Summary Information about DTC Microbiome Testing Companies

We identified thirty gut or vaginal DTC microbiome-based testing companies in operation as of October 2024, 23 of which sell to consumers in the U.S. A summary of each company's products and claims along with whether the company is a CLIA certified lab appears below in **Table 1**. **Table 2** includes a list of companies and whether they also sell supplements and **Table 3** indicates whether the company is based in the US or another country.

Methodology: To identify DTC Microbiome Testing Companies selling in the United States, we conducted internet searches of these targeted phrases: "DTC Microbiome Testing"; "gut microbiome testing" 'buy gut microbiome testing"; "buy gut health test"; "vaginal microbiome testing"; "buy vaginal health test." These searches were conducted on multiple search engines periodically throughout a 3-year (2021 – 2024) period. During each search, we considered both the "Results" tab and any advertisements that were promoted based on the search. During each search, we considered the first 50-75 results. Companies that were entirely based outside of the United States, do not currently sell in the United States, and do not state an intention of expanding to the U.S. market on their website, were omitted from any analysis of CLIA certification but kept in the overall data set.

Once a company was identified, we relied on its website and self-reported information to identify whether it markets itself as "direct-to-consumer." Some companies appear to have changed their business model over the time we conducted the study from DTC tests to tests that must be ordered by a physician. If the company requires a physician's order and a consumer cannot order the test directly, we did not count it as a DTC Testing company, however, it is included in the chart for purposes of comparison. (Four such companies are included in the chart.) Second, we relied on the company's website and self-reported information to identify whether the company marketed itself as independently certified, reliant on CLIA certified labs, or other forms of certification. Where information was ambiguous, we utilized the "chat" inquiry function of the website to seek further clarification. Where no affirmative information on certification could be found, that absence is reflected in the chart. Of the 23 companies that may reasonably use CLIA labs, meaning they are based in the United States or sell to customers in the United States, eleven state they use CLIA labs.

To identify whether a company sold or marketed supplements, we relied on the "shop" function of websites to determine whether a product was available and at what point it may be promoted to potential customers. Where available, we relied on sample results from a company's DTC tests to determine whether specific supplements would be marketed to consumers.

Green –companies that now require physician order

Blue – companies that do not operate/sell in the US

Yellow – DTC microbiome testing companies included in final count

Table #1: DTC Microbiome Testing Companies

COMPANY	DESCRIPTION	CLAIMS	STATES IT USES CLIA LABS
(1) Affinity DNA https://www.affinity- dna.com/	Affinity DNA markets a variety of genetic tests, including a gut microbiome test and a skin care DNA test. Following analysis of a stool sample, the company provides a personalized GutWell analysis report with dietary recommendations. The company states it has offices in the USA and UK as well as a worldwide network of clinics and hospitals for sample collection.	 Microbiome analysis will show whether your nutrition and gut ecosystem are well balanced or if you need to make changes to your diet to improve your bacterial composition and improve your health. Your gut bacteria test results will include the following information: Which bacteria live in your gut. How your gut bacteria influence your body. Are there enough beneficial bacteria in your gut? Are there harmful bacteria in your gut? Do your gut bacteria favour obesity? Are your diet and microbiome community balanced or do you need changes to your diet? Diet recommendations to achieve a balanced gut microbiome community. 	Y – works with CLIA- accredited partner labs
(2) BIOHM https://biohmhealth.co m/collections/gut- testing	BIOHM, a US company, markets a variety of probiotics, prebiotics, and immunity supplements. The composition of the gut microbiome is analyzed from a DTC stool sample collection kit using metagenomic sequencing.	 As part of the test, you will receive a comprehensive report outlining: An overall gut score on a scale of 1 to 10. Think of it like a credit score for your gut. Comparison of your results to normal gut levels. Actionable wellness recommendations from BIOHM's Microbiome-Trained Registered Dietitians based on your personal results. The BIOHM Gut Test is one of the most comprehensive sequencing tests available to consumers. The final report is reviewed by a Microbiome-Trained Registered Nutritionist who will provide wellness recommendations to balance your overall digestive health. 	Ν

(3) Biomes https://biomes.world/en ∠	Biomes is a German company selling its product via internet in the US. It uses metagenomic sequencing to analyze the composition of the gut microbiome from a DTC stool sample collection kit. The company provides personalized dietary recommendations and markets dietary supplements.	Our analysis helps you to find your weak points and improve on them with the correct nutrition – based on the latest scientific findings. Personalized nutrition recommendations for reaching your goals: whether you want to improve your fitness level, have a stronger immune system, fewer digestive complaints or lose some weight. Understand intestinal complaints. Recognize immune deficiencies. Reduce weight problems.	Ν
(4) BiomeFx https://biomefx.com	BiomeFx is a test provided by Microbiome Labs, a US Company. They provide tests that analyze both gut and vaginal microbiome samples. In its results report to consumers, the company interprets a "dysbiosis ratio" to make lifestyle and dietary recommendations. BiomeFX requires consumers to identify a practitioner before ordering a test kit. Although identification of a provider is required to purchase a test kit, the consumer creates a personal account to select and pay for a test, and to view the test results. https://www.biomefx.com/how-to- order	By evaluating multiple aspects of microbial balance, strength, and resilience, BiomeFx provides detailed insights into your microbiome's health and suggestions for improving microbial balance. One of the most unique aspects of BiomeFX is the ability to evaluate the influence of the gut microbiome on disease risk. With the most robust database of healthy samples, BiomeFX can help you identify early deviation from a healthy population.	N

