#### **Summary Information about DTC Microbiome-Based Testing Companies**

We identified thirty-one DTC microbiome-based testing companies in operation as of January 2024. 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 microbiome testing"; "buy vaginal health test." These searches were conducted on multiple search engines periodically throughout a 3-year (2021 – 2023) 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 they market themselves 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 is reflected in the chart. To identify whether a company sold or marketing 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 a potential customer. Where available, we relied on sample results from their DTC tests to determine whether specific supplements would be marketed to consumers.

Of the companies that may reasonably use CLIA labs, meaning they are based in the United States or sell to customers in the United States, 12 of twenty-seven state they use CLIA labs.

	8		STATES
COMPANY	DESCRIPTION	CLAIMS	IT USES CLIA
			LABS?
	Atlas Biomed is a U.K. company	What you will learn:	N
	that states it does not market in	• Your microbiome health score,	
	the U.S. The company obtains a	inflammation profile, and	
	stool sample using a DTC	protection from 5 disease risks	
	collection kit and analyzes gut	• Proportion of probiotics and	
	microbiome composition using	beneficial bacteria, vitamin and	
	16S rRNA gene sequencing.	butyrate synthesis potential,	

#### Table #1: DTC Microbiome-Based Testing Companies

	Included with the test purchase is a 30 minute online consultation with a certified nutritionist.	<ul> <li>microbiome diversity score, lactose and gluten metabolism</li> <li>Weekly personalized food recommendations to improve your microbiome health in 17 areas.</li> <li>List of bacteria found in your microbiome (%) and what enterotype you belong to.</li> <li>Track your disease protection, microbiome diversity, dietary fiber ratings, and anti-inflammatory potential.</li> <li>Get fresh food and probiotic supplement recommendations.</li> </ul>	
BIOHM https://biohmhealth.com/ collections/gut-testing	BIOHM 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.	Test your gut and receive actionable recommendations on how to support your digestive health. The BIOHM Gut Test is one of the most comprehensive sequencing 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. [We] provide personalized dietary, lifestyle, and supplemental recommendations to support your overall digestive health.	N
Biomes https://biomes.world/en/	Biomes is a German company that 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.	Ν

		Recognize immune deficiencies. Reduce weight problems.	
BiomeFx https://biomefx.com	BiomeFx analyzes both gut and vaginal microbiome samples. The company partners with CosmosID, a CLIA-certified lab, to perform the microbiome characterization using metagenomic sequencing. In its results report to consumers, the company interprets a "dysbiosis ratio" to make lifestyle and dietary recommendations. BiomeFX requires tests to be ordered through a practitioner, but other third parties may sell the test DTC on their own company websites.	By evaluating multiple aspects of microbial balance, strength, and resilience, BiomeFx is able to provide a customized plan to re-balance pathogen occurrence. One of the most unique aspects of BiomeFX (in partnership with CosmosID) is the ability to evaluate the influence of the gut microbiome on disease risk. BiomeFX can help you identify early deviation from a healthy population.	N – but website once indicated it uses CosmosID to perform testing, which is CLIA- certified No longer mentions CosmosID on the website
Biomesight https://shop.biomesight.c om/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.	N "We have partnered with a research laboratory based in Culver City, California (USA) headed by Dr Jinliang Li (PhD Molecular Biology). They perform the full lab workflow within a single week."

		"improving your Gut health"	Ν
		"improve your vaginal microbiome"	
Blue Horizon Blood Tests https://bluehorizonbloodt ests.co.uk/products/micros biome-test	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	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 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. Our test looks at the whole biome and is sensitive enough to identify all 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.	

