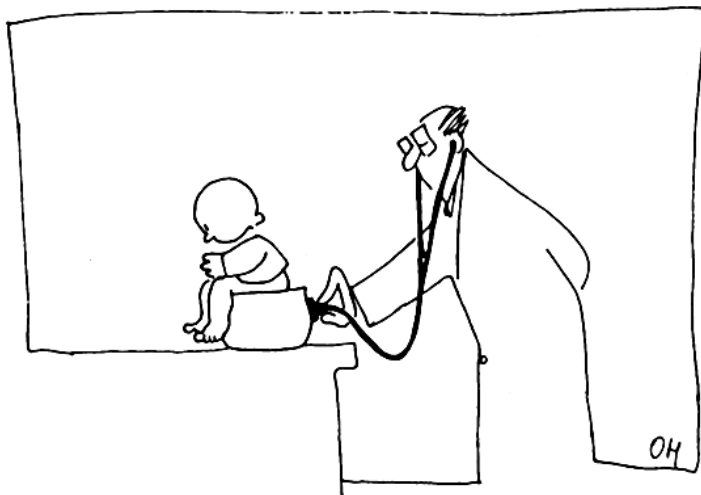


# Cystic Fibrosis Urine Test

Quantification of therapy success in CF patients treated with novel CF modulator drugs

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.



Oswald Hut

CF therapeutics are extremely expensive. Currently, only limited functional testing of therapy outcome is performed due to insufficiency of the available diagnostic tools.

We are developing a simple urine test to solve this.

## Technology Description

The present invention relates to a CF urine test allowing quantification of the function of CFTR in CF patients by measuring challenged  $\text{HCO}_3^-$  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 patients and clinicians with a clear classification of the disease status. It will thereby be possible to quantify therapy success in patients treated with novel CF modulator drugs.

## Intellectual Property Rights

European patent application filed May 8, 2019.

## Current State

Proof of concept has been generated on a small cohort of CF patients ( $\Delta\text{F508}$  homozygote genotype).

A larger multi-centre CF patient cohort with different genotypes is being established and the urine test is applied to the CF patients.

## Team

### Project Coordinator:



MS Ph.D  
Mads Vaarby Sørensen

### Coordinators of clinical trials:



Prof. Dr. med.  
Jens Leipziger



MD  
Peder Berg

## Call to action

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

A prototype device has been built. The next step is the creation of an easy to use device that allows detection of the biomarker in urine samples from patients.

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