Cystic Fibrosis, DNA Analysis

Order Name: **CYSTIC GEN**
Test Number: 1515700
Revision Date: 02/22/2023

TEST NAME	METHODOLOGY	LOINC CODE
Cystic Fibrosis Mutation DNA Analysis	Multiplex PCR	38404-0
Cystic Fibrosis Family History	Prompt	
Ethnicity	Prompt	
Reason for CF Testing	Prompt	
Previous CF Mutation Identification	Prompt	
CF Patient Information	Prompt	

SPECIMEN REQUIREMENTS

Specimen	Specimen Volume (min)	Specimen Type	Specimen Container	Transport Environment
Preferred	**5 mL (3 mL)**	**Whole Blood**	**EDTA (Lavender Top)**	**Room Temperature**

Instructions

To receive a complete personalized report based on results, patient demographics and clinical scenario, please completely fill out the Cystic Fibrosis Patient Information Form and include with specimen. This form can be downloaded from the following link: Cyctic Fibrosis Patient Information Form

Stability: Room Temperature 8 Days, Refrigerated 8 days, Frozen Not Acceptable. Do not centrifuge.

Specimen cannot be shared with other testing for risk of DNA contamination.

GENERAL INFORMATION

Testing Schedule	Wednesday
Expected TAT	Within 14 days
Clinical Use	This is a qualitative genotyping test that provides information intended to be used for carrier testing in adults of reproductive age, as an aid in newborn screening, and in confirmatory diagnostic testing in newborns and children. This test is not indicated for use in fetal diagnostic or pre-implantation testing. This test is not intended for stand-alone diagnostic purposes. Personalized reports include risk assessment, concise genotype results, and clinical relevance. Further assessment is recommended when appropriate. Genetic Counseling is available through Access Genetics. Method: Genomic DNA is evaluated using the Luminex xTAG Cystic Fibrosis 60 kit, an FDA-approved device employing a multiplex polymerase chain reaction (PCR) using oligonucleotide primers specific for regions of the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene. The resultant data is analyzed for 60 mutations and variants including the 23 mutations recommended by the American College of Medical Genetics and American College of Obstetricians and Gynecologists (ACMG/ACOG) for CF carrier testing. Reflex analysis is performed as recommended for intron 8-5T/7T/9T, I506V, I507V, and F508C variants. Results are interpreted by Board Certified Molecular Geneticists.
Notes	Reference Lab: Tricore Test Code: CFMUT Click Here to view the Tricore website. **United Healthcare Insurance requires that each component of this panel has a Pre-Authorization obtained.** Please submit the following tests for Pre-Authorization when the patient has United Healthcare insurance. 1515700MA - Cystic Gen Common Variants 1515700MB - Cystic Gen Del\Dup Variants
CPT Code(s)	81220, 81222; If reflex performed add 81224
Lab Section	Reference Lab