<b>Carbiotix</b> <u>https://carbiotix.com</u>	Carbiotix is a Swedish company that markets prebiotics, medical foods, and therapeutics to Europe and the U.S. Rather than market directly to consumers, the company offers behind-the- scenes laboratory analysis and customizable DTC stool sample collection kits with the purchaser's branding.	Carbiotix's mission is to increase the consumption of prebiotics in people's diets. LinkGut is the lowest cost, most reliable and flexible gut health testing service for companies interested in offering a gut health or microbiome test to their customers. LinkGut rises above the rest in offering a fully customizable white label testing solution.	Ν
Daye https://www.yourdaye.co m/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 costumer'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."	<b>T</b> T <b>1 1 1 1 1</b>	Ν
Diagnostic Solutions Laboratory https://www.diagnosticso 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.</i> <i>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. Also, other third parties may sell the test DTC on their own company websites.	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	Y – CLIA number 11D20977 95

		<ul> <li>parasite has resolved, dysbiosis has improved, and more.</li> <li>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.</li> <li>Some conditions that warrant testing are:</li> <li>Autoimmune diseases</li> <li>IBS/IBD</li> <li>Digestive complaints, diarrhea or constipation</li> <li>Brain fog</li> <li>Skin problems, like acne and psoriasis</li> <li>Mood disorders, depression, and anxiety</li> <li>Diabetes and weight loss issues</li> </ul>	
Doctor's Data/GI360 https://www.doctorsdata. 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, but other third parties may sell the test DTC on their own company websites.	<ul> <li>Gastrointestinal Symptoms</li> <li>Inflammation</li> <li>Joint Pain</li> <li>Mucosal Barrier Dysfunction</li> </ul>	Y – CLIA number 14D06464 70

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 offers a consultation service, but not in the United States.	Our at-home microbiome test can help you <b>improve your gut health</b> by providing you with detailed information about the abundances of your gut bacteria and instructions on <b>how to</b> <b>achieve or maintain a balanced</b> <b>microbial community</b>	Ν
Elsavie https://elsavie.com/en/ho me/main	Elsavie is an Estonian company that 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.	<ul> <li>Who should take the test?</li> <li>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.</li> <li>But if you're: <ul> <li>overweight</li> <li>underweight</li> <li>on a special diet</li> <li>about to start, or have finished an antibiotic treatment</li> <li>experiencing discomfort</li> </ul> </li> <li>then the test will illuminate what you can do to improve your health through dietary changes.</li> <li>The test clarifies: <ul> <li>What kind of bacteria are found in your intestines</li> <li>If your microbiome is diverse and balanced</li> <li>If your bacterial community suggests inflammation</li> <li>If and how you need to change your diet</li> <li>How food impacts your microbiota</li> <li>If you consume enough fiber</li> <li>What type of fiber you should consume</li> <li>If you consume too much fat</li> </ul> </li> </ul>	N

		and protein	
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
		Instead of recommending multiple supplements, we analyze the trillions of microbes in your gut microflora, and craft a unique formula for your unique gut needs.	Y – uses its own CLIA lab
	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.	Floré personalized probiotics help with abdominal pain, constipation, bloating, SIBO, leaky gut, and other digestive issues.	
Floré by Sun Genomics https://flore.com/		We create custom gut probiotics tailored and formulated to your unique microflora to improve your digestion, increase your energy, and reduce bloating; helping you perform at your best.	
		Our custom formulated probiotics can help alleviate bloating, stomach pain, and increase your energy helping you perform at your best.	
		Floré personalized probiotics help with your [baby's; toddler's; kid's] digestive issues, food allergies and overall gut health.	
Genova Diagnostics https://www.gdx.net/prod ucts/gi-effects	test called GI effects. It uses PCR, culture, and microscopic methods to test the composition and abundance of organisms in the gut microbiome,	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	Y – CLIA number 34D06555 71
	inflammatory markers, metabolic indicators, and other biomarkers.	database of hundreds of thousands of complete stool profiles.	

