1. **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 both lung impairment and impaired digestion, as well as problems in other organ systems.

2. **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. Where possible and appropriate, negative results will be used to calculate carrier risks for patients with no mutations found on the screening test.

3. **What is required to perform this test?** You will be asked to provide 5 ml of blood, which is equal to about on tablespoon. DNA will be extracted from the blood sample and tested. The only discomfort that you may feel is the stick of a needle in your arm. You may also experience a small bruise at the site of the needle puncture. You will also be asked to provide information regarding your medical history, which is necessary for proper interpretation of your test result. **Is there a cost for this test?** This is a routine clinical laboratory test and the results may aid in your diagnosis; thus, you or your health insurer will be billed for this procedure.

4. **What will happen to the DNA once the test is complete?** The only testing that will be performed on this sample is the test for CF. In most cases, the original blood sample will be discarded at the end of the testing process or stored not more than 14 days. The DNA will be retained for a minimum of 12 months. In some circumstances, a patient's DNA may be used as a control sample in future testing, but, in this event, all identifiers will be removed and the DNA sample will be anonymous.

5. **How will I get results from this test?** DNA testing and interpretation of results are complex. The information from this test will be provided in the form of a written report to your physician who will inform you of the results. The laboratory will NOT provide results directly to patients. Your physician may recommend follow-up genetic counseling. To the extent permitted by law, all of your laboratory records and results are confidential and shall not be disclosed without your written authorization.

My signature below indicates that I have received information about this test and 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 testing.

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**DATE**

**PATIENT SIGNATURE**

**NAME OF PARENT/GUARDIAN**

**SIGNATURE OF PARENT/GUARDIAN IF PATIENT IS A MINOR**

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**For the Physician:** As the referring physician, I understand the benefits and limitations of this study and have requested that the above named patient be tested. I attest to the fact that I have provided the patient with the information contained above and fully answered any questions. I believe the patient understands the information and is voluntarily signing the informed consent.

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**PRINTED NAME OF PHYSICIAN/HEALTH CARE PROFESSIONAL**

**SIGNATURE OF PHYSICIAN/HEALTH CARE PROFESSIONAL**

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8143NS (8/04) WHITE - Lab CANARY - Patient PINK - Physician