ASPiRA LABS®

Informed Consent for Genetic Testing

I request and authorize ASPiRA LABS® to test myself, or my child's sample for the stated testing.

_____

(Name of test/panel/gene)

My signature below indicates that I have read, or read to me, the information below and I understand the following:

TEST:

1. I understand that a buccal swab will be utilized to collect DNA for genetic testing.

2. The purpose of this test is to determine if I, or my child, are carriers of the disease gene or are affected with or at increased risk to someday be affected with this genetic disease. I understand that I can seek genetic counseling regarding the genetic testing prior to giving this consent, and was provided with written information identifying a genetic counselor or medical geneticist from whom I may obtain such counseling.

3. I have received verbal and/or written information from my physician or from a genetic counselor that described, in words that I understood, the nature of the genetic testing that I, or my child, will undergo. I have been given the opportunity to ask questions about the test and any concerns about the possible test results have been addressed.

RISKS:

1. DNA testing requires a blood or saliva sample each of which have risks associated with obtaining the sample. Additional samples may be needed if the sample is damaged in shipment or inaccurately submitted.

2. I may learn genetic information about myself/the patient or my child or my/their family members that is not related to the medical concern for which this test is ordered. This information might reveal: •Genetic risks for diseases that may develop later in life •Diseases unrelated to the primary reason for ordering the test •Disorders that do not have current treatment. Learning about this information might cause my family or me anxiety or psychological stress.

3. I authorize ASPiRA LABS® to release the medical information concerning my testing to my insurance company if the testing is billed through my insurance. The US Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits discrimination on the basis of genetic information with respect to health insurance and employment. However, GINA does not apply to life insurance, disability insurance, or long-term care insurance, which may be governed by state law. Laws and regulations outside the U.S. regarding the use and disclosure of genetic information may be different.

BENEFITS:

1. Results from this test may help my healthcare provider and me to make more informed choices about my health care, such as screening, preventive measures, and risk-reducing surgery, if applicable.

2. The identification of gene mutation(s) in a family helps other blood relatives determine whether or not they share the same hereditary health risks. If the test results are positive, I should discuss with my healthcare provider how hereditary cancer (if applicable) is inherited and learn about the chance my blood relatives may have inherited the same mutation(s) in the gene(s) tested.

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LIMITATIONS:

1. Genetic testing is complex and ASPiRA LABS® takes extensive measures to avoid errors and failed tests. Although the laboratory takes every precaution, technical, biological, and systematic errors may occur. My healthcare provider and/or I will be notified should such an event be discovered.

2. Accurate interpretation of test results is dependent upon the patient's clinical diagnosis or family medical history, as well as the fact that any reported family relationships are true biological relationships. An erroneous clinical diagnosis in the patient or family member can lead to an incorrect interpretation of the laboratory result.

This analysis is specific only for the test ordered. This test will not detect all variants in any evaluated gene. There are some types of DNA changes that cannot be detected by this test and there are some disease-related DNA changes that are outside the region of the genome that is queried by this test. My physician may determine that further/other DNA testing is necessary in addition to this test.

TEST REPORT AND INTERPRETATION:

1. Prior to giving this consent, I discussed with my ordering healthcare professional the reliability of positive or negative test results and the level of certainty that a positive test result for the specific disease or condition tested for serves as a predictor of such disease.

2. The results of this test will be interpreted in the context of my personal and family health history, the results of physical examination, and other laboratory tests. A positive result means that a pathogenic or likely pathogenic variant was identified and may be an indication that I am predisposed to or have the specific disease or condition tested for. However, the results should be interpreted in the context of the patient's clinical findings, biochemical profile, and family history. The level of certainty that a positive test result for that disease or condition serves as a predictor of such disease will be reported to me, and utilizing that information, I understand that I may consider further independent testing, consult my healthcare professional, or pursue genetic counseling. I understand that this test analyzes only the specific gene or portion of gene as stated on the requisition. A negative result does not rule out any pathogenic variants in areas not assessed by the test or in regions that were covered at a level too low to reliably assess. Also, it does not rule out variants that are of the sort not queried by this test. If no mutation is found, I may still be at risk for the specific disease or condition tested for due to a genetic predisposition that cannot be detected by this test, either in the gene I was tested for or in another gene linked to the specific disease or condition tested for.

