

## Informed Consent for Outpatient Referral Lab Genetic Testing

I, \_\_\_\_\_, request and permit an approved, licensed Genetic Reference Lab to analyze the gene(s) indicated by my clinician on:  My sample  My child's sample.

I hereby consent to genetic testing for \_\_\_\_\_.

### I UNDERSTAND THAT:

1. A single gene test or a panel of tests may involve out-of-pocket expenses depending on the reference lab selected, the test(s) requested by my clinician, and my insurance provider and/or coverage.
2. The reference lab selected for this testing may contact me regarding insurance coverage and to discuss payment options for this testing.
3. I am responsible for verifying whether the reference lab accepts my insurance, whether my insurance covers the tests ordered, and any financial responsibility I may have for reference lab testing.
4. I may receive invoices from a reference lab that is not affiliated with Johns Hopkins All Children's Hospital for services performed.
5. No testing apart from that which is ordered will be performed, and any additional testing requires my additional, express consent.
6. The results of this DNA test could be:
  - a. Positive, and may:
    - i. contribute to the diagnosis of a genetic condition.
    - ii. reveal carrier status for a genetic condition.
    - 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 my predisposition or risk for developing a genetic disease in the future.
    - iii. be uninformative.
    - iv. not remove the need for additional testing.
  - c. Uncertain significance and may:
    - i. lead to a suggestion that testing 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 (my child's) result.
7. Molecular genetic tests may not be diagnostic for the selected condition(s) in all individuals. This test may or may not provide actionable information or have an implication on my medical management.
8. Some types of DNA changes that could cause a specific genetic disorder may not be detected by this test. As with most molecular genetic tests, they have technical limitations that may prevent detection of rare variants, poor sample quality, current limits of medical knowledge and technology.
9. There may be possible sources of error including, but not limited to, contamination, technical error in the laboratory, rare DNA variants that compromise data analysis, inconsistent scientific classification systems, and inaccurate or insufficient reporting of family relationships or clinical diagnosis information.
10. The referral genetic lab will only interpret the parts of the DNA sequence of gene(s) indicated on the requisition form by my or my child's physician. However, the technology obtains the DNA sequence information related to a broad range of genetic conditions and interpretation and release of other parts of the remaining genetic data can be requested through my healthcare provider (additional charges may apply).

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11. Clinical reports are released only to the certified healthcare professional(s) listed on the test requisition form. Clinical reports are confidential and will only be released to other medical professionals with my explicit consent. It has been explained to me that my clinical report is available to me after it has been reviewed and released by my healthcare professional(s). Alternatively, my clinical report can be made immediately available upon completion of the test with the prior approval of my healthcare professional, as indicated on the test requisition form.
12. It is my responsibility to consider the possible impact of my or my child's test results as they relate to insurance rates, obtaining disability or life insurance and employment. 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>.
13. Results from genetic testing are analyzed with the assumption that correct information on family relationships has been provided. Due to the type of test performed there is the possibility that inconsistencies in information on family relationships could be identified if multiple family members are tested. For example, this test may detect misattributed paternity, where the stated father of an individual is found to not be the true biological father. It may be necessary to report these findings to an individual who requested testing.
14. I will be offered genetic counseling with a geneticist, genetic counselor or other qualified healthcare provider who can answer questions, provide information and advise me about alternatives before and after having this test. Further testing or additional physician consults may be warranted.
15. The results are confidential to the extent allowed by law. They will only be released to other healthcare professionals or other parties with my written consent or as otherwise allowed by law.
16. Because the understanding of genetic information will improve over time, the referral genetic lab may notify me of clinical updates related to my (my child's) genetic profile (in consultation with my primary clinician as indicated).
17. I have the right to receive a copy of this consent form.

### BY SIGNING BELOW, I ATTEST TO THE FOLLOWING:

1. I have been informed of the likelihood of finding a change in the gene(s) for which I, or my child, am being tested and have received test-specific clinical information.
2. I have read and understand the information provided on this form, I have discussed the recommended genetic testing with my physician, and I have had an opportunity to have any questions answered by my healthcare provider.
3. I have a good understanding of the concepts of the specific testing ordered and have elected to proceed.

Signature of Patient or Parent/Legal Guardian: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

Printed Name of Patient or Parent/Legal Guardian: \_\_\_\_\_ Relationship: \_\_\_\_\_

Signature of Witness: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_  
(May be a Physician)

Printed Name of Witness: \_\_\_\_\_ Credentials: \_\_\_\_\_

**For Telephone Consent see next page.  
Interpreter Services, if used see next page.**



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If interpreter used, please complete the following:  Remote  In-person

Interpreter ID Number  
(if phone/video interpreter used): \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

Signature of Interpreter  
(if in person): \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

Printed Name of Interpreter: \_\_\_\_\_

### Telephone Consent: Requires two witnesses.

Printed Name of Person  
Authorizing Consent: \_\_\_\_\_ Relationship: \_\_\_\_\_

Signature of Witness: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

Printed Name  
of Witness: \_\_\_\_\_ Credentials: \_\_\_\_\_

Signature of Witness: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

Printed Name  
of Witness: \_\_\_\_\_ Credentials: \_\_\_\_\_

### HEALTHCARE PROVIDER STATEMENT

By signing below, I attest that I am the referring physician or authorized healthcare professional. I have explained the purpose of testing for this patient. The patient has had the opportunity to ask questions regarding this test and/or seek genetic counseling. The patient has voluntarily decided to have this test performed.

Signature of  
Healthcare Provider: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

Printed Name of  
Healthcare Provider: \_\_\_\_\_