Cystic Fibrosis
INFORMED CONSENT

This is an elective clinical laboratory test. The majority of insurances WILL NOT COVER. The cost of the test will be your responsibility.

What is Cystic Fibrosis? Cystic Fibrosis (CF) is an inherited disease that results from mutations in a gene called, "CFTR." Although severity varies, affected patients may have lung disease and impaired digestion, as well as problems in other organ systems. *Cystic Fibrosis is included in the newborn screening panels performed at the hospital after delivery.*

What is the purpose of this test and what are its limitations? This test detects the presence of specific genetic changes (mutations) in the CFTR gene. Everyone has two copies of this CFTR gene; an individual may have two normal copies (unaffected non-carrier), two abnormal copies (affected with CF), or one normal and one abnormal (CF carrier). If mutations are not found by the testing procedure, it does not mean that the risk of carrying or developing CF is not present. It simply means that these specific mutations have not been found, although other mutations may be present. Where possible and appropriate, negative results will be used to calculate revised carrier risks.

What does it mean if the screening test is positive? If the CF screening test indicates a person is a carrier, the next step is to test your partner. Both partners must be carriers of a CF gene mutation to have an affected child. If the partner has a negative test result, the chance of having a baby with CF is very low. If the partner's test result is positive, the couple has a 25% chance with each pregnancy of having a child with CF.

My signature below indicates that I have received information about this test, Cystic Fibrosis, and that I have read and understood the material in this document. I have been given a full opportunity to ask questions that I may have about the testing procedure and related issues.

I agree to undergo this testing. Yes / No   (circle one)

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Patient Name   Patient Signature   Date of Birth   Date

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Provider/witness