(5) Biomesight https://shop.biomesight. com/products/gut- microbiome-test- snapshot	Biomesight is a London-based company that sells DTC gut microbiome tests to U.S. consumers. Their tests use 16S rRNA gene sequencing to measure microbiome composition. Their test report provides food, prebiotic, and lifestyle recommendations.	You will receive a count and relative abundance percentage of the bacteria in your microbiome, ranging from Phylum down to the species level. Using this method, we are able to provide relative abundances of all bacterial organisms in your sample rather than targeting just a small subset of bacteria. We provide interpretation using Dr Jason Hawrelak's (Probiotic Advisor) recommended ranges for a subset of key bacteria (Probiotics, Commensals and Pathogens) along with our scoring system, diversity calculations and personalized recommendations for food, prebiotic supplements and lifestyle adjustments based on up-to-date research findings. We provide full raw FASTQ data and CSV file downloads for those interested in analyzing their results elsewhere or working with a practitioner.	Ν
(6) Blue Horizon Blood Tests https://bluehorizonblo odt ests.co.uk/products/m icro biome-test; https://bluehorizonblo odtests.co.uk/product s/vaginal- microbiome?_pos=1& sid=1735519c8&_ss=r	Originally a blood testing company, Blue Horizon is based in the United Kingdom and offers both gut and vaginal microbiome tests. They claim to offer the "best" Microbiome Gut Health and Microbiome Vaginal test in the UK. The gut microbiome test relies on a swabbed stool sample which is tested for "pathogens" and "beneficial bacteria," where customers are given a full report of, "all detected organisms." The vaginal microbiome test now includes testing for chlamydia and gonorrhea.	The Blue Horizon Gut Health Microbiome Test Kit looks at Genetic Data from an easily collected stool sample. Our Laboratory analyses and reports on any imbalances in your gut bacteria profile, reports how the balance of bacteria could be affecting your health and offers suggestions for dietary change to rebalance your gut microbiome. It is now widely accepted that having a healthy balance of bacteria in your gut is essential for optimal health. The Blue Horizon Vaginal Microbiome Test looks at genetic data from an easily collected vaginal swab sample, tested at a fully accredited and cutting edge laboratory (the method used is qPCR, 16S rRNA amplicon sequencing). Our laboratory report includes a lot more detail both in terms of the targets tested, and in the content of the report which is far more comprehensive than other reports that we have encountered. For example - our laboratory includes detailed analysis of the 4 different species of Lactobacillus (which have been shown to be important in vaginal microbiome health and composition stability) whereas many reports will include all species under one headline. [O]ur test looks at the whole biome [] and it is a sensitive enough test to identify all relevant species, rather than grouping them together and losing relevant detail. These are important facts to keep in mind [as] both time and money is saved in the long run if a specific organism, and a solution, is identified.	Ν

(7) Daye https://www.yourdaye.c om/products/vaginal- screening/	Based in the U.K., Daye provides several gynae health services and products, including menstrual hygiene products like pads and tampons and health screenings. Instead of a vaginal swab, Daye's testing relies on customer's use of a tampon to collect a sample. Other Daye products (like their tampons) ship to the United States but it does not appear that their vaginal tests ship to the US. Tests can be purchased alone or with a 30 minute "Gynae Health expert consultation."	Understand your risk of vaginal infections like bacterial vaginosis or yeast infections, fertility implications, and other gynecological complications using a non-invasive at-home tampon screen Our Diagnostic Tampon can check for infection-causing microbes and fungi, as well as your levels of protective, good bacteria. Check for microbes that make it more difficult to conceive Understand your risk of contracting STIs and UTIs	Ν
Diagnostic Solutions Laboratory https://www.diagnostics o lutionslab.com/tests/gi- map	 Diagnostic Solutions Laboratory offers a gut stool test called GI- MAP to detect and measure levels of gut pathogens, <i>H. pylori</i>, commensal bacteria, and opportunistic microbes using quantitative PCR technology. A healthcare practitioner is required to order the test, but the company offers to help the consumer find a practitioner. The company states on its website that it does this for transparency when billing insurance companies and Medicare. The company further recommends receiving results through a clinician so that the clinician can "help in under-standing /interpreting" the test results. If a consumer wants to receive the results directly from DSL they must contact a member of the customer service team. 	 Detect bacteria that cause vaginal yeast infections The GI-MAP's accuracy and reliability allows practitioners to create personalized treatment protocols to address gut dysfunction based on which infections are urgent, which areas of the gut are already optimized, and which areas should be addressed after an infection is resolved. Additionally, the quantification offers a remarkable ability to see how treatment modalities are working because a retest after treatment can show whether a parasite has resolved, dysbiosis has improved, and more. Almost every patient can benefit from a GI-MAP gut health assessment. Some patients are looking to achieve optimal health, while other patients have been chronically ill and frustrated without a diagnosis for years. Some conditions that warrant testing are: Autoimmune diseases IBS/IBD Digestive complaints, diarrhea or constipation Brain fog Skin problems, like acne and psoriasis Mood disorders, depression, and anxiety Diabetes and weight loss issues 	Y – CLIA number 11D20977 95

