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References

1. Carrier Screening for Genetic Conditions. ACOG Committee Opinion 691. March 2017.
2. Cystic Fibrosis Foundation Patient Registry 2018.
3. Rohlfis, E, et al. Cystic Fibrosis Carrier Testing in an Ethnically Diverse US Population. *Clin Chem* 2011; 57(6):841-848.

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L10198-0422-6



PATIENT INFORMATION

Cystic Fibrosis Carrier Screen

A common chronic, life-shortening inherited disorder of children and young adults



Carrier screening for cystic fibrosis

The American College of Obstetricians and Gynecologists (ACOG) supports that cystic fibrosis (CF) carrier screening be offered to women who are currently pregnant, or are considering pregnancy.¹ Screening can help determine if a couple is at risk of having a child with CF.¹

This brochure contains general information about CF, how it is inherited and CF carrier screening.

If you have any additional questions or are seeking CF testing due to the presence of CF symptoms, male infertility, abnormal prenatal ultrasound findings, a family history of CF, or for testing of an unborn baby, please contact your doctor or genetics professional for additional information.

What is cystic fibrosis?

CF is a genetic disorder that affects approximately 1 in 2,500 individuals in the non-Hispanic white population, but less individuals from other ethnic groups.¹ CF causes the body to produce abnormally thick mucus, leading to life threatening lung infections, digestion problems, diarrhea, poor growth and male infertility. Symptoms of the disorder range from mild to severe. Individuals with mild CF may reach adulthood and be unaware that they have the disorder. However, the average life span for individuals with CF is 44 years.² CF does not affect intelligence.¹

What is a CF carrier?

Every person has two copies of a gene, one inherited from each parent. If a person has one normal CF gene and one altered CF gene, that person is a carrier of CF. Having only one altered copy of the CF gene is not enough to cause the disorder, so a CF carrier does not have symptoms.

How is CF inherited?

If both parents are carriers of an altered CF gene, there is a chance that each parent will pass an altered gene on to their child. Having two copies of an altered CF gene results in CF. With each pregnancy there is a:

- 25% (1 out of 4) chance the child will inherit two normal CF genes, and will be neither a carrier, nor affected with CF
- 50% (2 out of 4) chance the child will inherit one normal and one altered CF gene, and will be a carrier of CF
- 25% (1 out of 4) chance the child will inherit two copies of an altered CF gene, one from each parent, and will be affected with CF.

Can anyone be a CF carrier?

Yes. CF can occur in any ethnic background. If there is no one in your family with CF, your risk for being a CF carrier is determined by your ethnic background (See Table 1). CF is common among people of Caucasian and Ashkenazi Jewish descent. The disorder is less common among those of Hispanic, African American, Native American or Asian backgrounds.

If a relative of yours has CF, or is known to be a carrier of CF, your chance of being a carrier is greater based on your family history.

Ethnicity	CF carrier risk in people with no family history of CF ¹
Ashkenazi Jewish	1 in 24
Caucasian	1 in 25
Hispanic	1 in 58
African American	1 in 61
Asian	1 in 94

What is the purpose of CF carrier screening?

The purpose of CF carrier screening is to see if a couple is at increased risk for having a child with CF. The screening test requires a sample of blood and results are usually ready within 5 to 10 days. If a couple has not yet conceived, one partner is usually tested first. If a woman is already pregnant, a couple may opt to be tested at the same time.

What do the results mean?

A negative result significantly lowers, but does not completely eliminate, the risk of being a CF carrier. Less common alterations (mutations) in the CF gene are not included in carrier screening. For most individuals, no further testing is needed. Testing for rare CF mutations is available if indicated.

If your testing identifies one altered CF gene, then you are a carrier. Since both parents must be carriers for the baby to be at risk for CF, your partner should be tested.

Rarely, DNA testing may identify two altered genes in a healthy individual. When this occurs, further medical evaluation and testing of additional family members may be recommended.¹



What if both my partner and I are CF carriers?

If both you and your partner are found to be carriers of an altered CF gene, there is a 25% (1/4) chance with each pregnancy that the child will be affected with CF. In this situation, you may be referred for genetic counseling. There are several choices couples in your situation can make when thinking about possible future pregnancies. Some couples decide to:

- Have prenatal testing, such as amniocentesis or chorionic villus sampling (CVS), to determine whether or not the unborn baby has inherited the two altered CF genes, and therefore is predicted to be affected with CF.
- Accept this level of risk and have children without further prenatal testing
- Go through in vitro fertilization and test the embryos using preimplantation genetic testing (PGT)

- Adopt children
- Use donor sperm or donor eggs
- Not have children

If a couple does not want prenatal diagnosis, then newborn screening for CF is available in all states.

Is CF screening required?

No. The decision to accept or decline screening is entirely up to you.

CF can occur in any ethnic background. If there is no one in your family with CF, your risk for being a CF carrier is determined by your ethnic background.

Consent for cystic fibrosis carrier screening

- The purpose of this test is to determine whether I am a carrier of the common genetic abnormalities that cause CF
- This test does not detect all carriers of this disorder
- The laboratory needs accurate information about my family history for the most accurate interpretation of the test results
- The decision to have carrier testing is completely mine
- No other test will be performed and reported on my sample unless authorized by my doctor, and any unused portion of my original sample will be destroyed within two months of receipt of the sample by the laboratory
- The laboratory will disclose the test results ONLY to me and my doctor, or to his/her agent, unless otherwise authorized by me or required by law
- If I am a carrier, testing my partner will help me learn more about the chance that our baby could have CF
- If one parent is a carrier and the other is not, it is still possible that the baby will have CF, but the chance is less than 1%
- If both parents are carriers, prenatal testing is available to find out whether or not the baby will have CF

I have read, or had read to me, the information in this brochure and I understand it. Before signing this form, I have had the opportunity to discuss carrier screening further with my doctor, someone my doctor has designated, or with a genetics professional. I have all the information I want, and all my questions have been answered. I have decided that:

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

Patient signature: _____ Date: _____

Obtained by: _____

This consent form is provided by Labcorp as a courtesy to physicians and their patients. For additional information and the model informed consent form, visit womenshealth.labcorp.com.