prevention genetics

Test details and online ordering:
PreventionGenetics.com

PREVENTIONGENETICS USE ONLY

All testing must be ordered by a qualified Healthcare Provider

RESET FORM

Informed Consent

My healthcare provider has ordered one or more genetic tests offered by PreventionGenetics, a clinical laboratory.

Patient information

Last (family) name	First name	MI	Date of birth (MM/DD/YYYY)

Address	City	State / Province	Zip / Postal code

Email	Phone number	Medical record number (MRN)

Test(s) requested (Name of test and.or test code)

Purpose and Description of Testing

The healthcare provider has explained the recommended testing (listed above), which is performed to help diagnose [insert disease description]:

More information about this test is available at the PreventionGenetics website, PreventionGenetics.com.

Limitations of Testing

The healthcare provider has explained the effectiveness and limitations of testing, and I understand the following:

- In some cases, certain genetic variants may not be identified either due to limitations in the technology and/or current medical knowledge.
- While genetic testing is very accurate, in rare instances, inaccurate results could be issued. There are many reasons for this but some of the more common include, mislabeled samples, technical errors, poor DNA quality, and incorrect reporting of clinical/medical information.
- Genetic testing can reveal true biological relationships in a family including a reported parent not being the biological parent (i.e., nonpaternity, egg donor) and consanguinity (when parents are biologically related). I understand that these findings may be disclosed to my healthcare provider who ordered the test.
- This genetic test may not detect all my possible medical risks and may not help my provider better understand my health; other diagnostic tests may be needed.

Test Results

I may learn the following from my test results, which will be disclosed directly to the ordering healthcare provider:

- Positive: A variant(s) was found in my DNA that is likely the cause of my symptoms or predisposes me to a specific condition. This result may be used to determine a clinical management plan and may have implications for my family members who may also be affected, carry an increased risk of being affected, and/or be at risk of passing the variant to their children. Additional testing and/or genetic counseling may be indicated by my healthcare provider.
- Negative: No variants were found in the test(s) ordered by my provider which explain my symptoms. While this result might mean there is a reduced possibility that I have a genetic condition that explains my symptoms, there is still a possibility that there is a genetic basis for my condition that was not identified by the test. My healthcare provider may discuss more testing options.
- Indeterminate: Variant(s) were identified that may or may not be associated with my symptoms. More information, such as further family testing or other diagnostic tests could help clarify if this finding is associated with my symptoms. My healthcare provider may be notified of any changes to the classification of identified variant(s) related to my result.
- Incidental finding: On occasion, a variant(s) may be identified by the test ordered that is not expected to be associated with my symptoms but may increase my risk for a different condition. In accordance with established medical guidelines, these results may be shared with my healthcare provider who will discuss these results with me. PreventionGenetics may disclose this information to the ordering healthcare provider if the finding may impact medical care.

My healthcare provider is encouraged to contact PreventionGenetics if anything associated with my condition changes. As we are constantly learning more about medicine and genetics, this new information could impact the results of my test. PreventionGenetics can rereview my genetic results in light of significantly new clinical information. Additionally, my healthcare provider can contact PreventionGenetics to discuss the classification of any identified variants.

Comparator Testing

If comparator testing is ordered, I understand the comparator result will be indicated on the proband report, including any secondary or incidental findings reported in the proband. The comparator will not receive an independent analysis or report of secondary or incidental findings.

How My Samples and Information May Be Used and Shared

PreventionGenetics protects my sample and health information, including information generated from testing my sample ("information") in accordance with the Health Insurance Portability and Accountability Act (HIPAA). My samples and information may be used and disclosed by PreventionGenetics and its affiliates for the following purposes:

- To analyze my sample and information, perform testing, and generate a clinical report with my test results.
- To conduct additional testing with appropriate documentation from my ordering provider.
- To disclose information to the ordering healthcare provider (or their designee), other healthcare providers involved in my medical care, to me or my personal representative, to another individual if authorized by me or my personal representative, or as otherwise required by law or regulation.
- To disclose information to health plans

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or others in accordance with HIPAA, including for payment-related activities in order to bill for tests.
- For operational purposes, such as quality assurance, quality improvement, and validation purposes.
- To use and disclose de-identified samples and information for educational and scientific programs and commercial purposes. No identifying information will be used or disclosed.
- For research on genetic variants associated with the diseases or conditions I was tested for, and any related diseases or conditions, which may include further testing of my retained samples, subject to approval by an Institutional Review Board or as otherwise permitted under applicable law.
- To contact me or the ordering healthcare provider about research opportunities that may be of interest or relevant to my treatment or condition.
- To send me communications relevant to my treatment or condition, including email and text messages. While PreventionGenetics takes precautions to safeguard these communications, there is a risk of interception associated with communications by email or text.
- As otherwise described in: i) the Privacy Policy available at https://www.exactsciences.com/privacy-policy; and ii) the Notice of Privacy Practices available at https://www.exactsciences.com/hipaa-compliance.

Retention

My sample and information may be retained for as long as reasonably necessary to fulfill the purposes described above. For samples drawn in New York state: I will refer to the New York State Sample Retention form to indicate if I would like PreventionGenetics to retain my sample indefinitely for the purposes described above.

In accordance with applicable law, I may update my consent preferences for certain activities by contacting PreventionGenetics.

By signing below, I confirm that*: (a) I have read (or had read to me) and understand the information provided in this form; (b) I understand that testing is voluntary and that I may obtain genetic counseling prior to signing this form; (c) all my questions have been answered; and (d) I hereby consent to the genetic testing and the uses, disclosures and retention of my sample and information as described in this form.

*Where I sign this form on behalf of another person as legally authorized representative (LAR), I confirm that I have the legal authority to consent on behalf of such person.

Patient signature _____ Patient's printed name _____ Date _____

Patient/patient's LAR signature _____ Patient's LAR printed name _____ Date _____

If signed by patient's LAR, relation to patient (e.g., parent, guardian) _____

Family Member/Comparator Signatures Complete for family members and/or individual whose specimens are being sent as comparators.

Comparator one signature _____ Comparator one printed name _____ Date _____

Comparator one's LAR name _____ Comparator one / Comparator one's LAR signature _____

If signed by comparator one's LAR, relation to comparator 1 (e.g., parent, guardian) _____

Comparator two signature _____ Comparator two printed name _____ Date _____

Comparator two's LAR name _____ Comparator two / Comparator two's LAR signature _____

If signed by comparator two's LAR, relation to comparator 1 (e.g., parent, guardian) _____

Comparator three signature _____ Comparator three printed name _____ Date _____

Comparator three's LAR name _____ Comparator three / Comparator three's LAR signature _____

If signed by comparator three's LAR, relation to comparator 1 (e.g., parent, guardian) _____

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