Informed Consent for **VistaSeq**℠

Integrated GENETICS
LabCorp Specialty Testing Group

Integrated ONCOLOGY
LabCorp Specialty Testing Group

Patient's name: _____ Date of birth:_____

Ordering physician's name: _____ Account #: _____ Telephone #: _____

Background on Testing

VistaSeq Hereditary Cancer Panel is a multi-gene test that detects inherited mutations in genes which have been associated with an increased risk of developing hereditary cancers. VistaSeq looks for any changes in these specific genes that increase the risk for hereditary cancer to develop.

Limitations

- VistaSeq does not look for all genetic causes of cancer. It is designed to study a set panel of genes known to cause certain inherited cancers.
- VistaSeq does not provide any risk information about genes or cancers that are not included in the test panel or related to non-genetic causes of cancer.
- VistaSeq requires a minimum amount of quality DNA. In some cases, an additional blood specimen may be needed to complete the testing.

Who should consider VistaSeq testing?

There are many reasons a physician may order a VistaSeq Hereditary Cancel Panel, including but not limited to:

- Patients with more than one family member diagnosed with cancer at a young age, or
- Patients with multiple family members diagnosed with the same or related cancers, or
- Patients with a family member diagnosed with a rare cancer, or
- Patients with multiple primary cancers.

Should my child (under 18 years old) have VistaSeq testing?

Genetic testing for children under 18 years old is not recommended except when an inherited condition is known to cause signs or symptoms in childhood. You should talk with your health care provider and/or a genetic counselor about whether VistaSeq or other genetic testing is right for your child.

How is VistaSeq testing performed?

VistaSeq uses next generation sequencing (NGS), a technique that looks at a large amount of genetic information very quickly and finds very small changes in the genes. Another technique is used to find any large missing or extra pieces of a gene. The clinical staff at the testing laboratory – which may include scientists, doctors, and genetic counselors – review any changes (called variants) found by VistaSeq to determine if a variant might be benign (harmless) or pathogenic (known to be associated with an increased risk for cancer).

What can I learn from the VistaSeq?

You may learn if you have a higher risk to develop certain cancers compared to another person in the general population. The results of this genetic test may change the way your health care provider manages your screening or treatment for cancer. The results of your VistaSeq test, along with your personal and family medical histories, should be discussed with a health care provider and/or a genetic counselor. If you are found to have a variant (a change in the DNA sequence) that increases your risk to develop certain types of cancer, this information is important for your blood relatives to know, as well. They share some of the same DNA as you, which means that they might also have the same variant. If they are found to have the same variant, they may also benefit from increased cancer screening.

What are the possible VistaSeq results I could receive?

With a panel, many genes are tested at the same time. Your report may have one or more of the following results for any of the genes tested in the panel:

1) **Positive —** A variant in the gene and DNA sequence is found; it is known to be associated with an increased risk for an inherited cancer. The risk of developing cancer in your lifetime depends on the gene in which this variant is located. Consult with your health care provider to learn more about how this result may affect your health care management. Options may include risk-reducing surgeries, cancer-specific screenings, and/or preventative medication.
2) **Negative —** No harmful variant is found in the gene. Your risk to have a cancer in your lifetime is still at least the same as the general population. However, if you have a family history with several members on the same side of your family affected with cancer, your risk to develop hereditary cancer may still be greater than the general population risk.
3) **Uncertain —** A genetic variant is found, but it is unknown if the variant increases your risk to have cancer. The variant may be a normal variation in your DNA sequence and be harmless to you. You would still have the same risk of cancer as the general population. Alternatively,

the variant may increase your risk for an inherited cancer. Without additional information, the test result is inconclusive. Testing other family members may be helpful to learn more about the variant. Over time as more information is learned about the variant, LabCorp will contact your health care provider's office with an update if the variant is re-classified as cancer-causing (pathogenic) or as harmless (benign). On annual basis, you should contact your health care provider for any available variant updates and also discuss any new cancer diagnoses in you and your family.

After you receive your VistaSeq results, you may have questions. Your health care provider can answer your questions and/or refer to a genetic counselor for additional information.

What will happen to my specimen?

Specimens are stored according to applicable federal, state, and professional regulations. If no regulation applies, specimens will be stored no longer than 60 days from the collection date. The data generated by the VistaSeq test will be saved for at least one year after testing is completed. To continually improve the analysis process, your test result may be shared with a HIPAA-compliant public database in a way that is not possible for anyone to determine your identity. Confidentiality of each specimen will be maintained.

VistaSeq Genetic Test Consent

- I understand the following and freely give my consent to have this genetic test performed.
- I have had an opportunity to read the information provided above and/or my health care provider has explained the risks, benefits, and limitations for the test ordered below. I am aware that genetic counseling is an option available to me both before and after testing.
- The test may provide me additional information about my inherited risk for cancer which may also have consequences for my blood relatives
- The ability of genetic testing to provide risk information or a diagnosis varies with the type of test. I have been provided with information about VistaSeq's ability to detect changes in the genes tested, and/or my health care provider has discussed it with me in detail.
- I understand that I may have variants in genes that increase my risk of inherited cancer that are not tested by VistaSeq.
- This test may not provide informative (helpful) results for a number of reasons. Some of the reasons include: 1) the need to test other family members; 2) no information known about the variant detected 3) technical reasons.
- All test results are confidential and will be released only to the ordering health care provider or that health care provider's designated representative. I understand that in some states I may have to disclose this information to third parties, such as life, disability or health insurers.
- Procedures to obtain blood specimens may have associated risks, such as bruising from blood collection.
- An additional blood specimen may have to be obtained in the absence of results, or if the results are inconclusive.
- All specimens are coded with unique identifying information to assure quality and, to the extent humanly possible, prevent error.
- My specimen will be securely stored in case retesting is necessary. Specimens are stored according to applicable federal, state, and professional regulations. If no regulation applies, specimens will be stored no longer than 60 days from the collection date. At the end of that time, the specimen will be destroyed unless otherwise instructed below.

All rights to the samples will belong to the laboratory conducting the testing. There will be no compensation in the event of an invention resulting from research and development using this sample.

❍ I agree to allow my blood specimen provided for genetic testing to be used for the purpose of (diagnosis/research) (development/quality control). I understand that if I agree, any information identifying me will be kept confidential so that it will not be possible to determine from whom the sample was drawn.

❍ I request that the sample be destroyed after testing. I understand that it will not be available if retesting is required.

Your signature on this form indicates that you understand to your satisfaction the information about VistaSeq and agree to have the test done. In no way does this waive your legal rights or release anyone from their legal and professional responsibilities. If you have further questions concerning matters related to this consent, you may wish to seek professional genetic counseling prior to signing this form. Consultation with a medical geneticist, genetic counselor, or your referring health care provider also may be warranted after the test has been completed.

Signature of patient or legal guardian: _____ Date: _____

Signature of health care provider: _____ Date: _____

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