



## Informed Consent for Cystic Fibrosis Testing

Internal Use Only CUMC MRN: \_\_\_\_\_

Acc #: \_\_\_\_\_

Please read the following form carefully and discuss with your ordering physician/genetic counselor before signing consent.

1. This is a test for an abnormality (mutation(s)) in the CFTR gene using PCR with a bead probes.
2. The purpose of this analysis is to test for a Cystic Fibrosis carrier status.
  - 2a. You (or the person for whom you are signing) may want genetic counseling before signing consent.
3. This is a test for genetic susceptibility (“genetic predisposition”), the risk of having the disorder may be altered by family history and/or other factors. If the test is positive for the disorder or for an increased risk of the disorder, you may wish to have further independent testing, consult your physician or have genetic counseling.
4. The condition being tested is cystic fibrosis, which affects or leads to lung and digestive problems.
5. When two mutations are found, there is almost 100% likelihood of disease. When no mutation is found, in an asymptomatic person, there is almost 0% likelihood of disease in the tested person, but the risk of being a carrier depends upon race and family history. When one mutation is found, the person is a carrier. The risk of having an affected child depends upon mutation status of the partner.
6. The results of the above test become a part of the patient’s medical record, and may be made available to individuals/organizations with legal access to the patient’s medical record, on a strict “need-to-know” basis, including but not limited to the physicians and nursing staff directly involved in the patient’s care, the patient’s current and future insurance carriers, and other specifically authorized by the patient/authorized representative to gain access to the patient’s medical records.
7. No additional tests will be performed on this sample, without specific, signed authorization by the patient. After 60 days, unless consent is given the sample will be destroyed – please see below.
8. Medicare/Insurance Carriers may not pay for the test, in which case, the patient/responsible party will be billed for the test.

### Person obtaining consent:

\_\_\_\_\_ **Date:** \_\_\_\_\_  
Print Name of Person Obtaining Consent                      Signature of Person Obtaining Consent

**I have read and fully understood the above, and give my consent for this testing.**

### Patient (person being tested):

\_\_\_\_\_ **Date:** \_\_\_\_\_  
Print Name of Patient/Authorized Representative                      Signature of Patient/Authorized Representative

Relationship to Patient: \_\_\_\_\_

### Consent for Sample Retention:

\_\_\_\_\_ I do not consent to research. My blood may be used for routine laboratory use only.

\_\_\_\_\_ I consent to possible future genetic research on my blood id all identifying information is removed (name, address, date of birth, medical record number). The duration of the retention of mu blood sample will depend on the individual research study. If the blood is not used in a study, it will be destroyed or anonymously used as described above.