

This document should be read with the understanding that mentions of “my healthcare provider,” “my sample,” “my results,” and so on refer to the patient being tested. If the patient is a minor, the parent or guardian will provide consent on the minor’s behalf.

My healthcare provider has ordered one or more genetic screens or tests offered by Labcorp Genetics Inc. (“Labcorp Genetics”). Labcorp Genetics performs all Invitae genetic screens and tests. More information about _____ (condition(s) tested or other reason for testing), as well as the screen(s) or test(s) ordered, is available from my healthcare provider and can also be found on the Invitae website (www.invitae.com).

How is testing performed? Testing is performed on a small sample of blood, saliva, buccal swab or isolated DNA. Once collected, the sample will be sent to the laboratory for testing. The testing will be looking for changes in genetic sequence, known as “variants.”

What might I learn from this test? The results of this test could be:

- a. Positive, and may:
 - i. contribute to the diagnosis of a genetic condition.
 - ii. reveal carrier status for a genetic condition that my child could inherit.
 - iii. reveal a predisposition or an increased risk for developing a genetic disease in the future.
 - iv. have implications for other family members.
- b. Negative, and may:
 - i. reduce but not eliminate the possibility that my condition has a genetic basis.
 - ii. reduce but not eliminate the possibility that my child could inherit a genetic disorder.
 - iii. reduce but not eliminate my predisposition or risk for developing a genetic disease in the future.
 - iv. be uninformative.
 - v. not remove the need for additional testing.
- c. Of uncertain significance or indeterminate and may:
 - i. lead to a suggestion that additional testing, or the genetic testing of additional family members, may be helpful.
 - ii. remain uncertain for the foreseeable future.
 - iii. be resolved over time. My healthcare provider will be notified of any changes to the classification of previously reported variants that relate to my result.

What are the risks and limitations of this test? This test may or may not help my healthcare provider better understand my health and treatment options. Some types of DNA variants that could cause a specific genetic disorder may not be detected by this test. When available, testing an affected family member may be more informative. As with all molecular genetic tests, this test has technical limitations that may prevent detection of some rare gene variants, or may give an inaccurate result, due to: poor DNA quality, rare technical errors in the laboratory, incorrect reporting of family relationships or clinical diagnosis information, or other types of limitations. In some circumstances, additional testing or testing of other family members may be appropriate and provide additional information. Labcorp Genetics generates a report for the test(s) that were ordered by the healthcare provider. In the course of performing the ordered tests, Labcorp Genetics may rarely find variants that are unrelated to the clinical concern that prompted my having the test but are associated with a significant risk for another condition that could negatively impact my health. These are known as “incidental findings.” In accordance with well established medical guidelines, Labcorp Genetics will include these in my report when there are accepted medical interventions available and my healthcare provider can discuss these with me. There is a possibility that, if multiple family members are tested, this test may find that my family relationships are not what I believe them to be. For example, this test could find that the stated father of an individual is not the biological father. Labcorp Genetics will only report these findings if necessary to provide correct test results. In cases where a specimen is also collected for RNA analysis, the specimen will begin processing upon receipt, however depending on the result of the DNA analysis, the RNA data may not be analyzed or used as evidence in DNA variant classification. Rarely, RNA analysis may lead to an indeterminate overall test result. It is my responsibility to consider the possible impact of my test results as they relate to insurance rates, obtaining disability or life insurance and employment. Within the United States, the Genetic Information Nondiscrimination Act (GINA), a federal law, provides some protections against genetic discrimination. For information on GINA, visit <http://www.genome.gov/10002328>.

How will I learn my results? Labcorp Genetics’ clinical reports are released to the certified healthcare provider(s) listed on the test order form. Clinical reports are confidential and will only be shared in accordance with applicable laws. My clinical report is available for me to download from the Invitae patient portal (www.invitae.com/patients/signin) after it has been released to me by my healthcare provider(s) or upon my request in accordance with the law.

Who can I speak to about my test and results? Labcorp Genetics recommends that I consult with a genetic counselor or my healthcare provider before consenting to this test, and that I speak to a genetic counselor or my healthcare provider about my results.

Will my test results ever change? Knowledge of genetic information will improve over time, so new information may become available in the future that could impact the interpretation of my results. Labcorp Genetics may notify me of clinical updates related to my genetic test, in consultation with my ordering healthcare provider. I may request additional notifications and resources relevant to my genetic test by creating an Invitae patient portal account at www.invitae.com/patients/signin.

This section describes how Labcorp Genetics uses and protects my data and the choices available to me to determine how it is used.

What types of data does Labcorp Genetics use? As a genetic testing laboratory, Labcorp Genetics receives my sample (e.g. blood, saliva) along with my relevant health information. The laboratory then analyzes the genetic information contained within the sample and delivers a genetic test report to my healthcare provider. My sample and the health and genetic information received and generated about me (collectively, “my data”) is considered as sensitive personal data by regulators. My data is subject to strict legal requirements regarding how it can and cannot be used and how it must be protected.

