

Sanford Medical Genetics

Informed Consent for Pharmacogenetic Testing

This test is for pharmacogenetic testing as ordered by my, or my child/dependent's, healthcare provider and I give my permission for a sample to be collected.

Pharmacogenetics

Pharmacogenetics (fahr-muh-koh-juh-net-iks) is the study of how your genes may affect the way your body processes some medications. Medication processing is controlled by more than one gene. Most people have at least one group of medications that are processed differently compared to others.

I understand:

- I can choose or refuse pharmacogenetic testing.
- This test can detect small differences (variants) in my DNA that can affect the way I process some medications.
 - These variants can decrease the effectiveness of some medications or increase the risk of side effects.
 - Medications chosen based on this test may not be more effective or safe, but do not increase the risk of standard treatment, which is trial and error.
- The results may show that I:
 - Am predisposed to (at risk) for a certain genetic condition.
 - Have a specific genetic condition.
 - May be a carrier of a genetic condition.
- The result may help make informed choices about future health care, but some genetic results do **not** have health care guidelines.
- Testing may **not** show results because of different reasons, which may include issues with the specimen, incomplete knowledge of all the genetic markers, or technical reasons.
- Additional testing may be recommended by my healthcare provider based on my test results.
- Sanford has genetic counseling resources available for questions I may have. I may call 605-312-GENE (605-312-4363) for more information about genetic counseling.

Limits of testing

- This test is only looking for genetic changes in the areas covered by the test.
- There may be a genetic change outside the area tested. This change will **not** be found by the test.
- The quality or amount of sample sent for testing may not be good enough for testing or that a genetic change is **not** found.
- Although genetic results are usually without error, there may be an error in the test results. This can be caused by:
 - Incorrect information provided regarding family history.
 - Sample mislabeling or contamination of the sample.
 - Past blood transfusions or bone marrow transplantation.
- Errors in test results may lead to a medication being ordered that your body may not process. This may lead to treatment that is not more effective or safe.



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Privacy

I understand:

- My genetic test results will be a part of my health record and I will receive notice (via MyChart) when they are available.
 - The Sanford laboratory team will have access to my sample.
 - I and my healthcare team will have access to my results.
- The confidentiality of my medical record is protected by the federal privacy law known as HIPAA (Health Insurance Portability and Accountability Act).
- How information in my medical record is accessed, used, and disclosed (shared) is explained in Sanford Health's Notice of Privacy Practices.
- Federal law does **not** allow health insurers and employers to discriminate based on genetic information. This law is known as the Genetic Information Non-discrimination Act of 2008 (Public Law 110-233).
- I can consult with my legal advisor to find out what impact the genetic test results may have on my life, long term care, or disability insurance.

Sample Storage

- The laboratory will keep the sample after the result is issued for a period of time in the case that follow-up testing is needed.
- After follow-up testing, personal information will be removed from your sample.
 - Samples without personal information will be kept and may be used for research and making new clinical tests or improvements to current tests. If you do not want us to keep your sample for any reason other than follow-up diagnostic testing, call 605-312-GENE (605-312-4363).

My signature below indicates:

- I have read this form, or it has been read to me.
- I have been given the chance to ask all my questions.
- I understand the risks and choices I have related to genetic testing.

I consent to have a sample collected for pharmacogenetic testing.

Patient/Parent/Guardian Signature

Date

Time

If not the patient, write your relationship to the patient: _____

Fax completed form to 605-312-9002

