Genetic Carrier Screening Analysis

ADVANCED MOLECULAR DIAGNOSTICS, LLC

Test Request Form and Statement of Medical Necessity

GeneID The Future Today

NewbornGene ID

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ORDERING PHYSICIAN				SEND RESULTS TO (IF OTHER THAN ORDERING PHYSICIAN)			
NAME (LAST, FIRST, DEGREE)			NPI #	NAME (LAST, FIRST, DEGREE)			NPI #
ADDRESS	CITY	STATE	ZIP	ADDRESS	CITY	STATE	ZIP
OFFICE PHONE	FAX	EMAIL		OFFICE PHONE	FAX	EMAIL	

PATIENT INFORMATION (COMPLETE INFORMATION REQUIRED FOR INSURANCE COVERAGE)

PATIENT NAME (LAST, FIRST, INITIAL) ☐ FEMALE ☐ MALE BIRTH DATE (MM/DD/YYYY) PHONE BEST TIME TO CALL (IF NEEDED)

ADDRESS CITY STATE ZIP CAN WE LEAVE A DETAILED MESSAGE AT THIS NUMBER? ☐ YES ☐ NO

ANCESTRY – CHECK ALL THAT APPLY

☐ AFRICAN ☐ AFRICAN AMERICAN ☐ CAJUN ☐ CAUCASIAN ☐ DUTCH ☐ FRENCH CANADIAN ☐ GREEK ☐ HUNGARIAN ☐ ICELANDIC ☐ ITALIAN
☐ JEWISH, ASHKENAZI ☐ LATIN AMERICAN/CARIBBEAN ☐ MENNONITE ☐ MIDDLE EASTERN/MEDITERRANEAN ☐ NATIVE AMERICAN ☐ SOUTHEAST ASIAN
☐ SWEDISH ☐ ADOPTED ☐ OTHER _____

INDICATION(S) FOR TESTING INDICATE ALL THAT APPLY

☐ GENERAL REPRODUCTIVE POPULATION – FAMILY PLANNING ☐ PREGNANT ☐ PARTNER PREGNANT

PERSONAL INFORMATION

☐ **FAMILY HISTORY OF GENETIC DISEASE**

INCLUDE MEDICAL RECORDS AND ANY TEST RESULTS IF AVAILABLE

RELATIONSHIP DISEASE

☐ **FAMILY MEMBER IS A KNOWN CARRIER** (INCLUDE MEDICAL RECORDS) Z14.1, Z84.41

RELATIONSHIP DISEASE MUTATION

UNEXPLAINED MEDICAL CONDITIONS IN FAMILY

PARTNER'S INFORMATION

☐ **PARTNER W/ FAMILY HISTORY OF GENETIC DISEASE**

INCLUDE MEDICAL RECORDS AND ANY TEST RESULTS IF AVAILABLE

RELATIONSHIP (TO PARTNER) DISEASE

☐ **PARTNER IS A KNOWN CARRIER** (INCLUDE MEDICAL RECORDS)

DISEASE MUTATION (ATTACH CLINICAL REPORT)

PARTNER'S ANCESTRY AND ETHNICITY

TEST REQUESTED

☐ ***NewbornGeneID Inherited Disease Screening – Expanded Test***
☐ ***Include testing for Fragile-X (Female Patients Only)***
☐ ***Custom (specific genes from NewbornGeneID Panel)*** _____

ICD10 CODES – COMMONLY USED CODES LISTED BELOW – INDICATE ALL RELEVANT CODES

ICD10	DESCRIPTION	ICD10	DESCRIPTION
☐ Z13.0	Encounter for screening for diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	☐ Z82.0	Family history of Seizures
		☐ Z82.0	Family history of Spinal Muscular Atrophy
☐ Z13.228	Encounter for screening for other metabolic disorders	☐ Z83.49	Family history of Cystic Fibrosis
☐ Z31.440	Encounter of male for testing for genetic disease carrier status for procreative management	☐ Z83.49	Family history of Tay Sachs
☐ Z31.440	Encounter of female for testing for genetic disease carrier status for procreative management	☐ Z82.69	Family history of other diseases of the musculoskeletal system and connective tissue
☐ Z13.79	Encounter for other screening for genetic and chromosomal anomalies	**CORRESPONDING ICD-10 CODES BASED ON PATIENT'S PERSONAL AND FAMILY HISTORY**	
☐ Z15.89	Genetic susceptibility to other disease	☐ Z13.0	Encounter for screening for diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism
☐ Z81.0	Family history of intellectual disabilities		
☐ Z34.01	Encounter for supervision of normal first pregnancy, first trimester	☐ Z13.228	Encounter for screening for other metabolic disorders
☐ Z34.02	Encounter for supervision of normal first pregnancy, second trimester	☐ Z15.89	Genetic susceptibility to other disease
☐ Z34.03	Encounter for supervision of normal first pregnancy, third trimester	☐ Z13.79	Encounter for other screening for genetic and chromosomal anomalies
☐ Z34.80	Encounter for supervision of other normal pregnancy, unspecified trimester		
☐ Z84.81	Family history of carrier of genetic disease		
☐ Z81.8	Family history of ADHD		
☐ Z81.8	Family history of Autism		
☐ Z81.8	Family history of Anxiety		
☐ Z81.8	Family history of Speech Impediments		
☐ Z81.8	Family history of Hyperactive Behavior		
☐ Z83.2	Family history of Sickle Cell Anemia		