	Genova only sells its tests to licensed health care providers, but other third parties may sell the test DTC on their own company websites.	GI Effects Stool Profiles can reveal important information about the root cause of many common gastrointestinal symptoms and non-GI conditions including:	
		<ul> <li>Gas</li> <li>Bloating</li> <li>Indigestion/reflux</li> <li>Abdominal pain/cramps</li> <li>Diarrhea</li> <li>Constipation</li> <li>Inflammatory Bowel Disease (IBD)</li> <li>Irritable Bowel Syndrome (IBS)</li> <li>Atopic dermatitis/eczema</li> <li>Allergies</li> <li>Autoimmune diseases</li> <li>Mood disorders (depression)</li> <li>Joint aches</li> <li>Diabetes</li> <li>Weight issues</li> </ul>	
<b>i-screen</b> <u>https://www.i-</u> <u>screen.com.au/</u>	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.	N
Juno Bio https://www.juno.bio/	Juno Bio is a U.K. company that markets a DTC vaginal microbiome-based test. The kit includes a swab for vaginal sample collection and a pH	The only 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.	N

	applicator, and consumers consult with a "vaginal coach" to discuss the analysis results.		
Machemehl Method Institute https://www.m2institute. com/	company's test for gut health consists of a collection kit for stool and saliva samples. The stool samples are analyzed using both genetic and culture techniques. The company also markets a variety of probiotics and supplements. Testing is only available as upon referral from a	M <sup>2</sup> 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 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.	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.	N
		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.	
Microba https://insight.microba.co		See how your microbiome compares to our 'healthy group' and monitor changes over time.	
<u>m</u>		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 bacteria.	
MyDiagnostics https://mydiagnostics.in/p roducts/gut-dysbiosis- test-at- home?variant=33401765 822563	and delivers to 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" test uses a blood and urine sample. The purchase of a gut microbiome test comes with a personal consult and 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	
Myota https://myotahealth.com/ products/gut- microbiome-test-kit	This company offers DTC gut microbiome testing as well as a 1:1 consultation on your results. Currently, tests are only available in the U.K. but they are in the process of expanding	<ul> <li>With our kit you'll learn:</li> <li>Which types of gut bacteria you have, how many of each, and how this compares to the general population</li> <li>What role these gut bacteria play in improving your health</li> <li>How efficient your gut microbiome is at producing short-chain-fatty-acids (SCFAs)</li> <li>What fiber-rich foods you should eat to maximize SCFA production, based on your gut bacteria</li> </ul>	N
OME https://ome.health	blood samples using DTC collection kits. The company provides a 12-week personalized	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	Y – uses CLIA certified labs

		nutritional needs. Shoppable with major retailers.	
Thorne https://www.thorne.com/	Thorne markets a multi-omic testing platform called Onegevity Health Intelligence using stool, blood, or saliva DTC sample collection kits. Its microbiome-based test analyzes the gut microbiome from a stool sample to make personalized dietary recommendations and recommendations for a variety of supplements, probiotics, and prebiotics marketed under the brand name Effusio.	Thorne's gut microbiome test gives you a detailed analysis and a personalized plan that targets your GI discomfort and optimizes wellness. Onegevity is the AI and health intelligence engine of Thorne HealthTech. The test combines cutting-edge sequencing with Onegevity's Health Intelligence to make meaningful changes. Your gut microbiome is analyzed to identify potential health risks and specific areas of improvement using whole-genome sequencing powered by Onegevity Health Intelligence. Receive a personalized report with precise recommendations that include dietary, supplement, and lifestyle habits based on your unique results. [We] help individuals take a proactive and actionable approach to improve and maintain their health over a lifetime.	Y – uses CLIA certified labs
	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.	<ul> <li>Analyze the microorganisms in your gut</li> <li>Tall you about your microba</li> </ul>	Y – CLIA number 49D21725 99