How does Labcorp Genetics protect my data? Robust measures are taken to help keep my data safe and secure and limit use of my data only for permitted purposes. Technical, administrative and physical safeguards are in place to secure my data and protect it against misuse, loss, or alteration. Steps are also taken to de-identify or anonymize my data in accordance with applicable laws. De-identified data (also called pseudonymized data) is data that has been stripped of identifying information (such as my name or email address), although the data may contain a key that Labcorp Genetics can use to link back to the individual where required. Anonymized data is similar to de-identified data except that there is no ability to link the data back to an individual.

How may my data be used or shared? The following activities are a core part of the laboratory’s genetic testing services such that when I consent to a genetic test, **I am consenting to and understand I cannot opt out** of these activities:

- Providing genetic testing services, including preparing and delivering a genetic test report to my healthcare providers.
- Performing operational activities in support of genetic testing services, such as billing for services provided. Labcorp Genetics may contact me via text or email (per my contact preference) as part of delivering the genetic testing services.
- Internal uses for validation, quality improvement, refining and updating the laboratory’s classification of genetic variants, and product development related to genetic testing.
- Sharing of anonymized variant information with ClinVar, a federal program that enables research on genes and health.
- Sharing of data that is summarized at a group or aggregate level rather than data that is specific to a single individual.
- Sharing of the contact information of my healthcare provider with third parties if my healthcare provider has provided consent.

I am also consenting to the research and commercial activities as set forth below, **and I understand I can opt out of any of the following activities** by setting my preferences in the Invitae patient portal or by emailing clientservices@invitae.com. Samples originating in the State of New York will not be eligible for the research and commercial activities described below, nor for quality assurance activities. No tests other than those authorized shall be performed on my biological sample, though my de-identified data may still be utilized unless I opt out as described above.

- Performing internal research activities. These are activities where Labcorp Genetics uses patient samples or data to generate new knowledge.
- Sharing de-identified data and samples with third parties for research or commercial activities. Third parties may include academic researchers, commercial entities, and other genetic testing laboratories. Recipients of the de-identified data and samples are prohibited from attempting to re-identify me. Recipients may link de-identified data from Labcorp Genetics with other data sources to create a combined data set as long as the data remains de-identified. Labcorp Genetics will NOT share my identifiable data or sample without my additional, explicit consent. If I opt out of data sharing after my data has already been shared, I understand my data cannot be “un-shared”.
- Contacting me about research opportunities, opportunities to connect with others, product feedback, and new products and services.

Sponsored Testing Programs and Data Sharing. If I choose to participate in a sponsored testing program or other data sharing program offered by Labcorp Genetics to help individuals access genetic testing, I am consenting to de-identified data sharing through the program. I understand that (1) I cannot opt out of data sharing through the program (except where required by law) and (2) my general data sharing preference will not apply to data sharing through the program.

What happens to my data if I am outside the United States? Labcorp Genetics is located in the United States and Labcorp Genetics will process my data and sample in the United States.

How long may my data or sample be retained? The laboratory may retain my data and sample for as long as reasonably necessary for the purposes described above. **However, if I am a resident of New York**, my sample will be destroyed no more than 60 days after the sample was taken or at the end of the testing process, whichever is later.

How can I find more information about how my data is used and shared? Labcorp Genetics provides more information about its data use practices on its privacy homepage at www.invitae.com/privacy. On that page, Labcorp Genetics provides a link to the Privacy Policy, HIPAA Notice of Privacy Practices, and other privacy resources.

BY SIGNING BELOW, I CONFIRM THAT: (1) I have read (or had read to me) and I understand the information provided in this consent; (2) I understand that genetic testing is voluntary, and I may choose not to have my sample tested; (3) I have received a copy of this consent form; (4) All my questions have been satisfactorily answered; and (5) I hereby consent to genetic testing and to the retention, use, and sharing of my data and sample as described in this form.

Signature	Date (MM/DD/YYYY)
Printed name	I am the (select): <input type="radio"/> Patient <input type="radio"/> Parent/guardian (if patient is a minor)
Email address	

HEALTHCARE PROVIDER STATEMENT: By signing below, I attest that: (1) I am the referring physician or authorized healthcare provider; (2) I have explained the purpose of test described above; (3) The patient has had the opportunity to ask questions regarding this test and the retention, use, and sharing of his/her data and sample, and to seek genetic counseling; and (4) The patient has voluntarily decided to have this test performed by Labcorp Genetics.

Healthcare provider signature	Date (MM/DD/YYYY)
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**Where I sign this form on behalf of another person, I confirm that I have the legal authority to consent on behalf of such person.*