Informed Consent Form

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Review and Approval	• Reviewers: Norman Moore; Christina Deer; Jonathan Hayden • Approver (Laboratory Director Only): Terrence Hallahan
Reason for Revision	Process to obtain Informed Consent for Genetic Testing

Revision Log

Date	Rev.	Author	Description
Jun 20, 2017	1	Margaret Palladino; Eurofins D CDS US Reporting Department; Eurofins D CDS US Quality Management Department	Process to obtain Informed Consent for Genetic Testing

Electronic Signatures

Jonathan Hayden;Review;Tuesday, June 13, 2017 1:41:06 PM EDT
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1. Cystic Fibrosis (CF) is an inherited disease caused by mutations in a gene called the cystic fibrosis transmembrane conductance regulator (*CFTR*). The degree of severity of the disorder varies widely. Some patients exhibit mild "breathing problems" while others may have lung disease and pancreatic disorders and problems with other organs.

2. The test detects the presence of specific genetic changes (mutations) in the *CFTR* gene. Everyone has two copies of the *CFTR* gene:

   a. An individual with two normal copies is unaffected and is not a carrier of a defective gene.

   b. On the other hand, a person can have one normal and one abnormal gene, this makes them a carrier of the mutation, but they are unaffected.

   c. A person with two abnormal copies is affected and has cystic fibrosis.

3. If mutations are not found by the test, it does not mean that there is no risk of carrying or developing CF. This means that specific mutations for which we tested were not found. However, other mutations may be present.

4. The specimen is a dried blood spot on filter paper. DNA is extracted from the blood sample spot. The only discomfort that you may feel is the stick of the needle on your finger or heel in the case of an infant. The chances of injury caused by the collection of the specimen are very low.

5. You will be asked to provide information regarding your personal and family medical history. This is necessary for the proper interpretation the test results.

6. This is a routine clinical laboratory test and the results may aid in your diagnosis. You or your health insurer will be billed for this procedure.

7. The original blood sample will be stored for 60 days and then destroyed unless otherwise requested by the patient. The extracted DNA from the sample will be consumed in the analysis. In some cases, a patient's blood may be used as a negative or positive control sample in future testing. When this is done, all patient identification is removed and the DNA sample and the results remain anonymous.

8. The results of this test will be provided in a written report to your healthcare provider who will inform you of the results. The laboratory does not provide results directly to patients. Your healthcare provider may suggest genetic counseling prior to performing this test or if your results are abnormal. In accordance with existing laws, your laboratory records and results are protected health information and will not be disclosed without your written authorization.

9. Testing of parents, children, or siblings may reveal discrepancies in paternity or maternity.

Patient Acknowledgment of Informed Consent

I have read and understand the material above. I have been given the opportunity to ask questions about the test and related issues. I understand and agree that any of my specimen remaining after testing will be destroyed after 60 days unless requested otherwise.

_____ _____

Signature of Patient or Guardian Date

_____

Printed Name

Healthcare Provider Acknowledgment

As the ordering healthcare provider, I understand the purpose, benefits, and limitations of the test and have requested that the patient above be tested. I attest to the fact that I have provided the patient with the information contained above and fully answered any questions. I affirm that the patient understands the information and has voluntarily signed this informed consent.

_____ _____

Signature of Healthcare Provider Date

_____

Printed Name

Do not return this consent form to Eurofins NTD, LLC. This consent form is provided as a convenience for the ordering physician. It is the physician's responsibility to obtain the proper form of consent from the patient or the person who is authorized to act for the patient when the patient lacks capacity.