		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.	
smartDNA https://www.smartdna.co m.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. The test results are then sent to the health care professional who interprets them for the consumer.	<ul> <li>Your smartGUT<sup>TM</sup> insights includes:</li> <li>How your microbiome sample compares to our healthy population.</li> <li>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.</li> <li>A dysbiosis compass which maps the imbalance between the types of bacteria present in your gut microbiome.</li> <li>The ratio of the two main microbiome groups which correlates with obesity.</li> <li>Learn how old your gut microbiome is. Includes your gut age relative to your chronological age.</li> <li>Dietary profiling of your gut microbiome to determine how your dietary intake is affecting your microbiome.</li> </ul>	N
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 tests. The DTC gut test includes a stool 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 microbiome ProfileEcologiX is the most	N

	collection kit to collect five stool samples over three consecutive days, and the DTC vaginal test includes a vaginal sample collection kit to obtain one non- menstruating vaginal sample.	comprehensive evaluation available. It includes microscopic examination of vaginal fluid, and also looks for evidence of different types of bad bacteria and yeast as well as checking for Lactobacillus, the protective bacteria that is easily removed by oral antibiotics. Who this test is helpful for; This test will be useful for women who have or are at risk of pregnancy and fertility issues, bacterial vaginosis, candida, pelvic inflammatory disorder and other vaginal problems.	
Sova https://www.sova.health/ products/gut- microbiome-test	Based in India, Sova provides DTC gut microbiome testing via genomic sequencing on 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.	<ul> <li>Benefits: decode missing bacterial strains; identify root triggers; expert consultation and guidance; access disease susceptibility; personalized nutrition plan; supplement recommendations</li> <li>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.</li> <li>Identifies nutrient deficiencies and intolerances, estimates susceptibility to 15 diseases and checks how your body handles medications.</li> <li>Gut Health Profiling to evaluate digestion, metabolism, diet, lifestyle, and nutrient levels.</li> <li>Practical food &amp; probiotic supplement recommendations to boost your health and well-being</li> </ul>	Ν

			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.	
			<i>Mess free gut microbiome health tests for adults</i>	N
		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 purports to offer a 1-on-1 microbiome coaching call. TinyHealth also markets DTC vaginal tests.	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	
	https://www.tinyhealth.c		Learn if you have any red flags for leaky gut	
- E	om/store/adult-gut- health-test		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!	
	<b>Ombre</b> https://www.ombrelab.co m/	Ombre markets both DTC gut and vaginal health tests. From a stool sample collection kit, the company analyzes the composition of the gut microbiome, makes dietary recommendations, and formulates a custom probiotic. Using a vaginal swab collection kit, the company analyzes the	Our program helps you get your gut bacteria back in balance through personalized diet and probiotics. Monitor your wellness and save all year long with an at-home microbiome test subscription. Target your symptoms by learning which gut bacteria are causing your issues. Identify which foods you should avoid or eat. Discover which of	Ν

	of the vaginal Ombre's proprietary probiotic blends
microbiome	and makes food and we recommend for your gut microbiome.
probiotic re	ommendations. The Ombre Difference: Prevent IBS and leaky gut symptoms Boost alertness without caffeine
	<ul> <li>crashes or jitters</li> <li>Promote cardioprotective benefits</li> <li>Support the body against colds</li> </ul>
	<ul> <li>and viruses</li> <li>Address inflammation that causes weight gain</li> <li>Increase serotonin to enhance mental wellness</li> </ul>
	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?
	<ul> <li>The Ombre Difference:</li> <li>Improve fertility and prenatal health to support full-term pregnancy</li> <li>Increase immunity by</li> </ul>
	optimizing vaginal pH

		<ul> <li>Target uncomfortable symptoms naturally without the use of harsh antibiotics</li> <li>Reduce the risk of cervical cancer and endometriosis</li> <li>Prevent recurring urinary tract infections (UTIs), bacterial vaginosis (BV), and aerobic vaginitis</li> <li>Decrease risks of sexually transmitted infections (STIs) and Human papillomavirus infection (HPV)</li> <li>Ease vaginal discharge, itching, or malodors</li> <li>Boost lactic acid-producing bacteria to prevent Candida overgrowth and yeast infections</li> <li>Strengthen vaginal lining to reduce inflammation No more reoccurring UTIs</li> <li>Lower your risk of infections</li> </ul>	
<b>Verisana</b> <u>https://www.verisana.co</u> <u>m</u>	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 analytes, such as zonulin and <i>H.</i> <i>pylori</i> , are measured at an additional cost.	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 well-being.	N – Terms of Service state it is not subject to regulation under CLIA
Vibrant Wellness Vibrant Wellness   Testing Menu (vibrant- wellness.com)	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	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:	Y – CLIA number 05D20788 09