Doctor's Data/GI360 https://www.doctorsdat a. com/GI360-stool https://www.gi360.com/	Doctor's Data markets a gut test called GI360 that uses multiplex PCR, culture, MALDI-TOF, biochemical assays, and microscopy to detect and measure relative abundance of bacteria. Doctor's Data only sells its tests to clinicians and will only discuss results with the ordering provider.	 [D] etect[s] and assess[es] the status of pathogens, viruses, parasites and bacteria that may be contributing to acute or chronic gastrointestinal symptoms and disease. Useful for: Gastrointestinal Symptoms Inflammation Joint Pain Mucosal Barrier Dysfunction Autoimmune Disease Food Sensitivities Chronic or Acute Diarrhea Abdominal Pain IBD/IBS Nutritional Deficiencies Bloody Stool Fever and Vomiting 	Y – CLIA number 14D06464 70
(8) EasyDNA https://www.easy- dna.com/gut-health- microbiome-test/	This company primarily sells DNA tests (like paternity tests) but has expanded into gut microbiome testing. EasyDNA offers a DTC gut microbiome test, which relies on a stool sample. EasyDNA recommends taking at least two tests, 1-2 months apart. The company is located in California and offers a consultation service, but not in the United States.	Our at-home microbiome test can help you improve your gut health by providing you with detailed information about the abundances of your gut bacteria and instructions on how to achieve or maintain a balanced microbial community	Ν
(9) Elsavie https://elsavie.com/en/h ome/main	Elsavie is an Estonian company that markets its products in Europe. The gut microbiome test measures the composition of the gut microbiome using 16S rRNA gene amplicon sequence analysis from a DTC stool sample collection kit. The company provides dietary recommendations and, for additional purchase, four types of fiber supplements. Also, for an additional charge, a nutritionist will explain the test results and create a personalized nutrition plan.	 Who should take the test? Obviously, if you're curious about what's going on inside your gut, then this test will tell you and help to prevent chronic diseases. But if you're: overweight underweight on a special diet about to start, or have finished an antibiotic treatment experiencing discomfort 	Ν

		 then the test will illuminate what you can do to improve your health through dietary changes. The test clarifies: What kind of bacteria are found in your intestines If your microbiome is diverse and balanced If you have enough probiotic bacteria If your bacterial community suggests inflammation If and how you need to change your diet How food impacts your microbiota If you consume enough fiber What type of fiber you should consume If you consume too much fat and protein 	
(10) Evvy https://www.evvy.com/	Evvy offers a DTC vaginal microbiome- based test using an at-home vaginal swab collection kit. The company offers a one- time test or yearly membership consisting of one test shipped every three months. The test now includes STI testing.	Fully decode your vaginal microbiome. Get personalized reports and recommendations. Track how your interventions & lifestyle changes are working (or not!). Get 1-1 support from our certified health coaches.	Y – uses CLIA certified labs
(11) Floré by Sun Genomics https://flore.com/	Sun Genomics markets a personalized probiotic under the name Floré. After a consumer returns the DTC stool sample collection kit, the company analyzes the composition of the gut microbiome, makes dietary suggestions, and customizes the probiotic. The company also markets its custom probiotic to infants and children.	Instead of recommending multiple supplements, we analyze the trillions of microbes in your gut microflora, and craft a unique formula for your unique gut health needs. Floré personalized probiotics support GI motility, SIBO [small intestinal bacterial overgrowth], leaky gut, and overall digestive wellness. 87% of customers reported relief from bloating, gas, SIBO, leaky gut, & other digestive issues. Floré personalized probiotics support a child's GI motility and promote immunity.	Y – uses its own CLIA lab

(12) Genova Diagnostics https://www.gdx.net/pro d ucts/gi-effects	Genova offers a gut microbiome test called Gl effects. It uses PCR, culture, and microscopic methods to test the composition and abundance of organisms in the gut microbiome, inflammatory markers, metabolic indicators, and other biomarkers.	GI Effects® is a comprehensive assessment of complete gut health, assessing the root cause of most GI complaints. Data driven analysis is based on our database of hundreds of thousands of complete stool profiles. The GI Effects Stool Profiles are a suite of advanced stool tests that provide immediate, actionable clinical information for the management of gastrointestinal health. The GI Effects Stool Profiles can reveal important information about the root cause of many common gastrointestinal symptoms and non-GI conditions including: Gas Bloating Indigestion/reflux Abdominal pain/cramps Diarrhea Constipation Inflammatory Bowel Disease (IBD) Irritable Bowel Syndrome (IBS) Atopic dermatitis/eczema Allergies Autoimmune diseases Mood disorders (depression) Joint aches Diabetes Weight issues	Y – CLIA number 34D06555 71
(13) i-screen https://www.i- screen.com.au/	i-screen is an Australian company that limits its services to registered users in Australia. The company offers a variety of laboratory tests at a collection center, but it also markets a DTC microbiome-based test using an at-home stool collection kit. The company combines fecal microscopy with metagenomic sequencing to analyze the composition of the gut microbiome. For an additional charge, the company provides a nutritionist to interpret the test results and recommend a nutrition plan.	This holistic picture provides actionable insights to help you improve your gut health. In this assessment, our Nutritionist will interpret your results to identify the key dietary and lifestyle adjustments and supplemental support to help you improve your health and wellbeing.	Ν

<mark>(14) Juno Bio</mark> https://www.juno.bio/	Juno Bio is a U.K. company that markets a DTC vaginal microbiome-based test in the UK, as well as the US. The kit includes a swab for vaginal sample collection and a pH applicator, and consumers consult with a "vaginal coach" to discuss the analysis results.	The most comprehensive vaginal microbiome test you can take without ever even putting your shoes on. Brought to you by the world's leading vaginal microbiome scientists. We're building the standard of care women deserve. Get to the bottom of recurrent symptoms with a vaginal microbiome test	Ν
(15) Machemehl Method Institute https://www.m2institute . com/	The Machemehl Method offers a variety of DTC test kits. The company's test for gut health consists of a collection kit for stool and saliva samples. The tests measure "15 important biomarkers affecting overall gut health." The stool samples are analyzed using both genetic and culture techniques. The company also markets a variety of probiotics and supplements	M2 combines clinical experience, state- of-the-art laboratory testing, and professional-grade supplements to provide a full- service, personalized solution for patients of practices all over the world. We deliver quantifiable results and personalized wellness solutions using custom, professional-grade supplement blends and lifestyle recommendations	Y – uses CLIA certified labs
Microba https://insight.microba.c om	Microba is an Australian company offering a DTC stool sample collection kit for use in measuring gut microbiome composition. The company uses metagenomic sequencing to analyze the gut microbiome. As of Nov. 3, 2024, the company's website states that customers may only order their gut microbiome test through a physician.	Understand your unique microbiome, how it affects your health, and how you can achieve a better balance between desirable and less desirable microorganisms in your gut. Find out which bacteria are present and what they are doing. Dig deeper into how your microbiome may be influencing other areas of your health. See how your microbiome compares to our 'healthy group' and monitor changes over time. After you've received access to your detailed online report, you have the opportunity to book a coaching session with a Microbiome Coach – all qualified health professionals. Book a Microbiome Coach phone consult and talk through your findings with a practicing dietitian or nutritionist. Your coach will assist in the interpretation of results and will highlight beneficial dietary changes that may improve your microbial diversity and the functional potential of your <u>bacteria</u>	Ν

