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The Beauty of Science is to Make Things Simple

What to Consider Before Launching a Direct-To-Consumer Microbiome Test



For US writer Michael Pollan, viewing the results of his first microbiome test was a pivotal moment. In a 2013 [article](#) for *The New York Times Magazine*, Pollan recalled that the moment he opened the email with his microbiome test results was when he started to see himself, not as a “plain old individual human being”, but as a super-organism.

Pollan helped bring awareness of microbiome testing to a wider audience, and since that time, consumer interest in microbiome testing has continued to grow steadily. Consumers are increasingly savvy to the critical importance of the microorganisms living in and on their bodies, and interested in not only learning about the microbes they harbor, but also optimizing their function through products such as probiotics and prebiotics.

Fortunately, in parallel with this increased demand for consumer microbiome testing has come an increase in the precision of scientific insights related to the human microbiome. Beyond general analyses of the gut microbiome, more comprehensive analyses and bioinformatic processing can help consumers gain knowledge about specific issues of interest, which can be life-changing for people suffering from chronic infections who may feel as though traditional medicine has failed them. For example, those suffering from inflammatory bowel disease or chronic vaginal infections may feel marginalized in this way and may find empowerment in learning about their microbiomes. Thus, rich market opportunities exist for offering consumers tailored solutions for microbiome testing according to their specific needs and levels of understanding.

From a consumer point of view, the process of completing a microbiome analysis is straightforward: the consumer receives a microbiome testing kit by mail and collects the microbiome sample at home—whether it is from stool or from saliva, skin, or another site. The consumer then mails the sample to a lab, and a few weeks later, receives an online report describing the results along with health and wellness implications.

But for a company considering launching a direct-to-consumer microbiome testing service, many puzzle pieces must fit together perfectly to carry out this end-to-end service. Several important decisions must be made, which ultimately affect the consumer’s experience with the test. Below are the top considerations for setting up and launching a direct-to-consumer microbiome testing service:

1. Decide on the features and technical specifications of your sample collection kit.

The sample collection kit is critical to the success of a microbiome testing service. Not only must it be easy to use,

motivating the consumer to collect the sample and return it promptly, but it also needs to preserve the microbial profile of the sample from the time of collection until it reaches the lab.

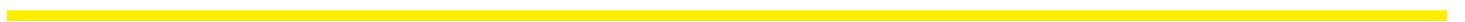
Using an industry-leading sample collection kit can facilitate smooth collection and transport of the microbiome sample. Fortunately, transportation of samples at ambient temperature has become standard practice for microbiome testing companies thanks to the DNA/RNA Shield™ sample preservation reagent, which inhibits microbial growth, protects nucleic acids, and inactivates pathogens. DNA/RNA Shield™ is featured in Zymo Research’s innovative [SafeCollect™ sample collection devices](#), which are spill-proof, user-friendly devices that facilitate safe at-home collection of a sample. A common problem for at-home sample collection is user error which could involve spilling or even ingestion of the sample preservation reagent. SafeCollect™ devices minimize liabilities associated with user error by sealing the reagent until a foil cover is punctured when the sample is added to the device. Zymo Research manufactures its own kits and reagents, so you need not worry about losing customers because of long delays caused by supply chain issues. Moreover, the kits are completely customizable, from the box to the label on the sample tube, so they are consistent with the brand you have created.

2. Choose the type of microbiome analysis you want to offer.

One key decision is which type of analysis to offer to your customers. Mostly, individuals expect to receive the kind of information accessible through [next-generation sequencing analysis](#)—either targeted or shotgun sequencing—as this offers a more complete picture compared to traditional culturing or PCR-based methods.

With targeted 16S rRNA gene sequencing, you may be able to offer customers the following:

- Determining taxonomic diversity of the microbiome (with high diversity often used as a proxy for a “healthy” microbiome).
- Quantifying genera or species known to be beneficial for gut health, such as *Lactobacilli* and *Bifidobacteria*.
- Profiling bacterial composition.
- This is ideal for testing the diversity of sample types that are dominated primarily by bacterial species, such as gut samples.



While targeted sequencing is more economical, shotgun sequencing may be worthwhile if you add sufficient value to the customer through more precise interpretation or targeted recommendations. With shotgun sequencing, you may be able to offer customers all of the above, plus the following:

- Profiling bacterial composition with better resolution, usually to the strain level.
- Identifying antibiotic resistance genes.
- Detecting fungi, DNA viruses, and parasites.
- This is ideal for comprehensive analysis and pathogen detection in sample sites where bacterial, fungal, and parasitic infections can occur, such as vaginal samples.

3. Decide whether to outsource the microbiome analysis.

Microbiome analysis for a direct-to-consumer test can be carried out in-house or by an external provider. Setting up a microbiome analysis lab, recruiting all the required personnel, and obtaining the necessary certifications can bring many unexpected factors that may delay the launch of your microbiome testing service or compromise your ability to deliver seamless service to the end consumer. Timeliness is also difficult for smaller labs—because without a critical mass of customers to justify the cost of sequencing runs, it can be difficult to perform the required analysis and send results in a time frame that is acceptable to customers.

Outsourcing the microbiome sequencing to a trusted service provider is a way to reduce costs and hassles while streamlining the end-to-end process. [Zymo Research is an industry leader for microbiome analysis](#), processing thousands of samples per week based on over 20 years of expertise in the field. The company's high-throughput, automated process ensures consistency and reproducibility in the data from sample to sample. This is in addition to the benefit of quick turnaround times: for certain applications, the company can deliver the microbiome report within two days of receiving the sample.

In an outsourcing scenario, your company sends a sample collection kit to the consumer, who sends the collected sample directly to a Zymo Research lab for completion of DNA extraction, next-generation sequencing library prep, sequencing, and custom bioinformatic analysis. The data is then promptly forwarded to you and then accessed by the consumer via your education and results portal. Ultimately this helps you get the results into the consumer's hands with minimum delay.

A sophisticated sample accessioning and tracking system ensures full transparency: barcoded samples are accessioned when they arrive at the Zymo Research facility, logged into the system, and tracked throughout the workflow.

Zymo Research also places a high importance on data privacy and security. No personal information is required for sample tracking; data is generated and transferred to your company in a secure manner, and ownership of the data is at your sole discretion.

4. Develop your education and results portal to help consumers interpret the microbiome analysis.

For the consumer, the things that add value to microbiome analysis are the data interpretation, analysis, and recommendations. Because raw microbiome data is too complex for consumers to understand without some guidance, your company can add significant value by presenting the data in an understandable way and guiding toward practical recommendations.

In addition, marketing this type of test often relies on educating potential customers more generally about the importance of the microbiome and its role in their health and wellness. Educational information can be delivered online, perhaps via the same portal as their analysis results. Both the educational information and the results can be tailored to a specific consumer group, creating a memorable user experience that inspires loyalty.

Zymo Research's comprehensive bioinformatics and customized data reports can feed into the back end of your portal. Your proprietary algorithms may then be applied to create recommendations, helping consumers interpret their results and determine next steps.

Decisions on these four key issues go a long way to determining the success of a direct-to-consumer microbiome testing service. The market is primed for specific microbiome testing service offerings, and undoubtedly more of them will launch in the years ahead. In the best-case scenario, a direct-to-consumer company focuses on what they know best—reaching a particular consumer group—and streamlines the process by picking a fast, reliable service provider for the laboratory microbiome analysis. Zymo Research is a trusted partner for direct-to-consumer microbiome testing companies, for sample collection kits as well as lab analysis, and helps ensure the end customer has the best possible experience.





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