PREVENTION GENETICS

PREVENTIONGENETICS USE ONLY

Test information is available on our website:
www.PreventionGenetics.com

All testing must be ordered by a qualified Healthcare Provider

THIS FORM MUST ACCOMPANY ALL SPECIMENS

GENETIC TESTING
HEALTHCARE PROVIDER STATEMENT

NOTE: This statement must be signed by the ordering Healthcare Provider indicating the following informed consent has been provided to the patient. (REQUIRED for New York State specimens)

PATIENT INFORMATION

LAST (FAMILY) NAME	FIRST NAME	MI	DATE OF BIRTH
			_____ / _____ / _____ MONTH DAY YEAR

TEST(S) REQUESTED

TEST DESCRIPTION, METHODS, AND LIMITATIONS

See specific full test description at www.PreventionGenetics.com for information about clinical features, genetics, indications for testing, test procedure, test description, clinical sensitivity, analytical validity, analytical limitations, and turnaround times.

Purpose of Testing (mark all that apply)

- ☐ Diagnosis
- ☐ Assessing carrier status
- ☐ Confirming research findings
- ☐ Serving as a control or helping to interpret results for family members
- ☐ Predictive/presymptomatic testing
- ☐ Other (please describe):

_____

_____

RESULTS

- Positive genetic testing results may mean a person carries or has the condition or disease being tested. Often this means pathogenic or likely pathogenic genetic variation(s) has/have been identified. Consulting with a Physician or Genetic Counselor prior to and after completion of testing is recommended to learn the full meaning of the results and their implications.
- Negative results may mean, within limitations of the test, no Pathogenic or Likely Pathogenic genetic variations were identified. However, consultation with a Medical Geneticist, Genetic Counselor or Specialty Provider is recommended should the patient or Ordering Provider have additional questions or concerns.
- Uncertain results may mean a Variant(s) of Uncertain Significance (VUS) was/were identified. It is not clear if these variants are linked to the patient's phenotype or are associated with disease.
- Pathogenic variants, Likely Pathogenic variants, and Variants of Uncertain Significance in genes thought to be associated with the clinical phenotype will always be reported.
- We recommend the patient stay in touch with their Healthcare Provider(s) to discuss any updated information regarding results and our interpretation(s). An ordering Healthcare Provider can request a re-interpretation from us by contacting our laboratory periodically (i.e. yearly).
- Upon request, PreventionGenetics can provide raw data for sequencing tests. This data will be provided once testing is completed and final reports have been released. PreventionGenetics does not supply software for data review and interpretation.

INCIDENTAL FINDINGS

- Testing could reveal information unrelated to the patient's clinical features. If we learn of information which could be medically actionable, we will relay this information to the Healthcare Provider(s) for discussion.
- If we learn that family relationships are not as expected (for example, due to possible specimen mix-up or possible non-paternity), this information will be relayed to the Healthcare Provider(s) for discussion, but will not be included in the patient's report.

WHO HAS ACCESS TO TEST RESULTS?

- The patient tested or his/her Authorized Representative (Preventions Genetics requires a signed patient authorization form which is available upon request).
- Any person specifically authorized in writing by the patient tested or his/her Authorized Representative.
- A researcher for medical research or public health purposes if the research is done under federal or state law governing clinical and biological research, or if the identity of the individual is not disclosed.
- The ordering Healthcare Provider or an Authorized Agent or employee of the Healthcare Provider, if they are authorized to obtain the test results, provide patient care, treatment, or counseling, and need to know the information to perform or improve the patient care, treatment, or counseling.
- The hospital or Healthcare Provider for purposes of quality assurance.
- Federal, state, or county health agencies, as they may be authorized.

CONFIDENTIALITY

We take confidentiality and patient privacy very seriously. We follow confidentiality laws related to protected health information and are a CAP and CLIA certified laboratory.

RISKS

- Blood draws can have risks associated including bruising and bleeding. There is also a small chance of infection, excess bleeding, or the patient may become dizzy, or faint from the blood draw.
- Learning about test results can be stressful and upsetting for the patient and their family.
- The patient and/or patient's family may have concerns about genetic discrimination, including health insurance, life insurance, employment and long-term disability. These should be addressed according to federal and state laws. The Genetic Information Non-discrimination Act (GINA) prohibits the use of genetic information for discrimination in health insurance and employment. We recommend patients discuss specific concerns with their Healthcare Provider.
- As genetic knowledge and understanding changes over time, it is possible a patient's result may be reclassified. This could lead to changes in medical management recommendations or care of family members.

RIGHT TO GENETIC COUNSELING

The patient has the right to genetic counseling prior to having testing and again when results have been issued.

My signature below indicates all of the following:

I take responsibility for the appropriateness of the requested testing. I have explained the purpose of the testing I have requested. I have provided appropriate genetic counseling to my patient. I have given the opportunity for the patient to ask questions. I am responsible for obtaining written or verbal informed consent (ensuring my patient understands risks, benefits, and limitations of the testing and the implications of the results).

HEALTHCARE PROVIDER SIGNATURE | PRINTED NAME | DATE

RETENTION OF UNUSED DNA STATEMENT (NY SPECIMENS ONLY)

PreventionGenetics' general policy is to retain all excess DNA from patient testing indefinitely. This allows for easier ordering of additional testing in the future and saves considerable phlebotomy and shipping costs to the patient and healthcare system. Excess DNA specimens can also be used for quality control measures. New York (NY) law requires patient consent in order to retain excess DNA beyond 60 days. If patient specimen was collected in NY and this statement is not signed, excess DNA will be discarded 30 days after testing is completed.

I authorize PreventionGenetics to retain unused DNA for potential future testing ordered by my Healthcare Provider and for quality control testing.

PATIENT OR LEGAL REPRESENTATIVE SIGNATURE | PRINTED NAME | DATE

OR

HEALTHCARE PROVIDER SIGNATURE ON BEHALF OF PATIENT | PRINTED NAME | DATE