Informed Consent/Decline for Carrier Screening

(Continued from other side)

My signature below indicates that I have read, or had read to me, the above information and I understand it. I have also read or had explained to me the specific diseases(s) or condition(s) tested for, and the specific test(s) I am having, including the test descriptions, principles, and limitations.

I have had the opportunity to discuss the purposes and possible risks of this testing with my doctor or someone my doctor has designated. I know that genetic counseling is available to me before and after the testing. I have all the information I want and all my questions have been answered.

I have decided that:

☐ I want carrier screening.
☐ I do not want carrier screening.

Patient Signature

Date

Obtained by

This model informed consent form is provided by Integrated Genetics as a courtesy to physicians and their patients.

Integrated Genetics is a business unit of Evalues Genomic Laboratories, LLC, a wholly-owned subsidiary of Laboratory Corporation of America Holdings.

www.mytestingoptions.com/inheritest

www.integratedgenetics.com
X-Linked Inheritance
With X-linked diseases, the mother has an altered copy of a gene located on the X chromosome and is said to be a "carrier." For most X-linked diseases, the risk that a carrier mother will have an affected son is 50%. The chance for a carrier mother to pass the altered gene to a daughter is 50%. For most X-linked diseases, girls inheriting an altered gene will not be affected, but will be carriers. An exception is fragile X syndrome.

Can anyone be a carrier?
Yes, the disorders included in the Inheritest Carrier Screen can be found in individuals of any ethnicity. Some of the disorders are found to be more frequent in certain populations. You can find additional information on these population-based risks on www.mytestingoptions.com/inheritest. Having a relative who is a carrier or is affected by a disease can also increase your risk of being a carrier. It is important to discuss your family history of genetic diseases with your doctor or genetics health professional.

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What if both partners are carriers?
If both you and your partner are carriers of a mutation for the same disease, then there is a 1 in 4 chance with each pregnancy that you could have a pregnancy affected with that disease. You should speak to your doctor or genetics health professional to help assess your options and risks. There are several options couples in this situation could consider, including:
- Prenatal testing, such as amniocentesis or CVS (chorionic villus sampling), which would determine whether or not the pregnancy has inherited the disease-causing mutations.
- In vitro fertilization, which could include testing the embryos using preimplantation genetic diagnosis (PGD).
- Additional family planning options.

Is carrier screening required?
No. The decision to accept or decline screening is entirely up to you. Your physician or genetics health professional can help you determine which testing is right for you.

Does insurance cover Inheritest?
Integrated Genetics has contracts with over 400 health insurance plans. If you are a member of a plan, Inheritest Carrier Screen may be covered. The best way to confirm if the Inheritest test is covered by your particular insurance policy is to contact your insurance company.

For your convenience, our billing team will file claims with your health insurance company, and we offer a variety of simple and convenient ways for you to pay any balance you may owe. The best way to confirm if the Inheritest test is covered by your particular insurance policy is to contact your insurance company.

In vitro fertilization, which could include testing the embryos using preimplantation genetic diagnosis (PGD).

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Additional family planning options.
This brochure contains general information about carrier screening and the inheritance of some of the more common genetic diseases. The Inheritest Carrier Screen provides genetic information regarding more than 114 different inherited diseases, providing you with useful information about risks for certain genetic diseases. It is important to remember that most pregnancies result in a healthy baby. Genetic carrier screening can provide you with information regarding risks of having a pregnancy affected with certain inherited diseases and allow you to make informed decisions for this and future pregnancies. It is important to discuss your carrier screening options with your doctor or a genetics health professional.

How are the diseases inherited that are included in the Inheritest Carrier Screen?
There are different ways genetic diseases can be passed down or inherited in families. The Inheritest Carrier Screen provides information about the risk of certain disorders that are inherited in an autosomal recessive and X-linked fashion.

Autosomal Recessive Inheritance
With autosomal inheritance, every person has two copies of each gene, one inherited from each parent. With autosomal recessive disorders, if a person has one normal gene and one altered gene, then that person is a carrier. An exception is fragile X syndrome.

Can anyone be a carrier?
Yes, the disorders included in the Inheritest Carrier Screen can be found in individuals of any ethnicity. Some of the disorders are found to be more frequent in certain populations. You can find additional information on these population-based risks on www.mytestingoptions.com/inheritest. Having a relative who is a carrier or is affected by a disease can also increase your risk of being a carrier. It is important to discuss your family history of genetic diseases with your doctor or genetics health professional.

What is the purpose of Inheritest Carrier Screen?
The purpose of Inheritest Carrier Screen is to see if you are at increased risk for having a pregnancy affected with an inherited disease. The screening test requires a sample of blood and the results are returned to your physician in approximately two weeks.

