**Performing Laboratory:**

National Jewish Health Advanced Diagnostic Laboratories

Invitae

Blueprint Genetics

Ambry Genetics

Other: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Test(s) to be Performed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Test Indication/Description of the Disease: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Performing Lab Test Code & Principle of the Test (refer to appropriate test directory): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*Before agreeing to have this treatment or procedure it is important that you read and understand this consent form. This consent describes the treatment or procedure and any risks it may involve. Please ask your doctor to explain any words or information you do not clearly understand.*

# What is involved in the testing?

* A blood, saliva or tissue sample is collected by medical professionals and sent to performing laboratory for isolation and purification of DNA for molecular genetic testing.

# What are the benefits of having this test?

* This test is designed to detect disease-causing mutations. Whether or not mutations are present, this information may help diagnose and manage your condition. It will not detect all mutations within this gene, nor detect mutations in other genes. This test may have 3 possible outcomes:
  + Positive: The test shows that I have this condition or am at risk for developing this condition.
  + Negative: The test failed to find any significant abnormality in the gene. A negative result does not rule out a hereditary cause for this condition. There may be a small chance that I have this condition. Due to limitations in technology and incomplete knowledge of genes, some changes in DNA or protein products that cause disease may not be detected by the test.
  + Inconclusive: 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.
* This test may reveal unrecognized biological relationships (such as non-paternity). It may also reveal some other unknown familial genetic patterns.
* The results of this test may have implications for other family members. They may predict whether another family member has or is at risk for developing this condition, or is a carrier of this condition.
* Although genetic analysis often yields precise information, several sources of error are possible. These include, but are not limited to:

-Clinical misdiagnosis of the condition -Sample contamination

-Sample misidentification -Inaccurate information regarding family relationships

# What are the risks and limitations of the test?

* DNA testing may cause emotional stress, and you may have concerns about discrimination (insurance or work-related). National Jewish Health is committed to protecting your privacy. We treat all results with medical confidentiality. There are federal and state laws in place that protect you from discrimination by health 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**](http://www.genome.gov/10002328).
* The results of this test might be inconclusive about your genetic status. Depending on the results of this test, your physician may recommend genetic counseling or further testing and/or my family members.
* There may be technical limitations that prevent detection of rare gene variants or may give an inaccurate result, due to poor DNA quality, rare technical errors in the laboratory, other types of limitations.

# Will my health information be kept confidential?

* Genetic testing is complex and there are important implications of test results. Results will be released only to:

-the doctor ordering the test

-an insurance provider requiring test results for reimbursement purposes

-persons designated by me in writing

-or as required by law

# What if I have questions?

* If I have any questions about the test, I can ask to speak with my doctor or a genetic counselor before signing this consent. National Jewish Health recommends speaking to your healthcare provider about the results after the test is complete. Participation in genetic testing is completely voluntary. Genetic counseling is recommended prior to and following genetic testing. See nsgc.org or acmg.net to find a medical genetics professional.

# What may happen if you refuse this treatment or procedure?

* If you decide not to have this test, it may make the diagnosis and treatment difficult.

# What are the alternatives to the treatment or procedure?

* You may choose not to undergo this procedure.
* At this time, there are no substitute tests available that provide the same information.

# What are the benefits and risks of the alternatives?

* If you decide not to have this test, it may make the possibility of correct and/or appropriate diagnosis and treatment difficult.

**What will happen to my sample?**

* Because NJH 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 early disposal of your sample by calling NJH ADx at 800-550-6227.

# No Guarantee:

* I understand that no guarantee or assurance has been made concerning the results of the test and that it may not diagnose my condition.
* National Jewish Health may contact me or my health provider if new information is learned that affects the interpretation of previously reported test results. A reasonable effort will be made to contact me through my doctor, or another person designated in writing. I may indicate my desire to opt out of being contacted by checking this box
* **DNA analysis is a fee-for-service test.** I understand that the performing laboratory will submit a claim to insurance on my behalf, and I authorize my insurance benefits to be paid directly to the performing laboratory. The performing laboratory is authorized to release medical information concerning the testing to my insurer and act on my behalf for denial appeals. I am responsible for all charges for testing in the event my health plan does not reimburse for the test.
* My (or my child’s or my unborn child’s) sample may be used for test validation or education after personal identifiers are removed. Refusal to permit the use of my sample will not affect my test result. For such use, the sample may be stored indefinitely. I can withdraw my consent at any time by contacting the laboratory at (800) 550-6227 or by checking this box

**My signature below indicates:** (1) I have read, or had read to me, the above information and understand it. (2) I have also read or had explained to me the specific disease(s) or condition(s) tested for, and the specific test(s) I am having performed. (3) I have had the opportunity to discuss the purposes or possible risks of this testing with my doctor, a genetic counselor or someone my doctor has designated. (4) The significance of a positive or negative test result based on my family history has been explained. (5) I know that genetic counseling is available to me before and after the testing. (6) I have all the information I want, and all my questions have been answered. (7) I give my consent to have blood, saliva or a tissue sample sent to National Jewish Health Advanced Diagnostic Laboratory or other performing laboratory specified above for DNA analysis for the above test.

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|  |  |  |  |  |
| **Date** |  | **Time** |  | **Patient or Authorized Representative** |

|  |  |
| --- | --- |
|  |  |
|  | **Patient Printed Name** |

If signed by Authorized Representative:

Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

State how Authorized: □ Legal Guardian □ Medical Durable Power of Attorney □ Parent of Minor □ Power of Attorney □ Proxy Decision Maker □ Other: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Provider Statement:**

By signing below, I attest that: (1) I have discussed the test, benefits, risks, consequences and alternatives, along with the benefits, risks and side effects related to the alternatives, and the risks related to not receiving the test with the patient or guardian. (2) The patient has had the opportunity to ask questions regarding this test, and to the best of my knowledge, the patient or his/her guardian understands information in the consent. (3) The patient has voluntarily decided to have this test performed.

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| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Date** |  | **Time** |  | **\*Health Provider Signature (who is reviewing this information with the patient**) |