The information below is required to perform cystic fibrosis testing.
Please fill out this form and sign below. See informed consent for Molecular Genetic Testing on second page.

PATIENT HISTORY FOR CYSTIC FIBROSIS (CF) TESTING

Patient Name _____ Date of Birth_____ /_____/_____

Gender [ ] F [ ] M

Physician _____ Physician Phone (_____)_____
Practice Specialty_____
Genetic Counselor _____ Counselor Phone (_____)_____

Is the patient pregnant? [ ] No [ ] Yes [ ] NA

Is this routine carrier screening? [ ] No [ ] Yes

Patient's Ethnicity (check all that apply)

[ ] African American [ ] Ashkenazi Jewish [ ] Asian [ ] Caucasian
[ ] Hispanic [ ] Middle Eastern [ ] Native American [ ] Other _____

Does the patient have a FAMILY HISTORY of CF? [ ] No [ ] Yes [ ] Unknown
If yes, what is the specific RELATIONSHIP of the family member to the patient? _____

Is the relative [ ] a healthy carrier [ ] affected with CF
List the mutation(s) _____

Is the patient's REPRODUCTIVE PARTNER a CF carrier? [ ] No [ ] Yes
List the mutation_____
Does the patient's reproductive partner have a FAMILY HISTORY of CF? [ ] No [ ] Yes [ ] Unknown
If yes, what is the specific RELATIONSHIP of the family member to the partner? _____
Is the relative [ ] a healthy carrier [ ] affected with CF

Has the patient undergone previous DNA testing for CF? [ ] No [ ] Yes [ ] Unknown
If yes, please describe test(s) and results _____

Available test to order:
[ ] **2001933 Cystic Fibrosis (*CFTR)* Maternal Carrier Screen**

Physician/Genetic Counselor:
I have explained DNA testing and its limitations to the patient or legal guardian and answered all questions.

Physician/Genetic Counselor Signature_____ Date_____

Patient/Guardian:
I have read the information on the back of this form and would like to proceed with carrier screening for cystic fibrosis.

Patient/Guardian Signature_____ Date_____

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ARUP LABORATORIES

INFORMED CONSENT FOR MOLECULAR GENETIC TESTING

I request DNA analysis for the condition(s) ___Cystic Fibrosis Carrier Screening_____

The intended purpose is: ☐ Diagnosis X Carrier status ☐ Predictive ☐ Prenatal

I request and authorize ARUP Laboratories to test my (or my child's or my fetus') sample for the above-designated genetic condition(s). My signature below constitutes my acknowledgment that the benefits, risks, and limitations of this testing have been explained to my satisfaction by a qualified health professional and I have been provided a copy of the corresponding technical bulletin describing testing for the condition(s) listed above.

1. DNA test results may:
   a) diagnose whether or not I have (or my child/fetus has) this condition or am at risk for developing this condition
   b) indicate whether or not I (or my child/fetus) am a carrier for this condition
   c) predict another family member has, is at risk for developing, or is a carrier of this condition
   d) be indeterminate due to technical limitations or familial genetic patterns
   e) reveal non-paternity

2. DNA testing is specific only for the condition(s) named above and will not detect all causative mutations.

3. The significance of a positive and a negative test result based on my family history has been explained.

4. Although DNA testing usually yields precise information, several sources of error are possible. These include, but are not limited to, clinical misdiagnosis of the condition, sample misidentification, and inaccurate information regarding family relationships.

5. If a gene mutation is identified, insurance rates, obtaining disability or life insurance, and employability could be affected. Federal law extends some protections regarding genetic discrimination (http://www.genome.gov/10002328). It is my responsibility to consider the possible impact of these results. All test results are released to the ordering health care provider and those parties entitled to them by state and local laws.

6. The performance characteristics of this test were validated by ARUP Laboratories. The U.S. Food and Drug Administration (FDA) has not approved this test; however, FDA approval is currently not required for clinical use of this test. ARUP is authorized under Clinical Laboratory Improvement Amendments (CLIA) and by all states to perform high-complexity testing. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions.

7. I will be responsible for payment after the genetic testing has begun, even if I decide not to receive results.

8. Genetic counseling is recommended prior to, as well as following, genetic testing.

9. My (or my child's or my fetus') DNA sample may be stored indefinitely to be used for test validation or education after personal identifiers are removed. No clinical tests other than the ones authorized will be performed. I may request disposal of my blood and DNA sample following completion of the test requested above by contacting the laboratory at (800) 242-2787, ext. 3301. For more information about ARUP, please refer to www.aruplab.com. All samples from New York clients will be disposed of 60 days after testing is complete.

Please sign the front of this form