PAYMENT INFORMATION

☐ **OPTION 1**: **PLEASE BILL MY INSURANCE** (requires patient signature and enlarged copy of both sides of insurance card(s). If two cards are submitted, indicate which is primary)

Name of Policy Holder: _____ **DOB:** _____ **Insurance Carrier:** _____

Patient Relationship to Policy Holder: ☐ Self ☐ Spouse ☐ Child ☐ Other **Insurance ID #:** _____

I hereby represent that I am covered by insurance and authorize Advanced Molecular Diagnostics, LLC to furnish my designated insurance carrier, health plan, or third party administrator the information on this form and other information provided by my healthcare provider necessary for reimbursement. I authorize Advanced Molecular Diagnostics, LLC to utilize a licensed third party laboratory for test processing when deemed necessary. I authorize Plan benefits to be payable to Advanced Molecular Diagnostics, LLC. If requested, I agree to assist Advanced Molecular Diagnostics, LLC in resolving insurance claim issues and if I do not assist, I may be responsible for the full test cost. I permit a copy of this authorization to be used in place of the original. I authorize Advanced Molecular Diagnostics, LLC to inform my plan of my test result ONLY if test results are required for reimbursement for testing or preauthorization of or payment for reflex/ additional testing.

Please include a copy of both sides of all insurance card(s)

Patient / Responsible Party Signature **Date**

☐ **OPTION 2**: **PATIENT PAYMENT** (Patient will be contacted for secure credit card information and to arrange payment plan)

INFORMED CONSENT AND STATEMENT OF MEDICAL NECESSITY - TEST REQUESTS WITHOUT A SIGNATURE WILL NOT BE PROCESSED

I have supplied information to the patient regarding genetic testing and the patient has given consent for genetic testing to be performed. I further confirm that this test is medically necessary for the diagnosis or detection of a disease, illness, impairment, symptom, syndrome or disorder, and the results will be used in the medical management and treatment decisions for the patient. The sample collection was done on the date indicated below unless otherwise noted. I confirm that the person listed in the Ordering Physician space above is authorized by law to order the test(s) requested herein.

Medical Professional Signature **Date**

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INFORMED CONSENT FOR GENETIC CARRIER TESTING

Patient Name: _____

I request DNA Analysis for the following test:
☑ NewbornGeneID Comprehensive Panel
☐ Custom _____

INTRODUCTION

I have discussed genetic testing with my doctor, an individual designated by my doctor or a genetics professional and understand the function and limitations of carrier screening testing and I am interested in obtaining genetic testing by submitting a biological sample of my own body fluids (such as saliva) blood or tissue. I may be pregnant at the time of this genetic test or not pregnant. This is a voluntary test to determine whether I have gene mutations that indicate that I am a carrier for one or more inherited diseases.

TEST PURPOSE AND METHODOLOGY

The purpose of this molecular test is to determine whether I am a carrier for specific inherited diseases. I understand that as a carrier, I may not show any symptoms, but my children may be at significantly increased risk if the child's other parent is also a carrier for the same disease. I understand that the body fluid, blood or tissue specimen submitted is required for isolation and purification of DNA for molecular genetic testing. Advanced Molecular Diagnostics, LLC will analyze the DNA of a specific gene(s) to look for mutations associated with carrier status for these diseases.