(16) MicroGenDX https://microgendx.com/	MicroGenDX is a U.S. company that markets globally. U.S. consumers require a doctor's order to obtain the tests for insurance purposes but consumers may order directly if they self pay. Several types of DTC test kits are available, including gut microbiome test on stool (qPCR only), and individual tests for vaginal pathogens and STIs.	We understand your frustration. You shouldn't have to suffer with the ongoing pain and discomfort of an unresolved infection. MicroGenDX specializes in low-cost, highly accurate qPCR + NGS microbial DNA diagnostics – providing answers where cultures or PCR alone have failed.	Y – CLIA certified lab
(17) MyDiagnostics https://mydiagnostics.in /p roducts/gut- dysbiosis- test-at- home?variant=33401765 822563	MyDiagnostics is based in India and delivers DTC health tests and supplements to several of the major cities in the country. Their "super gut test" tests the microbiome through DNA collected from a stool sample, while the general "gut health test" uses a blood and urine sample. The purchase of a gut microbiome test comes with a personal consult, report analysis, and recommendations by "Microbiome experts."	The Super Gut microbiome test is an at home stool test that provides deep insight into the health of your digestive system. Key indicators of the gut microbiota will be tested, along with risk factors for specific diseases such as Crohn's disease, IBS, Kidney disease, etc. The key areas that our microbiome impacts are: obesity and weight loss (management); sports performance (nutrient absorption and metabolism); mental health (depression, anxiety, etc.); metabolic disease (diabetes, cardiac etc); auto- immune conditions	
(18) Myota https://myotahealth.com / products/gut- microbiome-test-kit	This company offers DTC gut microbiome testing, supplements, and a 1:1 consultation on results. Currently, tests are only available in the U.K., but they are in the process of expanding	 With our kit you'll learn: Which types of gut bacteria you have, how many of each, and how this compares to the general population What role these gut bacteria play in improving your health How efficient your gut microbiome is at producing short-chain-fatty-acids (SCFAs) What fiber-rich food you should eat to maximize SCFA production, based on your gut bacteria 	Ν
<mark>(19) OME</mark> https://ome.health	OME is a U.K. company that preferentially markets in the U.K; it collects stool, saliva, and blood samples using DTC collection kits. The company provides a 12-week personalized nutrition coaching program from the results of a gut microbiome analysis and, for an extra charge, includes genetic and metabolite analyses.	We harness the power of your gut microbiome and other health data to deliver a personalized plan to address your nutrition needs. Your dedicated coach will prepare recipes based on your individual nutritional needs. Shoppable with major retailers.	Y – uses CLIA certified labs

Parallel Health1 https://www.parallelheal th.io/	Parallel health, a US company, markets two DTC skin-based microbiome tests and a line of skin care products. Prior to ordering a test kit, customers are required to complete an onboarding call with a company team member. Sample collection involves swabbing the skin in specific areas.	 1. Skin Discovery Test is the most advanced, quantitative skin microbiome test on the market today, featuring four swabs for different facial areas. What's included: A report revealing your Skin Microbiome Type[™], skin age, and bacterial assessment associated with acneprone and eczema-prone skin, along with imbalances associated with melasma, rosacea, psoriasis, and hidradenitis suppurativa 1:1 medical consultation with a doctor certified in Microbiome Dermatology[™] Holistic recommendations across food and skincare ingredients Odor Discovery Test is the most advanced, quantitative skin microbiome test on the market today, allowing you to swab your armpits and understand your skin's microbial ecosystem as it pertains to your natural and unique scent. What's included: A report revealing your Skin Microbiome Type[™] and bacterial assessment 1:1 clinical consultation with a doctor certified in Microbiome Dermatology[™] 	Ν
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¹ We did not include this DTC skin-microbiota testing company but included it in the Table for purposes of comparison.

(20) Psomagen / Kean Health https://www.keanhealth. c om/guthealth	Kean Health (Psomagen, Inc.) is the U.S. subsidiary of South Korean Macrogen Corporation. The company offers combined gut microbiome and genetic analyses using a DTC stool and saliva sample collection kits, and will soon be offering a vaginal microbiome DTC test. The company also offers a standalone gut microbiome analysis for personalized dietary recommendations.	 Our test will give you a snapshot of what's going on inside your gut and give you personalized recommendations to improve your overall health and wellness. When you provide a stool sample for the gut health test, we use whole metagenome sequencing to: Analyze the microorganisms in your gut Tell you about your microbe profile, metabolism, nutrition utility, lifestyle status, and gut type Provide you with a full probiotics profile. Offer custom dietary suggestions to implement based on your metabolism and microbiome Kean Health can decode your vaginal microbiome and educate you on how your results could significantly impact your day-to-day lifestyle. Receive personalized information about your vaginal health, from the comfort of your own home. 	Y – CLIA number 49D21725 99
(21) smartDNA https://www.smartdna.c om.au	smartDNA is an Australian company that markets (primarily to Australian users) a variety of tests including a gut microbiome analysis and genetic testing. A clinician must order the DTC stool sample collection or saliva detection kit (for genetic testing), or the consumer may order the kits and select a health care professional contracted by the company to receive the test results. The test results are sent to the health care professional who interprets them for the consumer.	 Your smartGUT[™] insights includes: How your microbiome sample compares to our healthy population. The level of diversity in your microbiome sample is a key indicator of health. An average to high microbial diversity is associated with a healthier microbiome. A dysbiosis compass which maps the imbalance between the types of bacteria present in your gut microbiome. The ratio of the two main microbiome groups which correlates with obesity. Learn how old your gut microbiome is. Includes your gut age relative to your chronological age. Dietary profiling of your gut microbiome to determine how your dietary intake is affecting your microbiome. 	Ν