3. Because of the complexity of genetic testing and the implications of the test results, results will only be reported to the ordering healthcare professional and/or my genetic counselor. The results are confidential and will only be released to other medical professionals or other parties with my written consent, per the laboratory's privacy policy. All laboratory raw data are confidential and will not be released unless a separate consent is completed (NGS Data Release for Clinical Use) or a valid court order is received.

4. The interpretation of the test results will be based on the laboratory's current information at the time of analysis. As medical knowledge advances and new discoveries are made, the interpretation of results may change. It is possible that re-interpretation of results could lead to new information about potential medical conditions. Such re-interpretation must be requested by a physician and will involve additional costs. However, it may not be possible to re-interpret the test data at a future date, and it may instead require retesting with a new sample. While ASPiRA LABS® does not guarantee re-analysis of all detected or reported variants, if a significant change is identified the laboratory may issue an updated report or contact the original ordering healthcare provider.

5. Results may have clinical or reproductive implications for myself/child or the patient's family members. Participation in genetic testing is completely voluntary. I understand that I may wish to obtain professional genetic counseling prior to signing this consent form. ASPiRA LABS® will provide a local referral for follow-up genetic counseling at my request.

SAMPLE STORAGE/RETENTION:

1. The laboratory will not return the remaining sample to individuals or physicians. Samples will be retained in the laboratory in accordance with the laboratory's specimen retention policy.

New York residents only: All samples from New York patients will be destroyed within 60 days after ASPiRA LABS® receipt of the sample (or upon completion of the testing), unless I opt in to storage of my deidentified sample by initialing below.

_____(initial) I opt in to storage of my/the patient's or my child's deidentified sample. (Consent for research is addressed below.). I understand that I may revoke this authorization for continued storage at any time.

It may be possible to perform additional studies on the remaining sample. The referring physician or other authorized provider and patient/legal guardian must make the request for additional studies with the potential for additional charges.

RESEARCH/RECONTACT CONSENT:

I may choose whether to give consent to allow my sample to be used for medical research and/or education, as long as my privacy is maintained. All personal health information will be removed and the sample will be deidentified. Refusal to permit the use of my sample for research will not affect my test result, and no other risks are associated with this research consent. I understand that ASPiRA LABS® will not sell my data to a third party. For research use, sample may be stored indefinitely. I can withdraw my consent at any time by contacting the laboratory director.

I agree to the use of myself/child's de-identified data for research.

☐ YES ☐ NO _____ Initial

ACKNOWLEDGMENT OF CONSENT:

By signing this Informed Consent for Genetic Analysis, I acknowledge that I have read and understand the questions and answers set forth above, and that I have had the opportunity to have any additional questions answered by a physician or genetics professional. I understand that the results of this testing will become part of my medical record and may only be disclosed to individuals who have legal access to this record or to individuals who I designate to receive this information. I understand that genetic testing of appropriate individuals is often reimbursed by health insurance. I hereby agree to be responsible for any cost of the genetic test not reimbursed by insurance, including applicable co-pays or deductibles. I understand that I may contact my insurance company to determine coverage prior to giving this consent. With my signature below, I give my consent or consent on behalf of the patient for whom I am legal guardian:

1. To the genetic analysis by ASPiRA LABS® as ordered by my physician;
2. To the collection and processing by my physician and ASPiRA LABS® of my personal health information and sample as required to conduct the genetic analysis, including any necessary transfer of my personal health information between my physician and ASPiRA LABS® across national borders, specifically to the United States;
3. To the analysis of the obtained sample and its storage at ASPiRA LABS®, in accordance with ASPiRA LABS® specimen retention policy, together with my patient file to be able to verify results of the analysis if need be;

4. To inform me or my physician about the results of the genetic analysis; and
5. To provide upon request to me or my physician the raw data of the genetic analysis.

I am aware that I can withdraw my consent in full or in part subject to the terms of ASPIRA LABS® Privacy Policy (https://vermillion.com/about-us/legal/) and that I have the right not to know the results of the genetic analysis as described in this Consent Form.

My signature below acknowledges the voluntary participation of myself/the patient or my child's in this test but in no way releases the laboratory and staff from their professional and ethical responsibilities.

Physician's/Counselor's Statement: I have explained genetic testing to the consenting party. I have addressed the limitations of genetic testing to be performed, based on current data. I have answered the consenting party's questions.

Patient/Guardian Signature:	Date:
Patient Printed Name:	Date of Birth:
Witnessed by:	
Physician Signature:	Date:

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