

Counsyl Foresight™ Carrier Screen



Informed Consent

Please review this information carefully and then indicate with your signature if you wish to move forward with testing. This is a voluntary test. You may wish to seek genetic counseling prior to signing this form.



PURPOSE

- The Foresight Carrier Screen is designed to determine whether you carry genetic changes, called mutations, that could cause serious genetic conditions in your children.
- For most of the conditions on the panel, both parents must carry a mutation in the same gene for their children to be at risk of developing symptoms. However, there are certain conditions on the Foresight Carrier Screen for which only the mother needs to carry a mutation for her children to be at risk of developing symptoms.
- More information about each of the conditions on the Foresight Carrier Screen panel can be found at counsyl.com/foresight.



BENEFITS

- Your Foresight Carrier Screen results can help you and your partner make more informed decisions regarding your family, particularly if screening is performed prior to pregnancy.
- If it is early in your pregnancy, you can pursue further testing to determine if the pregnancy is affected, and receive guidance from your healthcare provider about how best to plan and prepare for birth.
- Your Foresight Carrier Screen results may also benefit your other family members. If you test positive, your biological relatives are more likely to test positive for the same mutation(s), thereby allowing them to discover previously unknown conditions and risks.



WHAT YOU MIGHT LEARN

- **Carrier (Positive):** A positive test result indicates that a mutation has been identified and that you are a carrier of the indicated condition. You may be identified as a carrier for more than one condition. Carriers usually do not experience symptoms of the condition.
- **No mutations detected (Negative):** A negative test result indicates that no gene mutations were identified. This reduces but does not eliminate the possibility of you being a carrier for a condition on the panel.

PROCEDURE

- The Foresight Carrier Screen can be done before pregnancy or early in pregnancy, as ordered by your healthcare provider.
- A small saliva or blood sample is taken and sent to Counsyl for screening.
- Except in rare cases, your sample will be kept a maximum of 180 days.*

RISKS

- Genetic testing may reveal sensitive information about your health and that of your family members.
- This test may provide information that can have an impact on your medical decisions.

LIMITATIONS

- The Foresight Carrier Screen is not intended to detect all genetic mutations.
- Only variants in the genes requested by the ordering healthcare provider will be reported. Your report will indicate which genes are included.
- As with all medical screening tests, there is a chance of error, including a false positive or false negative result.
 - A “false positive” refers to identifying a mutation that is not present.
 - A “false negative” is the failure to detect a mutation that is present in the sample.
- Certain factors, such as having blood cancer, prior blood transfusions, or previous bone marrow transplants can affect the accuracy of Foresight Carrier Screen results. Be sure to discuss your medical history with your healthcare provider.
- Occasionally it may not be possible to provide a result. A repeat specimen may be requested.

PRIVACY

- Genetic information is protected under the federal Genetic Information Nondiscrimination Act (GINA), which generally prohibits health insurers and employers from discriminating against you based on your genetic information. However, you should be aware current federal laws do not specifically prohibit genetic discrimination in life insurance, long-term care insurance and disability insurance. More information about GINA and its limitations is available at ginahelp.org.
- If you and your partner are receiving simultaneous Foresight Carrier Screen testing, each of your test results may be revealed to one another.
- Your Foresight Carrier Screen results will be reported to your healthcare provider or his/her agent.
- By agreeing to testing and signing this consent, you hereby authorize Counsyl to share your Foresight Carrier Screen results with other authorized representatives that you’ve identified to Counsyl or your healthcare provider, or as otherwise allowed by law.

- Counsyl may find information that is not included in the original test requested by your healthcare provider and may report these additional results, if clinically relevant. You authorize Counsyl to share these results with you and your healthcare provider.
- You authorize Counsyl to contact you about your test or sample, as well as about additional products and/or offers that may be relevant and/or interesting to you.
- Please refer to Counsyl’s Notice of Privacy Policy, available on the Counsyl website, for additional information about Counsyl’s privacy practices.

RESEARCH*

- Unless you contact us to tell us otherwise, by agreeing to testing and signing this consent, you authorize Counsyl and its partners to use your sample and any information derived from your sample or otherwise collected about you for educational and/or research purposes. You will not be paid for this use.
- De-identified information may additionally be submitted to external research databases.
- You authorize Counsyl to contact you about potential educational and/or research opportunities.
- Please contact us at support@counsyl.com or +1-888-COUNSYL if you wish to opt out of such research or future contact.

FINANCIAL RESPONSIBILITY

- By agreeing to testing and signing this consent you authorize Counsyl to submit to your insurance carrier any and all of the information, including test results, necessary for processing your insurance claim.
- If your insurance carrier does not reimburse Counsyl in full or in part because your insurance carrier determines the Foresight Carrier Screen is not a covered service, is not medically necessary, or for any other reason, you agree to be responsible for payment if you choose to proceed with the screen.

*Samples from residents of New York state will not be retained for more than 60 days after collection and will not be included in research studies.

I have read or have had read to me and understand all of the above information and have had an opportunity to ask questions about the purpose, procedure, risks, benefits and limitations of testing.

I HAVE DECIDED TO PURSUE TESTING and to be bound by the terms of this Consent and any policies referenced herein.

Patient Name Date of Birth Patient Signature Date

Physician Name Physician Signature Date