(22) Smart Nutrition https://smartnutrition.co . uk/	Smart Nutrition is a U.K. company that markets internationally. The company offers a variety of laboratory tests including multiple DTC gut microbiome-based PCR tests and a DTC vaginal microbiome- based test. The DTC gut test (there are 5 options) includes a stool sample collection kit to collect one to several stool samples over one or more days, and the DTC vaginal test includes a vaginal sample collection kit to obtain one non- menstruating vaginal sample.	Digestive testing provides important information about the state of your digestive health and is a sensible place to check when your health is struggling or if you are suffering from digestive symptoms. The Vaginal EcologiX test gives insight into levels of beneficial and harmful bacteria, yeasts and pH levels and includes inflammatory markers. This test is useful for women who have or are at risk of pregnancy and fertility issues, bacterial vaginosis, candida, pelvic inflammatory disorder and other vaginal problems.	Ν
(23) Snapi https://www.snapihealth .com/	Snapi markets DTC gut microbiome tests for children age birth to five years old. The stool collection kit includes a test tube and tools, and the results are provided in an email.	 What can I learn from the Snapi Health Test? Bacterial composition An organized list of bacteria found in the gut microbiome. This list is broken down into easy-to-read graphs that demonstrate the protective, disruptive, and neutral bacteria found in your baby's gut. Evolution scale & bacterial diversity scale An evolution scale that reflects the stage of your baby's microbiome determined by their age, as well as a diversity scale to determine the count of bacteria present in the gut. Connections to health conditions Snapi's associations help you identify the root cause of your baby's health problems while also helping you prepare or prevent potential health problems from occurring. We address some of the most common conditions related to gut microbiome such as eczema, loose stools, and allergies. Recommendations by professionals who care Your results are unique, that's why they require personalized recommendations. These recommendations focus on supporting key bacterias and aim to decrease the risk of current and future health concerns. 	Ν

		5. Changes in Microbiome The microbiome of your baby rapidly evolves during the first 3 years of life. These years provide a window of opportunity for improving and maintaining the gut microbiome as microbiome plays an essential role in their healthy growth and development. We recommend doing this test at regular intervals during the first 3 years.	
(24) Sova https://www.sova.health / products/gut- microbiome-test	Based in India, Sova provides DTC gut microbiome testing via genomic sequencing of a stool sample. Customers also get a consultation with a "Gut Expert" with purchase. Sova uses customers' results to create a nutrition plan and recommend supplements.	 Benefits: decode missing bacterial strains; identify root triggers; expert consultation and guidance; access disease susceptibility; personalized nutrition plan; supplement recommendations reveals missing bacterial strains in your gut, checks the degree of gut imbalance and its effect on weight, mood, digestive issues and progression of lifestyle diseases. Identifies nutrient deficiencies and intolerances, estimates susceptibility to 15 diseases and checks how your body handles medications. Gut Health Profiling to evaluate digestion, metabolism, diet, lifestyle, and nutrient levels. Practical food & probiotic supplement recommendations to boost your health and well-being Fix Chronic Acidity, Constipation, IBS with Science: As the gut microbes contribute to issues like constipation, diarrhea, and heartburn, use testing to identify root causes, uncover why previous solutions may not have been effective, and restore Gut balance for symptom relief. 	Ν

(25) Thorne https://www.thorne.com (Thorne markets supplements and stool, blood, or saliva DTC sample collection kits. Its Gut Health Test comes with a dissolvable wipe to collect the stool sample that is then dissolved in a DNA-stabilizing solution. The company uses metagenomic sequencing to analyze the gut microbiome. Results are reviewed by an independent, board-certified physician.	 The Gut Health Test analyzes the balance of the good, bad, and conditional bacteria levels present in your gut and their research-backed associations to health, wellness, and disease conditions. Measures the presence of any dysbiosis – an imbalance in the bacteria in the gut. The test can benefit individuals who are experiencing GI issues such as: IBS Diarrhea Constipation Gas Bloating Cramping Abdominal pain Nausea Heartburn [R]eceive your personalized results with meaningful insights and recommendations to improve your health and wellness. 	Y – uses CLIA certified labs
(26) TinyHealth https://www.tinyhealth.c om/store/adult-gut- health-test	TinyHealth markets DTC gut health kits for adults and babies, which include a stool collection kit to obtain a sample from soiled tissue paper. This company offers a single testing kit and a "gut baseline assessment" which includes a 1-on-1 microbiome coaching call. TinyHealth also markets DTC vaginal tests for adults. The company also markets a vaginal microbiome test kit.	Mess free gut microbiome health tests for adults Track candida, parasites, and bacteria associated with inflammation. Full list of all bacteria, years, parasites, archaea, and viruses in your gut Strain-level precision using deep- shotgun metagenomics, the microbiome gold standard. Learn if you have any red flags for leaky gut Get actionable dietary, supplement and lifestyle recommendations from our microbiome experts based on your results Tailored to mom and baby's biomarkers Tiny Health is for women who are trying to conceive, are currently pregnant, or have a child under 3 years of age. Any family member like dads or siblings are welcome too!	Ν

