

9. Sequenom Center for Molecular Medicine keeps test results confidential and is in full compliance with all Health Insurance Portability and Accountability Act (HIPAA) regulations. My test results will be released only to the ordering healthcare provider, his or her designee, or as required by federal or state laws. Results will be released to other parties with my prior written consent.
10. Unless I provide consent for my specimen to be retained by Sequenom CMM for Quality Control/Quality Assurance purposes on the Test Requisition Form, my sample will be destroyed as required by law.
11. I have had an opportunity to ask questions, and answers have been provided to my understanding and satisfaction.
12. The decision to have this test is completely mine.

**PATIENT INFORMED CONSENT/DECLINE
FOR CYSTIC FIBROSIS CARRIER SCREENING**

I have read this Patient Informed Consent/Decline form and I understand it. I have had the opportunity to ask questions and have been provided answers. I have decided that:

- I want CF carrier screening.
 I do not want CF carrier screening.

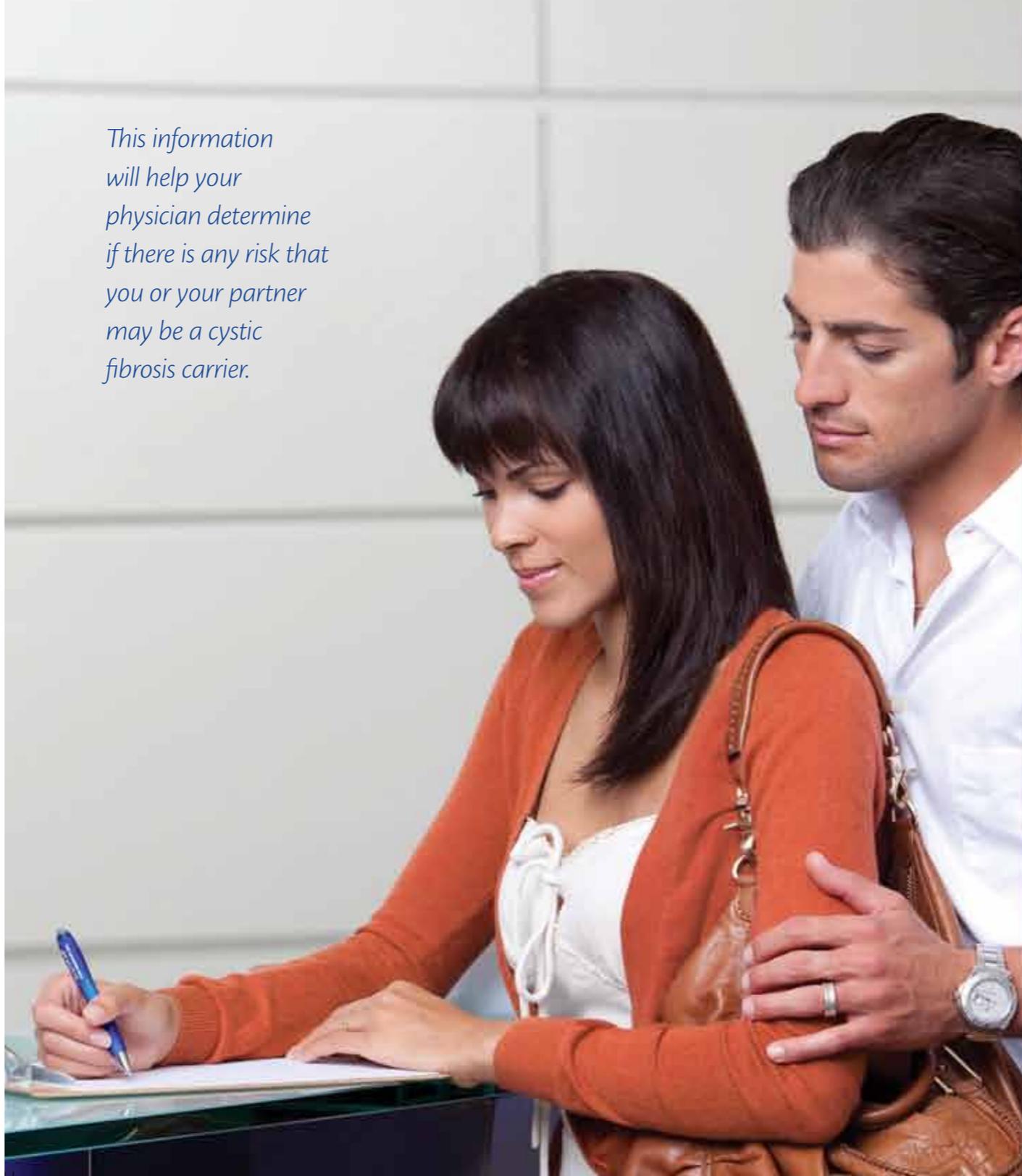
Patient Signature

Date

Printed Name of Patient

This example Patient Informed Consent/Decline Form (the "Form") is provided by Sequenom Center for Molecular Medicine (Sequenom CMM) solely as a courtesy to physicians and patients as a starting point, which may or may not be used in your sole discretion, for addressing the issue of informed consent. The actual informed consent form that you may need to use may differ in light of specific additional and/or different requirements that may be mandated on a state-by-state or other legal