TECHNOLOGY

Method for the identification of microbial community signature as diagnostic markers, including specific applications for the diagnosis of Crohn's disease and ulcerative colitis.

OVERVIEW

The two most common forms of inflammatory bowel disease (IBD), are Crohn's and ulcerative colitis, disease states in which the body elicits an immune response within the gastrointestinal tract causing chronic pain, inflammation, and intestinal distress. Though distinctly different, the two diseases often share common symptoms making a definitive diagnosis difficult. In order to accurately identify and classify each disease state, UMB researchers have developed a statistical, computational method to analyze genomic samples collected from human clinical specimens (e.g. stool, mouth, skin, vaginal swab) and/or non-human microbial communities (e.g. soil, water, animals) in various physiological or environmental conditions (normal vs. disease states) to generate a unique microbiome signature. Utilizing databases from the Human Microbiome Project as well as other microbiome databases, preliminary results from a small pool of healthy and Crohn's disease patients confirm accurate identification up to 98% using this statistical method. Current methods of detection are dependent on the interpretation of the practitioner and approximately 10-15% of colitis cases are labeled indeterminate colitis. This invention provides an alternative solution to accurately detect and classify the presence of microbiomes that are both normal as well as in disease states, in a minimally invasive manner, to provide the most effective treatment plan for a chronic, painful, and debilitating disease that currently has no cure and can lead to life threatening conditions.

APPLICATIONS

IBD is one of the five most prevalent gastrointestinal disease burdens in the United States, with an overall health care cost of more than $1.7 billion. Each year in the United States, IBD accounts for more than 700,000 physician visits, 100,000 hospitalizations, and disability in 119,000 patients. To begin the process of identifying IBD, a multitude of costly exams (endoscopic, radiologic, and histologic tests) are initiated and the results combined to generate a less than accurate diagnosis. This invention however provides an alternative method to accurately determine difficult to diagnose disease states of the gut in a low-cost and quantitative manner. The potential to generate risk profiles to detect early-onset disease states additionally allow the possibility for preventative treatments and avoidance of IBD itself. Other applications are possible in basic research, forensic diagnostics, soil and water testing, animal husbandry, cosmetics, nutrition, etc. With increased understanding of the importance of the microbial communities that live within our environment, application for this invention will expand for any circumstance that may need the detection of microbiome signatures.

ADVANTAGES

-Provides an accurate, low-cost diagnostic test to determine the presence of Crohn's or ulcerative colitis -Provides a method of early screening for Crohn's or ulcerative colitis to initiate preventative treatments -Minimally to non-invasive methods can be utilized to extract genomic samples from patients -Can detect microbiotic signatures in both human and non-human samples allowing for applications in any circumstance in which the detection of microbiome signatures are required.

STAGE OF DEVELOPMENT

-Preliminary results of 111 (96 healthy, 16 Crohn's disease) patient stool (whole-genome shotgun) WGS datasets showed an accuracy of over 98% in the identification and classification of individual microbiome signatures. -Additional studies with 27 samples from Crohn's and ulcerative colitis patients as well as 690 WGS dataset from 6 body sites showed high accuracy in the classification of each dataset. -Correctly classified 109 stool samples from 3 non-related studies in Europe, Japan, and US (used diff sequencing technologies)

R&D REQUIRED

Additional validation required.

LICENSING POTENTIAL

UM seeks to develop and commercialize by an exclusive or non-exclusive license agreement and/or sponsored research with a company active in the area.

CONTACT INFO

Office of Technology Transfer
620 W Lexington St., 4th Floor
Baltimore, MD 21201
Email: ott@umaryland.edu
Phone: (410) 706-2380

Additional Information

INSTITUTION

University of Maryland, Baltimore

PATENT STATUS

PCT Patent Application, pending

LICENSE STATUS

Available for non-exclusive license

CATEGORIES

- Diagnostics

INVESTIGATOR(S)

W. Florian Fricke
James White

EXTERNAL RESOURCES

- Proof of concept of microbiome-metabolome analysis and delayed gluten exposure on celiac disease...
- Resources and costs for microbial sequence analysis evaluated using virtual machines and cloud computing.
- CloVR: a virtual machine for automated and portable sequence analysis from the desktop using cloud computing.

WF-2012-079