<mark>(27) Ombre</mark>	Ombre markets both DTC gut and vaginal	Our program helps you get your gut bacteria back in balance	Ν
https://www.ombrelab.c	health tests. From a stool sample collection	through personalized diet and probiotics.	
<u>om/;</u>	kit, the company analyzes the composition		
	of the gut microbiome using 16s rRNA,	Monitor your wellness and save all year long with an at-home	
	makes dietary recommendations, and	microbiome test subscription. Target your symptoms by	
	formulates a custom probiotic. Using a	learning which gut bacteria are causing your issues. Identify	
	vaginal swab collection kit, the company	which foods you should avoid or eat. Discover which of	
	analyzes the composition of the vaginal	Ombre's proprietary probiotic blends we recommend for your	
	microbiome and makes food and probiotic recommendations.	gut microbiome.	
		The Ombre Difference:	
		Prevent IBS and leaky gut symptoms	
		Boost alertness without caffeine crashes or jitters	
		Promote cardioprotective benefits	
		• Support the body against colds and viruses	
		 Address inflammation that causes weight gain 	
		Increase serotonin to enhance mental wellness	
		Support vaginal health, fertility, immunity, and urinary tract health all year long with an at-home vagina microbiome test subscription. Beneficial for women who are trying to conceive, pregnant, premenopausal, or postmenopausal. Identify and correct imbalances in the vaginal microbiome through food, lifestyle, and probiotic recommendations. Target bacteria that leave you prone to UTIs, STIs, vaginal bacterial infections, and more. Discover which of Ombre's clinically-backed probiotics for vaginal health is best for your unique microbiome. Live confidently and comfortably with an at- home Vaginal Health Test subscription! Why is a healthy vaginal microbiome beneficial?	
		 The Ombre Difference: Improve fertility and prenatal health to support full-term pregnancy Increase immunity by optimizing vaginal pH Target uncomfortable symptoms naturally without the use of harsh antibiotics 	

Vibrant Wellness Vibrant Wellness Testing Menu (vibrant- wellness.com)	 analytes, such as zonulin and <i>H. pylori</i>, are measured at an additional cost. Vibrant wellness offers a wide variety of health tests including food sensitivity, hormone, and gut health analyses. Its gut microbiome test, called Gut Zoomer, uses microarray hybridization to detect microorganisms and examine their relative abundance and comes with dietary, prebiotic, and polyphenol recommendations. Tests are only available through participating providers. Patients cannot order without identifying a medical provider. Patients may either contact one of the providers already registered with the company, or the patient's provider may register with the company. A copy of the provider's license is required. Consumer and provider get the results. 	 well-being. Gut Zoomer is the most accurate microbiome test available to aid discerning healthcare providers in the assessment and treatment of gastrointestinal disorders. The Gut Zoomer report provides you with actionable recommendations that include potential risks for: Intestinal permeability (SCFA producing bacteria and tight junction integrity) Intestinal disorders (IBS and IBD related bacteria) Small Intestinal Bacterial Overgrowth (SIBO)- related bacteria Cardiovascular health (inflammation influencing and TMAO-related bacteria) Autoimmune health (celiac, Crohn's, rheumatoid arthritis, etc) 	Y – CLIA number 05D20788 09
<mark>(28) Verisana</mark> https://www.verisana.co m	Verisana offers a wide variety of health tests including hormone, STI, and gut health analyses using different types of biological samples. The gut health test consists of a gut microbiome composition analysis using a DTC stool sample collection kit. Specialty	 Boost lactic acid-producing bacteria to prevent Candida overgrowth and yeast infections Strengthen vaginal lining to reduce inflammation No more reoccurring UTIs Lower your risk of infections Get your fertility back The gut is our "second brain" – which is why bowel health plays a crucial role in our general well-being. Our Comprehensive Gut Biome & Health Test helps you to get a comprehensive picture of your gut health as the state of your gastrointestinal system is extremely important for your overall	N – Terms of Service state it is not subject to regulation under CLIA
		 Reduce the risk of cervical cancer and endometriosis Prevent recurring urinary tract infections (UTIs), bacterial vaginosis (BV), and aerobic vaginitis Decrease risks of sexually transmitted infections (STIs) and Human papillomavirus infection (HPV) Ease vaginal discharge, itching, or malodors 	

	See How it Works: https://www.vibrant- wellness.com/ForPatient	 Liver diseases (cirrhosis, hepatitis, cholangitis, and more) Metabolic health (Obesity, diabetes, etc) Nutrition (Vitamin production, oxalate metabolism) Microbiome and hormone connections (Beta-glucuronidase and Beta-glucosidase) 67 pathogenic bacteria 24 Intestinal parasites 8 viruses 5 Fungal or yeast species 6 antibiotic resistance genes measured The functional digestive analytes aid healthcare providers in determining if deficiencies in digestive enzymes, bile, or other critical metabolites are root causes of gastrointestinal inflammatory symptoms.	
(29) Viome https://www.viome.com	Viome markets custom prebiotics, probiotics, and supplements and makes dietary recommendations. The company analyzes the composition and expressed function of the gut microbiome using metagenome and metatranscriptome technologies from a DTC stool sample collection kit.	The current standards for personalization often fall short when it comes to improving gut health. That's why we take a deep dive into your body to help you identify which foods are beneficial for your unique microbiome and which ones may be contributing to inflammation. Your results include a detailed analysis of how your microbiome responds to over 300 foods, identifying those that contribute to things like poor blood sugar response, poor digestion, inflammation, and more. Each food recommendation is backed by your personalized Health Scores, providing clear explanations for why certain foods are beneficial or should be avoided at this time.	Y – CLIA number 50D22249 32

<mark>(30) Zoe</mark>	Zoe is headquartered in the U.K. but	A central part of ZOE's science has been an investigation of the	Y – uses CLIA
https://joinzoe.com	markets in the U.S. The company combines	microbiome and its links with an individual's diet and metabolic	certified labs
	microbiome analysis, blood testing, food	health. Through the PREDICT studies, we've collected the	
	logging, and continuous blood sugar	world's largest set of whole-metagenome sequenced gut	
	monitoring to provide full metabolic	microbiome data linked to in-depth metabolic responses and	
	analyses. The company also markets a	diet.	
	prebiotic. The DTC kit consists of a swab for		
	stool sample collection, finger-prick blood	We put our reputation to the test in a clinical trial. The findings	
	test, and test muffins for blood sugar	confirm what 150k+ members already know: ZOE works. See	
	monitoring. Personal coaching is available	https://www.nature.com/articles/s41591-024-02951-6.	
	at an additional cost.		