	comes with dietary, prebiotic, and polyphenol recommendations. Tests are only available through participating providers.	<ul> <li>Intestinal permeability (SCFA producing bacteria and tight junction integrity)</li> <li>Intestinal disorders (IBS and IBD related bacteria)</li> <li>Small Intestinal Bacterial Overgrowth (SIBO)- related bacteria</li> <li>Cardiovascular health (inflammation influencing and TMAO-related bacteria)</li> <li>Autoimmune health (celiac, Crohn's, rheumatoid arthritis, etc)</li> <li>Neurological health (MS, Parkinson's, and more)</li> <li>Liver diseases (cirrhosis, hepatitis, cholangitis, and more)</li> <li>Metabolic health (Obesity, diabetes, etc)</li> <li>Nutrition (Vitamin production, oxalate metabolism)</li> <li>Microbiome and hormone connections (Beta-glucuronidase and Beta-glucosidase)</li> <li>67 pathogenic bacteria</li> <li>24 Intestinal parasites</li> <li>8 viruses</li> <li>5 Fungal or yeast species</li> <li>5 worm species</li> <li>6 antibiotic resistance genes measured</li> </ul>	
Viome https://www.viome.com	Viome markets custom prebiotics, probiotics, and supplements and makes dietary recommendations. The company analyzes the composition and	We go below the surface to understand your unique biology and make it easy for you to get the nutrition your body needs with a custom-made supplement, probiotic + prebiotic formula.Our Gut	Y – CLIA number 50D22249 32

	expressed function of the gut microbiome using metagenome and metatranscriptome technologies from a DTC stool sample collection kit.	Intelligence Test analyzes your microbial gene expression and includes over 20 subscores related to immune responses, inflammation, microbial activity, richness & diversity, gut lining health, and more. The nutrition recommendations Included with this test encourage an optimal target the underlying cause of inflammation in your gut microbiome and represent the first step in improving your gut health! Viome's Gut Intelligence <sup>TM</sup> gut health test assesses your microbial gene expression in order to determine: • How your current diet and lifestyle are impacting your gut health today • Why you are experiencing the symptoms you are experiencing and what foods could be the cause • What you can do about it through a more precise diet and supplement routine, designed for your unique gut microbiome	
<b>Zoe</b> https://joinzoe.com	analysis, blood testing, food logging, and continuous blood sugar monitoring to provide full metabolic analyses. The DTC kit consists of a swab for stool sample collection, finger-prick blood test, and test muffins for	Our research [comes] from the ongoing PREDICT program, which is the world's largest in-depth nutritional research program. Based on the tests used in PREDICT, our at-home test kit can provide comprehensive insights into your biology, covering the gut microbiome and markers of dietary inflammation (including both blood sugar and fats).	Y – uses CLIA certified labs

## Summary of DTC Microbiome-Based Testing Companies' Supplement Sales:

We identified thirty-one DTC microbiome-based testing companies in operation as of December 2023. Of those, **fourteen also sold supplements**, **or approximately 45.16%**. For 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.

COMPANY	Offer Supplements?	Explanation
Atlas Biomed https://atlasbiomed.co m/uk/microbiome	N	
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
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."
BiomeFx https://biomefx.com	N	
Biomesight https://shop.biomesight .com/products/gut- microbiome-test- snapshot	N	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".
Blue Horizon Blood Tests	Ν	

