uBiome Completes ISO 15189 Assessment, Internationally-Recognized Clinical Testing Accreditation

The leader in microbial genomics announces it is expected to receive ISO 15189 accreditation in 2019 for its CLIA-licensed and CAP-accredited laboratory.

SAN FRANCISCO (PRWEB) January 03, 2019 -- uBiome, the leader in microbial genomics, announces it expects to receive ISO 15189 Accreditation for Clinical Testing Laboratories, which establishes requirements for medical laboratories to demonstrate competence to deliver timely, accurate, and reliable results to an international standard. The laboratory is already CLIA-licensed as well as College of American Pathologists (CAP)-accredited, a designation given to the top three percent of laboratories in the world.

First published in 2003, ISO 15189 is an international standard for laboratory testing developed by the International Organization for Standardization's Technical Committee and is currently accepted by more than 80 economies around the world, representing 95% of the global GDP. In the United States, ISO 15189 is voluntary and rather than merely meeting requirements, it promotes continual improvement and empowers employees to implement solutions. For patients and healthcare providers, it offers assurance that clinical lab services are safe and reliable for patient testing.

ISO 15189 accreditation involves an independent assessment of the clinical testing laboratory that includes an examination of personnel qualifications and competence, equipment, reagents and supplies, quality assurance, and pre-analytical, analytical, and post-analytical factors.

“This prestigious accreditation is evidence of uBiome’s high standard of quality and compliance, and will allow us to offer our clinical tests to patients in many countries worldwide,” Dr. Jessica Richman, PhD, co-founder and CEO of uBiome, said. “As inclusivity and accessibility are pillars of uBiome, we look forward to putting our products in the hands of those who will benefit most.”

For more information about our laboratory standards and certifications, please visit https://ubiome.com/#cliacap.

About uBiome

Founded in 2012, uBiome is the leader in microbial genomics. The Company’s mission is to advance the science of the microbiome and make it useful to people. uBiome combines its patented proprietary precision sequencing™ with machine learning and artificial intelligence to develop wellness products, clinical tests, and therapeutic targets. uBiome has filed for over 250 patents on its technology, which includes sample preparation, computational analysis, molecular techniques, as well as diagnostic and therapeutic applications.

uBiome’s commercial products include SmartGut™, the world’s first sequencing-based clinical microbiome test, which identifies microbes in the gut for patients with chronic gut conditions such as IBD, IBS, Crohn’s Disease, and ulcerative colitis; SmartJane™, the first sequencing-based women’s health screening test, which genotypes all 19 clinically relevant strains of HPV, identifies four common STDs, and surveys more than 20 vaginal microbes associated with bacterial vaginosis and other conditions; SmartFlu™, the world’s first sequencing-based clinical respiratory test, which identifies more than 20 clinically relevant targets for viruses and bacteria associated with the flu and common cold; and Explorer™, a health and wellness product to
understand the role that food and lifestyle can play in wellness.

uBiome’s platform has been used by hundreds of thousands of consumers, patients, and doctors and more than 200 research institutions around the world, including the US Centers for Disease Control (CDC), US National Institutes of Health (NIH), Harvard University, Stanford University, the Massachusetts Institute of Technology (MIT), University of California, San Francisco, Oxford University, and the University of Sydney.

Since its launch, the company has received widespread recognition including CNN 10: Startups to Watch, the IVY Technology Award, CNN Future 30, and was named one of Fast Company’s Most Innovative Companies in Healthcare in 2016 and in Data Science in 2018, as well as a Technology Pioneer from the World Economic Forum in 2018. For more information, visit www.uBiome.com.
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