TEST RESULTS

1. I understand that screening does not detect all genetic carriers. I understand that testing negative means that the likelihood that I am a carrier for a genetic disease is reduced, but not eliminated.
2. I understand that one or more of the diseases on the panel may be passed in dominant fashion and may only be expressed later in life. I understand that this means that a positive test result for those diseases may have implications for my health or the health of my family.
3. Should I test positive, it will be beneficial for my partner to be tested to better understand the risk of a relevant genetic disease in any offspring.
4. If I or my partner is a carrier, and the other is not, there is still a small possibility that a child will have a genetic disease.
5. If I and my partner are both carriers, I am aware that prenatal screening can be done to determine whether a child has inherited the genetic disease
6. I understand that results of this test will be evaluated in the context of personal and family history, ethnic information and other information. I have provided information as accurately as possible.
7. I understand the limitations of the results: the test could be based on probabilities, and may not provide 100% definitive conclusion regarding carrier status.
8. I understand that the molecular genetic test may not generate results and an additional sample may be needed to provide accurate results.
9. I understand that the molecular genetic test may not generate accurate results for many reasons, including but not limited to: sample mix-up, samples unavailable from critical family members, maternal contamination of prenatal samples, inaccurate reporting of family relationships, or technical problems.
10. I understand that only known positive mutations will be reported. Benign variants and variants of uncertain significance will not be reported.
11. I understand that if I am female, I have the option of getting tested for Fragile X. I understand that results for Fragile X testing may be more complicated than results for diseases tested for as part of this test. I have spoken to my doctor about any concerns I may have regarding receiving testing for Fragile X and dealing with results.
12. I understand that genetic testing has implications for blood relatives. In consultation with an appropriate healthcare provider, I may wish to discuss sharing the test results with certain blood relatives who may be at risk. If I decide to do this, I should consider the best way to make this disclosure.
13. I understand that Advanced Molecular Diagnostics, LLC keeps test results confidential and is fully in compliance with all Health Insurance Portability and Accountability Act (HIPAA) regulations and Advanced Molecular Diagnostics, LLC will only release test results to my healthcare provider, his or her designee, or to another healthcare provider as directed by me (or a personal legally authorized to act on my behalf) in writing or otherwise as required by federal or state laws.
14. I understand Advanced Molecular Diagnostics, LLC reserves the right to: 1) Suggest additional molecular testing if it would help in resolving the patient's clinical genotyping, 2) report additional testing results (other than requested) if they are clinically relevant to me and my family, and refuse testing if one of the conditions in the Patient Consent is not met.

USE OF SPECIMENS

After testing is completed, I understand that my blood, body fluid or tissue specimens may be disposed of or retained indefinitely for research, test validation, and/or education as long as my privacy is maintained. I understand that no compensation will be given nor will funds be forthcoming due to any invention(s) resulting from research and development using the specimens submitted. I understand that I may refuse to submit my specimen for use in this way and may withdraw my consent at any time by contacting the medical director. I understand that my refusal to consent to medical research will not affect my results. Indicate consent or denial below. If a box is not marked consent is implied.

Consent to the use of my sample for research: ☐ Yes ☐ No

RECOMMENDATIONS

I understand that due to the dynamics of this field, there continues to be new information and data. It is recommended that I keep in contact with my healthcare provider, annually, to learn of any new developments in cancer genetics and to provide any updates to my personal or family history which may affect my cancer risks.

FINANCIAL RESPONSIBILITY

Genetic testing of appropriate individuals is typically reimbursed by health insurance or covered by HMO's. I understand that I am responsible for any cost of the genetic test not reimbursed by insurance. I understand that if test cancellations are received prior to test set-up, processing will be honored at no charge. I understand that when requests for test cancellation are received after set-up, a cancellation report will be generated and a set-up fee will be charged. Once testing is initiated cancellation is not possible. I understand that I am responsible for all charges for testing and will be contacted for payment in the event my health plan does not reimburse for the test or AMD does not receive a response from my health plan in a reasonable length of time.

PATIENT CONSENT STATEMENT

By signing below, I, the patient having the test performed, acknowledge that:

I have read or have had read to me all of the above statements and understand the information regarding molecular genetics testing and have had the opportunity to ask questions I might have about the testing, the procedure, the risks, and the alternatives prior to my informed consent. I agree to have the molecular genetic testing. I consent to being tested to determine if I am a carrier for the diseases on the test selected and I will discuss the results and appropriate medical management with my healthcare provider/genetic counsellor. I am the owner of my medical history and test results. My healthcare practitioner should not discuss or disclose my test results and associated medical history to a third party, unless related to treatment or payment for treatment, without my express written authorization.

Patient Signature _____ Date _____