basis. The Form is provided as is without any representation or warranty as to its applicability, completeness, accuracy or compliance with state and/or federal legal requirements or otherwise. By providing this Form, Sequenom CMM is not, and should not be considered as, providing any legal or other advice with respect to informed consent or informed consent forms.

*This information
will help your
physician determine
if there is any risk that
you or your partner
may be a cystic
fibrosis carrier.*



Introducing *SensiGene*[™]
**Cystic Fibrosis
 Carrier Screening**



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SensiGene[™] Cystic Fibrosis Carrier Screening

WHY CARRIER SCREENING FOR CYSTIC FIBROSIS IS IMPORTANT...

Carrier screening tests help identify individuals who may have an increased risk of having a baby with certain genetic conditions. Even if you are healthy, have no family history of the condition, or even already have healthy children, you may be a carrier of a genetic condition. One of these conditions is CYSTIC FIBROSIS.

This brochure will provide you with information to help you learn more about Cystic Fibrosis Carrier Screening.

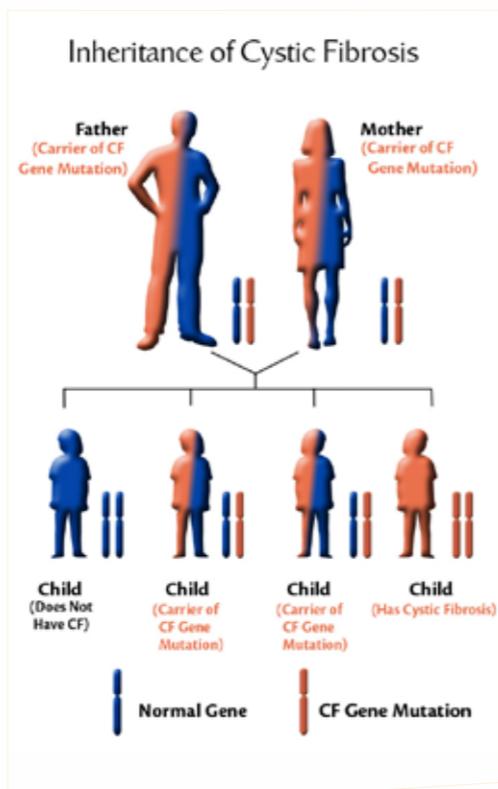
WHAT IS CYSTIC FIBROSIS?

Cystic Fibrosis (CF) is one of the most common genetic conditions in the United States. It is caused by changes in the CFTR gene. Changes in this gene cause the body to produce thick mucus that can affect breathing, digestion and other organs. CF does not affect everyone the same way, some people may be more severely affected than others. Symptoms range from moderate to severe—not everyone with CF is affected in the same way.

