At-Home/Point-of-Care Breath-Based Ammonia In-vitro Diagnostic Platform for CKD Patients (2021-033)

Simple, Low-cost Diagnostic to Measure Ammonia Concentration in Exhaled Breath for Routine, At-home Monitoring of Kidney Function for Patients with Chronic Kidney Disease

Market Overview

Chronic kidney disease (CKD), a condition in which a patient's kidneys fail to effectively filter blood, is estimated to affect more than one-in-seven Americans placing a significant burden on the US healthcare system costing Medicare over $120 billion in 2017. Commonly called the "silent disease," CKD presents with no symptoms in its early stages; therefore, most patients are diagnosed at an advanced stage leading to poor prognosis. Hemodialysis or kidney transplantation are the treatment options for the most advanced stage of kidney disease known as end-stage renal disease (ESRD). However, due to hemodialysis's deleterious effects on cardiac health,and a lack of available kidneys for transplant, ESRD mortality rates remain high. The ability to frequently monitor kidney function, especially in the later stages of CKD, is the key to providing improved management of this chronic condition.

Blood and urine tests are necessary to obtain the measurements needed to monitor and manage kidney disease progression. Glomerular filtration rates (GFR) and albuminuria are used as the criteria for diagnosing and staging CKD. Blood urea nitrogen (BUN) levels help decide when to start dialysis and/or make dietary adjustments. These tests require significant patient compliance as the patient must travel to the clinic for blood drawing for laboratory analysis, with results often taking several days to be returned. Current research has shifted to exploiting biomarkers other than blood and urine as a diagnostic aid to resolve existing clinical diagnostic issues. Measurement of clinically relevant volatile organic compounds (VOCs) in exhaled breath, such as ammonia, has emerged as an ideal solution to this problem due to its non-invasive nature and ease of use, thus leading to increased patient compliance.

Technical Summary

The components of the prototype device include a mouthpiece, pressure gauge, colorimetric sensor assembly, and breath-collection bag (Fig. 1: Photograph of Prototype Device; Fig. 2: Schematic Showing Principle of Operation). The critical control variables for the breath test are the volume of breath passed through the device, which is simply controlled by the volume of the breath-collection bag, and the flow rate of the breath, which is simply controlled by feedback to the user provided by the pressure gauge. Thus, unlike several other exhaled-breath-test systems, which rely on complex and expensive components such as electronic sensors, heaters, pumps, dehumidifiers, and filters, this system provides an accurate and immediate measurement of the ammonia concentration in exhaled breath without any electronic components. Clinical studies have demonstrated high correlation between exhaled-breath ammonia concentration measured using this device and laboratory-provided BUN-level values for patients with various stages of CKD.

Application

Clinical Diagnostics, Chronic Kidney Disease Monitoring, At-home Testing

Development Stage

Product validated from initial clinical studies showing high correlation with BUN levels

Advantages

- Non-invasive, real-time sample collection, and immediate results
- Simple control of breath flow rate and volume providing accurate measurement of breath ammonia concentration in physiological range.
- Reduced analytical complexity & cost
- At-home/Point-of-care portability & operation

Fig. 1. Photograph of Prototype Device

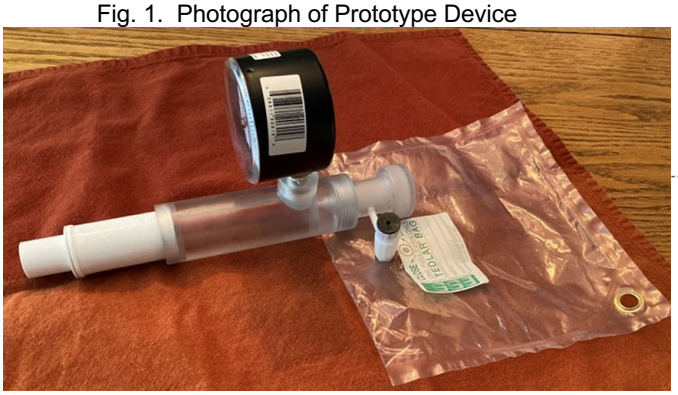
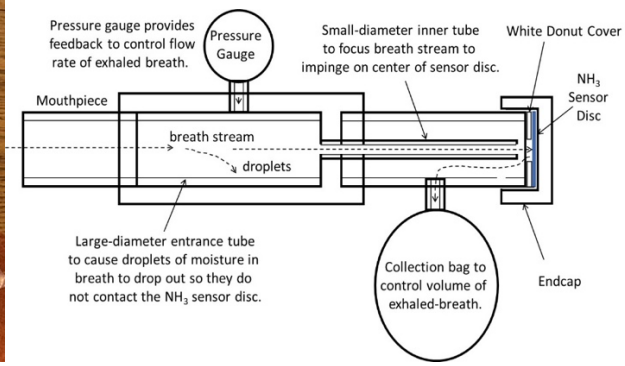


Fig. 2. Schematic Showing Principle of Operation



App Type	Country	Serial No.	Patent No.	CURF Ref. No.	Lead Inventors
Utility Application	United States	17/517,919	NA	2021-033	Dr. Robert Latour Dr. George Chumanov

About the Inventors

Dr. Robert Latour

McQueen-Qualttlebaum Professor of Bioengineering at Clemson University

Dr. Robert Latour earned his Ph.D. in Bioengineering from the University of Pennsylvania. Dr. Latour is the director of the Clemson Biomolecular Interactions Lab. His current research focus is on the development of colorimetric biosensor systems for non-invasive diagnostics. Dr. Latour also serves as the director of the Biomaterials Engineering and Testing (BET) Core of the NIH-supported SC COBRE Center of Biomaterials for Tissue Regeneration (SC BioCRAFT).

Dr. George Chumanov

Professor of Analytical Chemistry at Clemson University

Dr. George Chumanov eared his Ph.D. from Moscow State University working in the field of optics and spectroscopy of biomolecules. Dr. Chumanov did his Postdoctoral work at Iowa State University where he conducted research in bioanalytical applications of Raman spectroscopy. Dr. Chumanov's current research focus is the development and commercialization of in vitro colorimetric diagnostics for a variety of clinical applications.

For more information on this technology contact:

A. Chris Gesswein
Executive Director
Director of Licensing for Technology Transfer

E: agesswe@clemson.edu
P: (864) 656-0797