Summary of DTC Microbiome Testing Companies' Supplement Sales:

We identified thirty gut and/or vaginal DTC microbiome testing companies in operation as of October 2024. Of those, **fifteen also sold supplements, or approximately 50%.** For at least six of those, it was apparent from either sample reports or explicit statements provided on their website that those supplement recommendations are included as part of a customer's test results. This number may be higher, as not all companies provide full reports or images of the product. This does not include companies that make brand-neutral supplement recommendations.

Table 2: DTC Microbiome Testing Companies Supplement Sales

COMPANY	Offer Supplements?	Explanation
(1) AffinityDNA https://www.affinity-dna.com/	N	
(2) BIOHM https://biohmhealth.co m/collections/gut-testing	Y	Offers multiple types of probiotics/supplements, including package deals like the "reset regimen" and "superfoods bundle". These can be purchased without taking the BIOHM Gut Test. Test advertises as a highlight, "actionable and personalized recommendations from BIOHM's Microbiome-Trained Registered Dietitians". From the example of a "gut report" on their website, BIOHM does directly recommend their line of supplements in the Supplement Recommendations section of the report
(3) Biomes https://biomes.world/en/	Y	Biomes offers a general supplement targeted at those who have not done prior gut analysis, as well as "analytics-based" supplements for those who have done testing. Biomes does not have a full sample report on their website, so it is unclear if products are directly linked in those results or not, but the advertisement does state that it will provide "personalized recommendations."
(4) BiomeFx https://biomefx.com	N	

(5) Biomesight https://shop.biomesight .com/products/gut-microbiome- test-snapshot	Ν	Biomesight microbiome tests will provide supplement recommendations in their results, but they do not personally sell supplements on their website. Instead, Biomesight claims to, "leverage your unique microbiome test results and precisely match you to leading professional-grade supplements on the market".
(6) Blue Horizon Blood Tests https://bluehorizonbloo dtests.co.uk/products/m icrobiome-test; https://bluehorizonbloodtests.co. uk/products/vaginal- microbiome?_pos=1&_sid=173551 9c8&_ss=r	Ν	
(7) Daye <u>https://www.yourdaye.</u> com/products/vaginal-screening/	Y	Daye sells one "proViotic" that can be purchased separately or with the microbiome screening kit as a bundle.
Diagnostic Solutions Laboratory https://www.diagnostic solutionslab.com/tests/gi-map	N	
Doctor's Data/GI360 https://www.doctorsdat a.com/GI360-stool https://www.gi360.com/	Ν	
(8) EasyDNA https://www.easy- dna.com/gut-health-microbiome- test/	N	
(9) Elsavie https://elsavie.com/en/ home/main	Ŷ	Elsavie offers three different fiber supplements; "feel good inside", "calm your rumbly tummy", and "beauty inside and outside." Based on the sample report available on their website, Elsavie will recommend their own supplements in a customer's testing results, alongside food recommendations.
(10) Evvy https://www.evvy.com/	Ŷ	Evvy partners with a specialty pharmacy that, with a prescription, they "will develop a custom treatment program just for you that may include Rx medication and research-backed supplements."

(11) Floré by Sun Genomics https://flore.com/	Y	Floré offers custom probiotics for adults, kids, "tots", and babies. The formulation of the probiotics is based on a customer's results form the Complete Gut Microflora Test.
(12) Genova Diagnostics https://www.gdx.net/pr_oducts/gi- effects	Ν	
(13) i-screen_https://www.i- screen.com.au/	Ν	
(14) Juno Bio https://www.juno.bio/	Ν	
(15) Machemehl Method Institute https://www.m2institut e.com/	Y	Offers several supplements, many of which target serotonin production and mood more generally as it relates to the gut microbiome. Offers the "EZ Digest" supplement and "Biocidin Botanicals GI Detox". Because no sample report is available on their site, it is not clear whether these are recommended within a customer's results from a microbiome test.
Microba https://insight.microba.com	Ν	
(16) MicroGenDX https://microgendx.com/	Ν	
(17) MyDiagnostics https://mydiagnostics.i n/products/gut- dysbiosis-test-at- home?variant=334017 65822563	Y	MyDiagnostics sells seven supplements related to gut health. Supplements can be purchased without taking the microbiome test. Supplements can also be purchased in "kits," which come with a targeted consultation. Product description states that a Microbiome Gut Test includes, "prebiotics and probiotics recommendations."
(18) Myota <u>https://myotahealth.co</u> m/products/gut- microYbiome-test- <u>kit</u>	Y	Myota offers three supplements: "Gut Booster", "Metabolic Booster", and "Immunity Booster". In several of the FAQs on the website Myota says they offer food recommendations as part of the results but does not say anything about supplement recommendations. No sample report is available.
(19) OME https://ome.health	Ν	

