

Patient Name

DOB

MRN

Physician

FIN

Genetic testing requested for _____
_____ (condition)

by way of _____

(Note test: microarray, multiple gene sequencing, *DMD* sequencing and deletion/duplication, arylsulfatase B enzyme testing, etc.)

INTRODUCTION:

Based on my family and/or personal history, I am asking for genetic testing. I freely choose to be tested. The reason for the test is noted below. I have had a chance to talk about this(ese) test(s) in detail with my health care provider. To have my child (under 18 years of age) tested, a parent or legal guardian will need to give permission.

REASON:

The reason for this genetic testing is: *(check all that apply)*

- ☐ Carrier status ☐ Prenatal ☐ Diagnostic ☐ Pre-symptomatic
☐ Predictive ☐ Screening ☐ Other _____

PROCEDURE:

GENETIC COUNSELING: I may ask for genetic counseling by a genetics professional before being tested.

This counseling would include:

- Reviewing family and medical histories
- Talking in detail about the risks, benefits, and limitations of this genetic test.

WHAT WILL HAPPEN:

- A sample will be taken from me (such as blood, tissue, amniotic fluid, or chorionic villi).
- My sample will be sent for the genetic testing that is noted above. Testing will be done at the:
☐ Spectrum Health Laboratory
☐ Reference laboratory that is listed below by way of the Spectrum Health Referral Department:
_____ (laboratory name)
- Only the specific test(s), that my doctor orders, will be run on my sample. I will get results only for those specific tests.
- **Test results:**
 - Will come from the Laboratory.
 - Will be given ONLY to the doctor named below or their agent.
_____ (Ordering Physician name)
 - Will be given to me by my doctor or their agent.
When: When the test results are available, the choices for being given the results are:
 - I can choose to be given the results as soon as possible.
 - I can choose to be given the results at a later time.
 - I can choose to not be given the results at all.How: They will be given either in-person or by phone. A follow-up appointment for genetic counseling may be recommended.
- May be seen by:
 - Another person or entity, ONLY if I authorize it in writing.
 - A legal representative or entity, ONLY if the test results are required by law.
 - Other doctors or their agent who have access to my electronic medical record.



PROCEDURE: (CONTINUED)

WHAT WILL HAPPEN: (CONTINUED)

- Any unused part of my sample may be kept by the laboratory for quality control or validation reasons. My sample will not be used for research or other clinical testing unless I authorize it.

INTERPRETATION OF INFORMATION FOR TEST RESULTS:

The test results will be interpreted using my own personal and family history. The laboratory needs accurate information about my personal history, family history, and ethnic background for the most accurate interpretation of the test results.

POSITIVE TEST RESULT:

- Indicates that I:
 - Carry or may carry a gene mutation.
 - May be predisposed to developing the genetic condition.
 - May have the genetic condition.
- It is recommended that I talk to my doctor or genetic counselor to learn the full meaning of test results. More testing may be needed to confirm a diagnosis or to make the meaning of the test results more clear. Genetic testing may be available for at-risk relatives. It is rare, but results may suggest a condition which is different than the genetic condition which was originally considered.

NEGATIVE TEST RESULT:

- Indicates that no variations were seen.
- Unless otherwise stated, there still may be a chance I:
 - Am a carrier of the condition(s).
 - Am predisposed (susceptible) to develop this genetic condition
 - Have this genetic condition.

These things can happen because of the limitations of the testing technology and/or an incomplete knowledge of all the genetic causes of this condition.

UNCERTAIN TEST RESULT:

- Indicates the test results are either:
 - Not able to be interpreted.
- OR**
- Of unknown significance. This indicates a variation is seen, but it is not known whether this variation is related to this genetic condition or if it is a normal variation.
 - Additional genetic testing for this variation may be available for my family members. Their test results may help to make my test results more clear.

BENEFITS:

These genetic test results may:

- Give a diagnosis, whether I currently have symptoms or not.
- Give risk information.
- Make a difference on my treatment recommendations and decisions.
- Give family members information about their risk, if I choose to share results.

RISKS:

Some individuals who have genetic testing may:

- Have feelings of anxiety, depression, guilt, or anger.
- Have negative psychological reactions.
- Get results that show someone is not a biological relative (i.e. non-paternity, adoption).

By getting genetic testing, it may be harder or not possible to get life insurance in the future. Some life insurance companies may need information about genetic testing results to make a decision about coverage. There are federal laws that offer some protection for health insurance, long-term disability, and employment discrimination based on genetic test results. These laws include the Health Insurance Portability and Accountability Act (HIPAA) and the Genetic Information Nondiscrimination Act (GINA).

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LIMITATIONS:

- Genetic testing will only look for variations associated with this(ese) genetic condition(s).
- Unless otherwise stated, negative genetic test results may not completely rule out that I:
 - Am a carrier of the condition(s).
 - Am predisposed (susceptible) to develop this genetic condition.
 - Have this genetic condition.
- There may be different recommendations on the best way to proceed, if my results are positive.
- Genetic test results do not guarantee my health, the health of an unborn child, or the health of other family members.

CONFIDENTIALITY:

Genetic test results will become part of my electronic medical record. My medical record is confidential. Test results will only be given if I authorize it (in writing) to a specific person or company. My current or future insurance carriers will not have access to this information unless I authorize a release of medical information.

BY SIGNING THIS FORM I AGREE:

- I have read this form or it has been explained to me in words I can understand.
- I understand the above information.
- I have had time to speak with the doctor about this information. All my questions have been answered.
- The decision to consent to, or to refuse the above testing, is voluntary and entirely mine.
- I want to have this testing and get results.

Time Date Patient Signature TIME DATE Witness to Signature

If a patient is under 18 years of age or otherwise unable to consent, the following must be completed:

I, _____, hereby certify that I am the _____ of the patient; that patient is unable to consent because patient is a minor, or because:

Time Date Signature of Parent, Legal Guardian, Patient Advocate or Next of Kin TIME DATE Witness to Signature

PHYSICIAN/COUNSELOR STATEMENT

I have explained genetic testing (including the risks, benefits, and alternatives) to this individual. I have addressed the limitations outlined above, and I have answered this person's questions to the best of my ability.

TIME _____ DATE _____ Physician/Counselor signature _____