What do my Inheritest results mean?
A negative result reduces, but does not completely eliminate, the risk of being a carrier of the genetic disease. Inherited Carrier Screen is not a diagnostic test for all mutations or all diseases. If it is determined that you are a carrier for one of the inherited disorders, you can speak to your doctor or genetics health professional about the implications of your result and appropriate testing for your partner. With the exception of X-linked diseases, since both parents must be carriers for the pregnancy to be at risk of the disease, the next step is to have your partner tested.

What if both partners are carriers?
If both you and your partner are carriers of a mutation for the same disease, then there is a 1 in 4 chance with each pregnancy that you could have a pregnancy affected with that disease. You should speak to your doctor or genetics health professional to help assess your options and risks. There are several options couples in this situation could consider, including:
- Prenatal testing, such as amniocentesis or CVS (chorionic villus sampling), which would determine whether or not the pregnancy has inherited the disease-causing mutations.
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- Additional family planning options.

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Does insurance cover Inheritest?
Integrated Genetics has contracts with over 400 health insurance plans. If you are a member of a plan, Inheritest Carrier Screen may be covered. To determine if the Inheritest test is covered for your plan, please contact your health insurance company. The best way to confirm if the Inheritest test is covered by your particular insurance policy is to contact your insurance company.

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Informed Consent/Decline for Carrier Screening
You should be certain you understand the following points:

1. The purpose of my DNA test is to determine whether I have mutation(s) known to be associated with the following genetic condition or disease.

2. This testing is done on a small sample of blood.

3. Mutations are often different in different populations. I understand that my laboratory needs accurate information about my family history and ethnic background for the most accurate interpretation of the test results.

4. When DNA testing shows a mutation, then the person is a carrier or is affected with the condition or disease tested for. Consulting a doctor or genetic counselor is recommended to learn the full meaning of the results and to learn if the additional testing might be appropriate.

5. When the DNA testing does not show a known mutation, the chance that the person is a carrier or is affected is reduced. There is still a chance to be a carrier or to be affected because the current testing cannot find all the possible changes within a gene.

6. In some families, DNA testing might discover non-paternity (someone who is not the real father), or some other previously unknown information about family relationships, such as adoption.

7. In the case of twins or other multiple fetuses, the results may pertain to only one of the fetuses.

8. In the case of abnormal diagnostic results, the decision to continue or to terminate the pregnancy is entirely mine.

9. The decision to consent to, or refuse, any of the above procedures/testing is entirely mine.

10. No test(s) will be performed and reported on my sample other than those authorized by my doctor and any unused portion of my original sample will be destroyed within 60 days of receipt of the sample by the laboratory.

11. My doctor may release my pregnancy outcome or ultrasound and amniocentesis results to Esoterix Genetic Laboratories, to be used for statistical analysis of the laboratory’s performance.

12. Esoterix Genetic Laboratories will disclose the test results only to the named on this form, or to his/her agent, unless otherwise authorized by the patient or required by law.
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There are different ways genetic diseases can be passed down or inherited in families. The Inheritest Carrier Screen provides information about the risk of certain disorders that are inherited in an autosomal recessive and X-linked fashion.

Autosomal Recessive Inheritance
With autosomal inheritance, every person has two copies of each gene, one inherited from each parent. With autosomal recessive disorders, if a person has one normal gene and one altered gene, then that person is called a “carrier.” Having one altered gene is usually not enough to cause the disease and most carriers do not have any symptoms. Carriers can pass the altered gene to their offspring.

With autosomal recessive disorders, both parents must be carriers of the same disease-causing gene in order to have an increased chance (25%) to have a child affected with a disorder. Both males and females are affected.

X-Linked Inheritance
With X-linked diseases, the mother has an altered copy of a gene located on the X chromosome and is said to be a “carrier.” For most X-linked diseases, the risk that a carrier mother will have an affected son is 50%. The chance for a carrier mother to pass the altered gene to a daughter is 50%. For most X-linked diseases, girls inheriting an altered gene will not be affected, but will be carriers. An exception is fragile X syndrome.

Can anyone be a carrier?
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What do my Inheritest results mean?
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What if both partners are carriers?
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Is carrier screening required?
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Does insurance cover Inheritest?
Integrated Genetics has contracts with over 400 health insurance plans. If you are a member of a plan, Inheritest Carrier Screen may be covered. In some families, DNA testing might discover non-paternity (someone who is not the real father), or some other previously unknown information about family relationships, such as adoption.

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(Date)

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www.mytestingoptions.com/inheriter

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Ask your doctor about it today.

Because Knowledge is a Powerful Tool.

Broadening your testing options for genetic screening of inherited diseases.

Learn more about our genetic testing and counseling services by calling our client services team at 800-848-4436 or visiting our websites:

www.mytestingoptions.com www.integratedgenetics.com

Thanks for considering our services.

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