CF Foundation Specimen Banking	
Study Long Title	Multi-center Trial to Validate Protein Biomarkers of a Pulmonary Exacerbation in Cystic Fibrosis
Short Name	Biomarkers for Pulmonary Exacerbation (Sagel)
Specimens Currently Available to Other Researchers	Yes
Current Study Status	Study Complete

Study Timeline Metrics

	Planned	Actual (Sponsor)
Begin Enrollment		12/04/2007
Complete Enrollment	12/31/2009	01/01/2010
Study Complete		07/01/2012

Number of Patients Planned	130
General Study Information	
Study Type	Interventional
Intervention Type	Anti-Infective
Study Drug (Primary)	Multiple systemic antibiotics
Control Type	None
Blinded	No
Randomized	No
Duration of Subject Participation	14 Days
Endpoints Evaluated	Spirometry, Exacerbations, Blood Inflammatory Mediators, LRT Microbiology, CFRSD
Trial Specific Link on ClinicalTrials.gov	http://clinicaltrials.gov/ct2/show/NCT00788359?term=sagel+and+cystic+fibrosis&rank=1
Primary Manuscript Link	
Primary Manuscript Citation	Ann Amer Thorac Soc 2015;In Press
Eligibility Criteria	
Age	>= 10 Years
FEV1	No FEV1 requirement
P. aeruginosa status	Not Applicable
B. cepacia status	Not Applicable

Other Primary Eligibility Requirements

Additional key eligibility criteria: Initiation of IV antibioic therapy for a clinially diagnosed acute pulomonary exacerbation.

Biorepository Specimen Information

General Specimen Information

Baseline samples were taken from subjects who are having a new pulmonary exacerbation based on Rosenfeld score and within 24 hours of initiation of IV antibiotic therapy. A second sample was collected after 10 to 14 days of antibiotic treatment. Additional samples were collected at least 2 weeks after completing systemic antibiotics and then annually for the next 2 years.

Visit #	Time from Baseline	Specimens Collected
1	+0 Days	EDTA plasma
2	+14 Days	EDTA plasma
3	+28 Days	EDTA plasma
4	+1 Years	EDTA plasma
5	+2 Years	EDTA plasma