ARUP LABORATORIES | NATIONAL REFERENCE LABORATORY

A nonprofit enterprise of the University of Utah and its Department of Pathology

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INFORMED CONSENT FOR GENETIC TESTING

Patient Name: _____ **Date of Birth:** _____
Sex Assigned at Birth: ☐Female ☐Male ☐Intersex **Gender Identity (optional):** ☐Female ☐Male ☐_____
Sample Type: _____ **Test Indication:** _____
Test(s) to be Performed: _____

- Participation in genetic testing is completely voluntary. Genetic counseling is recommended before and following genetic testing. See nsgc.org or acmg.net to find a medical genetics professional.
- Providing accurate information about symptoms and family history enables correct test selection and interpretation. In cases where a family member has tested positive for a genetic change, a copy of that report may be required by the laboratory before testing can be started.
- Results from genetic testing may be positive, negative, or inconclusive.
  - A positive result may confirm whether a person is affected with, a carrier of, or at risk for developing a genetic condition.
  - A negative result does not exclude the possibility of being affected with or a carrier of a genetic condition. Genetic conditions may have many causes, some of which may not be completely known or testable.
  - An inconclusive result may occur due to limitations of laboratory methods, limitations in knowledge of the meaning of identified variant(s), or poor sample quality. Inconclusive results from biochemical tests may occur due to an individual's clinical status (fasting, illness, etc.) at the time the sample was drawn.
- Identified genetic variants are interpreted using current information in the medical literature and scientific databases. Since this information can change, ARUP may issue a revised report if the meaning of the variant changes. Individuals with a variant of uncertain significance should contact their healthcare provider periodically to determine if new information is available.
- Genetic testing results may provide information that was not anticipated, such as:
  - Identifying a genetic risk unrelated to the original reason for testing.
  - Predicting another family member has, is at risk for, or is a carrier of a genetic condition.
  - Revealing nonpaternity (the person stated to be the biological father is not, in fact, the biological father).
  - Suggesting the parents of the individual tested are blood relatives.
- Although genetic test results are usually accurate, several sources of error are possible, including clinical misdiagnosis of a condition, inaccurate information provided regarding family relationships, sample mislabeling or contamination, transfusion, bone marrow transplantation, and maternal cell contamination of prenatal or cord blood samples.
- If a genetic variant is identified, insurance rates, the ability to obtain disability and life insurance, and employability could be affected. The Genetic Information Nondiscrimination Act of 2008 extends some protections against genetic discrimination (genome.gov/10002328). All test results are released to the ordering health care provider and those parties entitled to them by state and local laws.
- Because ARUP is not a storage facility, most samples are discarded after testing is completed. Some samples may be stored indefinitely for test validation or education purposes after personal identifiers are removed. You may request disposal of your sample by calling ARUP Laboratories at 800-242-2787 ext. 3301.

  Note: All New York samples will not be used for research or quality assurance and will be destroyed automatically within 60 days of collection.
- In cooperation with the National Institutes of Health's effort to improve understanding of specific genetic variants, ARUP submits HIPAA-compliant, deidentified (cannot be traced back to the patient) genetic test results and health information to public databases. The confidentiality of each sample is maintained. If you prefer that your test result not be shared, call ARUP at 800-242-2787 ext. 3301. Your deidentified information will not be disclosed to public databases after your request is received, but a separate request is required for each genetic test. Additionally, patients have the opportunity to participate in patient registries and research. To learn more, visit ARUP's Genetics Resources website at https://www.aruplab.com/genetics.

My signature below constitutes my acknowledgment that the benefits, risks, and limitations of this testing have been explained to my satisfaction by a qualified health professional and I have been provided the additional technical information (as applicable) describing the test(s) to be performed at aruplab.com.

_____	_____	_____
Patient/Guardian Printed Name	Signature	Date

Physician/Genetic Counselor: I have explained this genetic test, its risks, benefits, and alternatives to the patient or legal guardian and addressed all their questions.

_____	_____	_____
Physician/Genetic Counselor Printed Name	Signature	Date