Approximately 1 in 30 Americans—more than 10 million people—are carriers of CF. While the risk of being a CF carrier is dependent upon one's ethnicity and family history, individuals of all racial and ethnic groups may be carriers of CF.

HOW IS CYSTIC FIBROSIS INHERITED?

To be affected with CF, an individual must inherit two disease-causing mutations—one from each parent, each of whom is a 'carrier' of a CF gene mutation. Carriers have only one disease-causing mutation and most often have no symptoms of CF. However, when an individual has two disease-causing mutations, it results in the individual having CF. If both parents are CF carriers, there is a 1 in 4 (25%) chance that a child will have CF. If only one parent is a CF carrier, there is no chance that a child will have CF; however, there is a 1 in 2 (50%) chance that a child will be a CF carrier.



WHO SHOULD CONSIDER CYSTIC FIBROSIS CARRIER SCREENING?

The American College of Obstetricians and Gynecologists (ACOG) and the American College of Medical Genetics (ACMG) recommend cystic fibrosis carrier screening be offered to all Caucasian couples (including Ashkenazi Jews) who are pregnant or considering pregnancy, and also made available to all patients regardless of ethnicity.

Indications for CF carrier screening include:

- Members of pregnant couples or couples planning a pregnancy
- Individuals with a family history of CF
- Individuals with negative results from smaller mutation panels when individual has family history of CF
- Individuals who have a reproductive partner who is a CF carrier

The CF carrier screening test is a simple blood test and results are typically available to your doctor within one week.

WHAT DOES A POSITIVE CF CARRIER SCREEN TEST RESULT MEAN?

A positive CF carrier screening test result means you have one copy of a mutation that is known to cause CF. It does not mean you have CF. If you are found to be a CF carrier, then your partner should be tested. If you are both found to be CF carriers, your doctor, genetic counselor or other healthcare provider will discuss reproductive and prenatal testing options with you.

The American College of Obstetricians and Gynecologists (ACOG) and the American College of Medical Genetics (ACMG) recommend:

Cystic fibrosis carrier screening should be offered to all Caucasian couples (including Ashkenazi Jews) who are pregnant or considering pregnancy, and also made available to all patients regardless of ethnicity.

WHAT DOES A NEGATIVE CF CARRIER SCREEN TEST RESULT MEAN?

A negative CF carrier screening test significantly reduces your risk to be a CF carrier, but it does not reduce your risk to zero. Because this test does not screen for all CF mutations, and because not all CF mutations may even be known at this time, your risk to be a CF carrier is reduced, but is not zero.

For more information, ask your doctor or visit www.scmmmlab.com.

PATIENT INFORMED CONSENT/DECLINE FOR CYSTIC FIBROSIS (CF) CARRIER SCREENING

I have read and understand the following:

1. The purpose of this test is to determine whether I am a carrier of one of the CF mutations included in this test.
2. This CF carrier test does not detect all changes (or mutations) that may cause CF.
3. Results from this test may:
 - indicate whether I am a carrier of CF.
 - predict another family member is a carrier of CF.
4. If I am a CF carrier, testing of my reproductive partner(s) will help me learn more about the chance that our child could have CF.
5. A negative test result significantly decreases, but does not eliminate, the chance that I am a CF carrier.
6. The types of test results and their significance have been explained to me by a healthcare provider.
7. The test requires a blood sample. While side effects of blood draws are uncommon, they may include dizziness, fainting, soreness, bleeding, bruising and rarely infection.
8. The performance characteristics of this test were developed and validated by Sequenom Center for Molecular Medicine. Sequenom Center for Molecular Medicine is authorized under Clinical Laboratory Improvement Amendments (CLIA) to perform this test. The results of this test are not intended to be used as the sole means for clinical diagnosis or patient management decisions.