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Buyer Beware: Consumer-Marketed Gut Microbiome Test Results Vary Wildly in New Study

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NEW YORK – Direct-to-consumer (DTC) gut microbiome test results are highly inconsistent both between different test providers and in repeat testing from the same providers, according to newly published research.

The findings, from a study published today in *Nature Communications Biology*, point to methodological variability and a lack of proper quality control as major culprits, suggesting a need for clearer testing standards and for the reporting of analytical test performance.

Stephanie Servetas, acting group leader of the National Institute of Standards and Technology's Complex Microbial Systems Group and first author of the study, said in a press briefing that two of the main challenges currently facing microbiome research are sample heterogeneity and the complexity of going from sample acquisition to final report, both of which introduce numerous possibilities for sources of analytical variation.

"If you think about a stool sample," she said, "you're going to have different samples, whether you take it from the beginning or the end of that bowel movement, or if you take it from the outside or the inside."

Similarly, analyzing stool samples is a multi-step process involving different technologies and computational analysis methods, and lacks a universally accepted set of best practices.

Servetas stressed that these challenges are not unique to DTC testing companies, however. "This is anyone doing microbiome research," she said.

Servetas and her colleagues from NIST and the University of Maryland School of Medicine evaluated the performance of seven DTC microbiome testing services using a fecal reference material developed by the NIST to help standardize microbiome comparisons. Each company's test was performed in triplicate to assess internal consistency.

"We wanted to send the same material to multiple companies and ask how similar the results we got back were," Servetas said. Additionally, sending the same material to the same company multiple times provided a measure of how consistent each company's processes are.

Protocols for sample collection varied widely across the seven companies, none of which were named in the study. Differences included sampling from whole bowel movements versus swabbing used toilet paper, and in stabilizing samples with buffer solutions versus sending them back to the lab "neat." Furthermore, although each company employed next-generation sequencing-based workflows, some

used 16S rRNA gene amplicon sequencing — differing in target amplicons — while others used whole metagenome shotgun sequencing.

Despite these different protocols, samples did not significantly cluster by sequencing method, raising the question of how the diversity observed for a single sample analyzed by multiple companies compared to biological diversity from different donors analyzed by a single workflow. Servetas and her colleagues processed samples from seven additional donors using an NIST workflow and observed that the microbial diversity found in samples from a single donor analyzed by different companies was at least equal — and in some cases greater — than that of the biologically distinct donors, suggesting that methodological variability can be greater than biological variability.

"Next-gen sequencing technology has advanced dramatically in terms of price reduction and data output, but that hasn't translated necessarily to better microbiome measurements," said Scott Jackson, founder of biological consulting firm NEST Consulting and a former NIST employee, as well as the study's corresponding author.

Additionally, although each company identified a narrow range of microbial genera, the total number of identified genera varied widely between companies, ranging from 34 to 906, with only three genera found across all samples. Most variability between replicates from a single company occurred among low-abundance taxa, highlighting the importance of empirically determined read cutoffs for inclusion in a report.

Customer reports from the microbiome testing companies evaluated in this study — as is fairly common across most companies in this field — included metrics related to gut health, such as beneficial versus harmful microbes. Although these metrics are typically calculated by measuring customer profiles against data from a comparator cohort, the choice of cohort varied widely. Some companies rely on an internally developed "healthy" cohort, for instance, while others use external datasets derived from sources such as the Human Microbiome Project or the American Gut cohort.

The investigators selected five clinically relevant genera to examine and found that these, too, varied considerably across all companies, with no clear correlation to library preparation methods. Results varied in particular between the three tests used from one company, although the outlier sample also had approximately half the number of reads as the other two tests, which may have skewed results.

Alongside measurements of gut health, microbiome testing companies often include recommendations for modifying gut microbe compositions, ostensibly to achieve a healthier microbiome and by extension, overall health. Research in this area remains highly unsettled, however. In the example of the company with the outlying result, two replicates were reported as healthy, while the outlier was reported as unhealthy, which the authors said could lead to a consumer taking unnecessary and potentially dangerous interventions.

Diane Hoffman, professor of health law at the University of Maryland and one of the study's authors, said that many clinicians from focus groups and surveys that she has conducted reported experiences in which patients sought medical help based on the results of at-home microbiome tests. This can be especially problematic in cases such as parents seeking help for autistic children. These children often have gastrointestinal problems but the science on how these issues relate to autism is far from settled.

"They are kind of desperate to find anything that might help their child," Hoffman said, noting that companies' recommendations often involve dietary changes. "If parents are restricting the intake of certain nutrients [based on these recommendations], this can be harmful for the child."

Hoffman also found at least one instance in her past research of an individual performing a fecal microbiota transplant based on their test results. "If you do that at home by yourself and it's not

screened appropriately and done with your physician's oversight, there's a real risk in terms of infection," she said.

There are also financial interests to be aware of when interpreting a test's results.

"Some of these companies also offer probiotics and other dietary supplements that they say will correct your microbiome," Jackson said. "It just so happens that the thing that is wrong with your microbiome happens to complement the product that they also sell."

While in many cases, this may at least do no harm, Jackson said that there are many unknowns in this area and that using probiotics when one doesn't need them could carry some negative consequences.

"You should be very careful in interpreting what companies are telling you," said Jacques Ravel, professor of medicine at the University of Maryland School of Medicine and one of the study's authors. "Especially be very cautious when they start recommending any kind of treatment or any kind of supplement or anything they [want to] sell you."

Jackson said that moving forward, there should be more rigorous clinical studies that are properly designed to identify microbial biomarkers of disease, while acknowledging that this is complicated by the high number of analytes to be measured in a microbial sample.

"Unlike measuring cholesterol and blood, where you're measuring one thing and you can do it really well, now you're measuring 1,000 things, and you're measuring all 1,000 pretty poorly," he said.

The investigators suggested that a good place to start would be a consensus document on minimal requirements for microbiome testing, like those developed for other high-complexity molecular diagnostic assays, such as quantitative real-time PCR and environmental microbiology testing.

As to what physicians can tell their patients now with respect to DTC microbiome tests, "buyer beware," Jackson said.

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