Cystic Fibrosis (CF) is the most common lethal genetic disease in Caucasians with a frequency of ~1 in 2000 newborns caused by loss of function of the Cystic Fibrosis Transmembrane Regulator gene (CFTR). Treatment with CF modulator drugs provides increased quality of life and improved survival.

CF therapeutics are extremely expensive. Therapy outcome needs functional testing. We predict that this can be done with a simple urine test.

**Technology Description**

Present invention relates to a CF urine test allowing quantification of the function of CFTR in CF patients by measuring the challenged HCO₃⁻ excretion. We are working towards developing the biomarker into a diagnostic tool, which from a measurement of the biomarker in a urine sample and an algorithm can provide clinicians with a clear classification of the patient, thereby being able to quantify therapy success in patients treated with novel CF modulator drugs.

**Intellectual Property Rights**

European patent application filed May 8, 2019 by Aarhus University and University of Regensburg.

**Current State**

Proof of concept has been generated on a small cohort of CF patients (ΔF508 homozygot). The project is at an early stage. Currently, a larger multi-centre CF patient cohort with different genotypes is being established and the urine test is applied to the CF patients.

**Call to action**

We are looking for partners to join us in creating the diagnostic tool based on the identified biomarker.

A prototype device has been built. The next step is the building of a bench top device to be used for fresh urine sample analysis in the outpatient clinics.

**Team**

Prof. Dr. med. Jens Leipziger  
Prof. Dr. med. Karl Kunzelman  
PhD student Peder Berg