinical laboratory genetic test report or will be calculated and reviewed with me during my post-test genetic counseling session. I understand that, depending on my risk score and other personal and family history factors, my healthcare provider may recommend that I receive modified cancer screening.

I understand that the results of this testing will become part of my medical record and may only be disclosed to individuals who have legal access to this record or to individuals I designate to receive this information. My test results will be explained to me by a genetic counselor or by my healthcare provider, who will have the opportunity to discuss my results with a geneticist.

There are federal and state laws that address genetic discrimination. The US Genetic Information Nondiscrimination Act may prohibit discrimination based on genetic information by employers and health insurers. This law, however, does not protect people in the military nor protect against discrimination by other types of insurance, such as life, disability, or long-term care insurance.

Please note that Sema4 labs are CLIA-approved and accredited by the CAP. Sema4 is a covered entity under HIPAA. I understand that Sema4 is obligated to retain medical records for regulatory purposes and cannot delete my clinical data.



Sema4 may deidentify and retain my left-over sample(s) to use for operational, quality control, validation and improvement purposes, to the extent permitted by law. If I reside in the state of New York, I understand that my sample(s) will not be used for these purposes and will be destroyed no more than 60 days after they were taken or at the end of the testing process, whichever occurs later.

Sample storage for future clinical purposes

I authorize and consent to Sema4 storing a portion of my sample indefinitely for the purpose of performing any future clinical testing to which I may consent. My sample will not be used for any other purpose without my consent, and no test will be performed on my sample other than the one(s) authorized by me and my healthcare provider. I understand that I may withdraw this consent by following the instructions at www.sema4.com/consent-options/ and any sample identifiable as mine will be destroyed promptly. The withdrawal will apply to all tests that I have undergone with Sema4 to date. I understand that if my sample does not meet Sema4’s criteria, it will be destroyed at the end of the testing process or within 60 days of sample collection, whichever is longer.

Research using de-identified data

Sema4 may de-identify and use all data and information generated and received in connection with this test to support medical and academic research relating to health, disease prevention, drug development, and other scientific purposes. I will receive no compensation in connection with such research. Data and information are "de-identified" by removing any information that could be used to identify a specific person, such as a name, email address, or date of birth. Sema4 may also give the de-identified data and information to its research partners and may submit it to research databases for use in scientific and medical research. Examples of such research include projects to understand the risk factors and outcomes for various conditions and can be found at www.sema4.com/research.

If I do not want to have my de-identified data and information used in research as set forth above, I may withdraw this consent by following the instructions at www.sema4.com/consent-options/, and I understand that the change will apply to all data generated from tests that I have undergone with Sema4. I further understand that this withdrawal will not apply to any information that has already been de-identified and cannot be identified by Sema4.

Financial agreement and guarantee

By my signature on the Sema4 Test Requisition Form or at the bottom of this form, I accept full and complete financial responsibility for all genetic testing ordered by my healthcare provider that is ordered at Sema4. For insurance billing, I authorize Sema4 to bill my health insurance plan on my behalf, to release any information required for billing, and to be my designated representative for purposes of appealing any denial of benefits. I irrevocably assign the payment to Sema4, and direct that payment be made directly to Sema4. I understand that my out-of-pocket costs may be different than the estimated amount indicated to me by Sema4 as part of a benefit investigation. I agree to be financially responsible for all amounts as indicated on the explanation of benefits issued by my health insurance plan. If my insurance provider sends a payment directly to me for unpaid services performed by Sema4 on my behalf, I agree to endorse the insurance check and forward it to Sema4 within 30 days of receipt as payment towards Sema4’s claim for services rendered. If I do not have health insurance, I agree to pay for the full cost of the genetic testing that was ordered by my healthcare provider and billed to me by Sema4.

I understand that a completed **Advance Beneficiary Notice (ABN)** is required for **Medicare** patients if the service is deemed non-covered.

Permission to contact

I understand that Sema4 may wish to contact me in the future, including for the following reasons: research purposes, and the provision of general information about research findings. If I wish to opt-out of future contact for research purposes, I will notify Sema4 by following the instructions at www.sema4.com/consent-options/. I understand that Sema4 may contact me regarding this test and/or the provision of information about the results of tests on my sample(s), and I cannot opt out of this type of contact.

My healthcare provider has discussed my test order(s) with me, and I hereby consent to have my specimen tested. I have been encouraged to ask questions and agree that any questions I have asked have been answered to my satisfaction. If my legal representative is signing this consent and authorization, my legal representative is satisfied that they have received enough information to sign on my behalf.

The most updated versions of our consent forms can be found at: <https://sema4.com/resources/>. Further information about managing your privacy options can be found at: <https://sema4.com/consent-options/>.

Please complete all required (*) fields and optional applicable fields below:

| | | |
|---|----------------|---------------|
| Patient Name* | Patient’s DOB* | Date* |
| Signature of Patient or Legal Representative* | Email Address* | Phone Number* |
| Legal Representative Name (if applicable) | | |

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