Parallel Health https://www.parallelhealth.io/	Y	Markets a phage serum, peptide cream, cleanser, and moisturizer.	
(20) Kean Health (Psomagen) https://www.keanhealt h.com/guthealth	N	Offers two gut tests, the more expensive of which provides supplement recommendations. However, there does not seem to be anywhere to buy the supplements on this website.	
(21) smartDNA https://www.smartdna.com.au	Ν		
(22) Smart Nutrition https://smartnutrition.c o.uk/	Ν		
(23) Snapi https://www.snapihealth.com/	Ν		
(24) Sova https://www.sova.healt h/products/gut- microbiome-test	Ŷ	 Sova sells ten different daily probiotics and prebiotics. Supplements can be purchased without taking the microbiome test. Supplements can also be purchased in "kits," which come with a targeted consultation. Sova provides a sample report on their website, which shows that results include a "supplementation needed" section where supplements are recommended based on a patients' deficiencies. On this part of the report, the probiotics are named but no branded products are included; the report generally states that these are available through, "online 	
		The site claims that part of the consultation with a Gut Expert (which comes with all tests) is, "personalized dietary and supplement recommendations".	
(25) Thorne https://www.thorne.com/	Y	Thorne offers a probiotics quiz separate from their at home tests to identify which supplements they recommend you take (or, in their words, "need"). If someone purchases a gut test, however, they will be provided with an Improvement Plan which will include recommendations for supplements.	
(26) TinyHealth Adult Gut Health Test – Tiny Health	Ν	Makes supplement recommendations, but there does not appear to be anywhere on the website to purchase them.	

(27) Ombre https://www.ombrelab. com/; https://www.ombrelab.com/produc ts/vaginal-health- test?srsltid=AfmBOoqwnRTpGY0FP kC48UZEf5Bk_Tr8z4loh8njHQx2aPR _Dh2CkF5H	Y	Ombre offers several different probiotics and prebiotics. One of the images on the site advertises that results from the gut test will help you, "discover which targeted Ombre probiotic blend will enhance your health."
(28) Verisana https://www.verisana.c om	Ν	
Vibrant Wellness Vibrant Wellness Testing Menu	N	Makes brand-neutral supplement recommendations but does not sell them.
(29) Viome https://www.viome.com	Y	Viome offers supplements with the Oral Health Solutions microbiome test and the Gut Solutions microbiome test. Viome also offers "Precision Supplements" which are only available if someone takes the Full Body Intelligence Test which includes a gut and oral microbiome test. There does not appear to be a way to purchase the supplements without also purchasing a test.
(30)Zoe https://joinzoe.com	Y	Markets Daily 30+, a thirty plant prebiotic blend for gut health.

Summary of Location Base for DTC Microbiome Testing Companies

We identified thirty gut and/or vaginal DTC microbiome testing companies in operation as of October 2024. **Of those, sixteen (53%) are based in the United States.** Of the 14 companies headquartered outside of the US, seven or one-half market to consumers in the U.S.

Table 3: Location of DTC Microbiome Testing Companies

COMPANY	Based in the U.S.?	If no, location
AffinityDNA	N	Australia
https://www.affinity-dna.com		
BIOHM	Y	
https://biohmhealth.com/c ollections/gut-testing		
Biomes	N	Germany
https://biomes.world/en/		
BiomeFx		
https://biomefx.com		
Biomesight	N	London, U.K.
https://shop.biomesight.com/products/gut-microbiome-test-snapshot		
Blue Horizon Blood Tests	Ν	Devon, U.K.
https://bluehorizonbloodte sts.co.uk/products/microbi ome-test;		
https://bluehorizonbloodtests.co.uk/products/vaginal- microbiome?_pos=1&_sid=1735519c8&_ss=r		
Daye	N	London, U.K.
https://www.yourdaye.com/products/vaginal-screening/		
Diagnostic Solutions Laboratory	Y	
https://www.diagnosticsol_utionslab.com/tests/gi-map		

Doctor's Data/GI360 https://www.doctorsdata.c om/GI360-stool https://www.gi360.com/	Y	
EasyDNA https://www.easy-dna.com/gut-health-microbiome-test/	Y	
Elsavie https://elsavie.com/en/ho_me/main	N	Estonia
Evvy https://www.evvy.com/	Y	
Floré by Sun Genomics https://flore.com/	Y	
Genova Diagnostics	Y	
https://www.gdx.net/prod_ucts/gi-effects i-screen https://www.i- screen.com.au/	N	Australia
Juno Bio https://www.juno.bio/	N	London, U.K.
Machemehl Method Institute https://www.m2institute.com/	Y	
Microba https://insight.microba.com	N	Australia
MicroGenDX https://microgendx.com/	Y	
MyDiagnostics https://mydiagnostics.in/pr oducts/gut-dysbiosis-test- at- home?variant=334017658 22563	N	Bengaluru, India

Myota https://myotahealth.com/p roducts/gut-microYbiome- test-kit	N	Berlin, Germany
OME https://ome.health	N	London, U.K.
Parallel Health https://www.parallelhealth.io/	Y	
Psomagen (Kean Health) https://www.keanhealth.com/guthealth	Y	
smartDNA https://www.smartdna.com.au	N	Australia
Smart Nutrition https://smartnutrition.co.u k/	N	Nottingham, U.K.
Snapi https://www.snapihealth.com/	Y	
Sova https://www.sova.health/products/gut-microbiome-test	N	Haryana, India
Thorne https://www.thorne.com/	Y	
TinyHealth https://www.tinyhealth.com/store/adult-gut-health-test	Y	
Ombre https://www.ombrelab.com/; https://www.ombrelab.com/products/vaginal-health- test?srsltid=AfmBOoqwnRTpGY0FPkC48UZEf5Bk_Tr8z4loh8njHQx2aPR_Dh2CkF5H	Y	
Verisana https://www.verisana.com	Y	

Vibrant Wellness Vibrant Wellness Testing Menu (vibrant- wellness.com)	Y	
Viome https://www.viome.com	Y	
Zoe https://joinzoe.com	N	London, U.K.