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HALO Precision Diagnostics™

Introduction

This informed consent will walk you through the benefits, risks, and outcomes of genetic testing. We recommend that you read this document carefully and ask questions to help you make an informed decision on testing.

What is Genetic Testing?

Genetic testing analyzes a specific gene or genes within the DNA and may identify pathogenic gene variants, called mutations. Hereditary mutations are passed down from generation to generation and can potentially cause diseases that run in families. Somatic mutations are changes to your DNA that occur throughout your lifetime and may also increase your risk of disease.

Combining genetic testing with your personal and family history leads to a more precise assessment of your lifetime risk of hereditary cancer or developing other health conditions that are linked to your DNA.

What are the Benefits?

Combining your genetic testing results with personal and family history is a more precise way to determine if you have an elevated genetic risk for developing certain cancers or diseases. An elevated genetic risk may lead to earlier onset of disease, a more aggressive form of disease, or a disease recurrence.

Genetic testing results permit better-informed healthcare choices and help by:

- Enabling the healthcare team to develop a specialized screening plan for prevention or early detection
- Providing crucial information for family members like children, siblings, parents, and other relatives that may be carrying the same hereditary gene mutation and may be at higher risk of disease
- Determining the most suitable treatment plan in case a disease is diagnosed
- Preventing the need for more costly and invasive procedures

How is Genetic Testing Performed?

Your DNA is collected through a simple saliva sample. The specimen is sent to a clinical laboratory for analysis. The sample will be analyzed for various pathogenic mutations in the DNA sequence. A report of the results will be generated and delivered to your ordering provider.

Your provider may order a test evaluating a group of genes or a single gene, based on guidelines and your personal and family history. Your provider may also order a polygenic risk score (PRS) test that evaluates multiple small changes across your DNA to calculate your risk of disease compared to the general population. These results, along with your personal and family medical history, can be used by you and your provider to make precise and personalized healthcare decisions.

What Are the Possible Results and Interpretations?

There are three possible results to hereditary genetic tests:

- **Positive or high risk**
  A mutation in a gene or genes reveals a predisposition or increased risk for developing a genetic disease in the future. Gene mutations may have health implications for other blood relatives, and genetic testing may also be recommended for them.

- **Negative or average risk**
  No pathogenic or likely pathogenic variants were identified. A negative result may reduce, but does not eliminate, the possibility of predisposition or risk of developing a disease in the future. This is the most common result.

- **Variant of Uncertain Significance**
  A change in DNA was identified that has an unknown impact on the risk of developing a disease.

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Genetic Counseling

It is recommended that you speak to a certified genetic counselor or your healthcare provider to discuss your results. Genetic counseling can help you understand the outcomes of your report and what it means for you and your family members. This allows you and your family to make informed decisions about your healthcare. Genetic counseling is recommended before genetic testing, so that you have your questions answered, and receive comprehensive and sufficient information. Genetic counseling may be performed by a genetic counselor or other qualified healthcare provider. Some insurances may require genetic counseling before and/or after a genetic test.

What are the Risks and Limitations?

There are minimal risks associated with genetic tests. Potential side-effects associated with sample collection may include dry mouth during saliva collection.

Genetic testing results may reveal sensitive information about your health and that of your family members. Thus, risks could include anxiety or other potential psychological impacts related to test results.

While this test is designed to identify the most detectable mutations in the genes analyzed, it is still possible that there are mutations that this testing is unable to detect. In addition, there may be other genes or variants associated with disease susceptibility that are not included in this test.

Sample Storage and Additional Testing

The genetic test(s) performed on your sample will be those directed by the ordering physician or by your written authorization. No tests other than those authorized shall be performed on your sample. Once the testing is complete, your sample will be destroyed no later than sixty (60) days from the date the sample was taken, even in the event the order is canceled or not completed in its entirety. Your deidentified data may be used for ongoing quality improvement and quality assurance within the lab to obtain/maintain lab certification, meet regulatory requirements, and for internal research and development.

By signing below, you are granting consent for the laboratory to perform genetic testing. The results of such testing and DNA analysis are the exclusive property of the person tested, are confidential, and may not be disclosed without your authorization. You will be notified when the reports with test results are released.

Financial Responsibility

Genetic testing may be covered by your insurance. Some insurance companies may view genetic testing as an investigational procedure and do not provide coverage. If your insurance company does not cover the full cost of the test, you will be financially responsible for any related payment for genetic testing. We always try to work with your insurance company first to receive payment.

Consent to Communication

I understand and agree that HALO Precision Diagnostics, and its subsidiaries and affiliates, may contact me using automated calls, emails, and text messaging sent to my landline and/or mobile device. These communications may notify me of preventive care, test results, treatment recommendations, outstanding balances, or any other communications from HALO Precision Diagnostics related to my healthcare. I understand that there will be detailed instructions and personal information left on the phone numbers I have provided. I understand that I may voluntarily “opt-in” to receive automated text message communications from HALO Precision Diagnostics and its partners by providing my mobile number and agreeing to any additional Terms and Conditions established by my mobile carrier.
If I agree to receive text messages, I understand I can opt out at any time by replying STOP to the text.

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Right of Revocation

If at any point you wish to revoke your consent to genetic testing, you may do so in writing. Please note that we will stop running the genetic testing as soon as we receive your written express revocation. In some cases, your test may already be completed when we receive your revocation. You may send an email to clinlab.customerservice@halodx.com with the subject line REVOCATION OF CONSENT.

Clinical Laboratory Partners

HALO Clinical Laboratory
21 Argonaut Ste B .
Aliso Viejo, CA 92656-4150 .

GoPath Laboratories Inc.
1000 Corporate Grove Dr,
Buffalo Grove, IL 60089

Mdxhealth Central
7000 Preston Rd Ste 1500
Plano TX, 75024-2815

Please note that HALO clinicians have a financial relationship with the labs listed. Other testing options exist and are available on request.

Statement of Consent

By signing this Informed Consent, I give the listed laboratory partners permission to:

- Analyze the gene(s) indicated on the test requisition form from my sample
- Perform genetic testing to determine my risk of disease, the results of which may affect me or my family members
- Share my results with a third-party genetic counselor
- Share my deidentified data and samples with third-party laboratories for testing and quality control to improve genetic testing services, and for research and development
- Destroy my sample within sixty (60) days unless it is forbidden by law or the clinical laboratory is using the specimen for future research and development purposes to better human healthcare
- Communicate my results with other healthcare providers and insurance entities as it relates to the continuity of care

By signing below, I attest to the following:

- I am granting written authorization to the listed laboratory partners to perform genetic testing on my sample
- I have been informed of the likelihood of finding a change in the gene(s) for which I am being tested and have received test-specific clinical information
- I have had the opportunity to ask questions and discuss the benefits and limitations of genetic testing with my healthcare provider or other qualified designee
- I authorize communications through electronic forms such as phone, text, and fax
- I give the listed laboratory partners permission to provide my results over the phone that may include automatic telephonic communications. I understand that I can opt out of this service at any time by expressed written permission to clinlab.customerservice@halodx.com
- I have read and understand the information provided on this form and that I may retain a copy of this Informed Consent

Patient name (printed)

Patient representative name and relationship

Signature of patient or patient representative

Date signed