## **Table 2: DTC Microbiome-Based Testing Companies**

https://bluehorizonbloo dtests.co.uk/products/m icrobiome-test	
Y       Carbiotix       https://carbiotix.com	Carbiotix offers customizable nutraceutical and cosmetic ingredients that can be, "used alone, blended with other prebiotics or probiotics, or used as a co-intervention with medical foods or therapeutics" to improve pharmacokinetics or desired effect, respectively. Carbiotix appears to be directly targeting businesses, however, not individuals.
DayeYhttps://www.yourdaye.Ycom/products/vaginal-screening/	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-mapN	
Doctor's Data/GI360 N https://www.doctorsdat a.com/GI360-stool https://www.gi360.com /	
EasyDNANhttps://www.easy-dna.com/gut-health-microbiome-test/	
Elsavie https://elsavie.com/en/ home/main	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.
Evvy https://www.evvy.com/	Evvy has recently added a line of vaginal healthcare products that provide, "clinically-proven symptom relief". Evvy's website states that, "after testing, order a personalized prescription treatment program developed by a provider." This treatment program includes Rx medication and supplements, as well as health coaching, depending on the customer's results. Examples of potential clinical care that are on the website include antibiotics/antifungals, medical-grade boric acid, probiotic

		<ul> <li>suppositories, and soothing ointments. Currently, this clinical care is not available in Arkansas, Delaware, Kansas, Mississippi, New Mexico, New York, Puerto Rico, Rhode Island, US Virgin Islands, Washington D.C., West Virginia, or the Armed Forces Europe/Pacific</li> <li>Evvy's site explains, "Please note that providers through Evvy's care platform may determine that a patient's Evvy results and health history are not sufficient to reach a proper diagnosis, or that the patient may require additional physical examinations prior to treatment (such as those with a history of gynecological cancer or active pregnancy). Providers will then refer the patient from Evvy's digital care platform to receive in person care and a physical examination to establish the best treatment plan. No matter what, all Evvy tests come with a custom plan of clear next steps to talk to your doctor about, as well as a free 1:1 coaching call!"</li> </ul>
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.
Genova Diagnostics https://www.gdx.net/pr oducts/gi-effects	N	
i-screen https://www.i- screen.com.au/	N	
Juno Bio https://www.juno.bio/	N	
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	N	
MyDiagnostics https://mydiagnostics.i n/products/gut- dysbiosis-test-at-	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.

home?variant=334017 65822563		Product description states that a Microbiome Gut Test includes, "prebiotics and probiotics recommendations."
Myota https://myotahealth.co m/products/gut- microYbiome-test-kit	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.
OME https://ome.health	N	
Thorne https://www.thorne.co m/	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.
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.
smartDNA https://www.smartdna. com.au	N	
Smart Nutrition https://smartnutrition.c o.uk/	N	
	Y	Sova sells eight 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 https://www.sova.healt h/products/gut- microbiome-test		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 retailers."
		The site claims that part of the consultation with a Gut Expert (which comes with all tests) is, "personalized dietary and supplement recommendations".

TinyHealth https://www.tinyhealth. com/store/adult-gut- health-test	N	Makes supplement recommendations, but there does not appear to be anywhere on the website to purchase them.
Ombre https://www.ombrelab. com/	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."
Verisana https://www.verisana.c om	N	
Vibrant Wellness Vibrant Wellness   Testing Menu (vibrant- wellness.com)	N	Makes brand-neutral supplement recommendations but does not sell them.
Viome https://www.viome.co m	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.
Zoe https://joinzoe.com	N	

# Summary of Location Base for DTC Microbiome-Based Testing Companies

We identified thirty-one DTC microbiome-based testing companies in operation as of December 2023. Of those, seventeen are based in the United States.

COMPANY	Based in the U.S.?	If no, location
Atlas Biomed https://atlasbiomed.com/u k/microbiome	N	Croydon, United Kingdom
BIOHM https://biohmhealth.com/c ollections/gut-testing	Y	
Biomes https://biomes.world/en/	N	Germany
BiomeFx https://biomefx.com	Y	
Biomesight https://shop.biomesight.co m/products/gut- microbiome-test-snapshot	Ν	London, United Kingdom
Blue Horizon Blood Tests https://bluehorizonbloodte sts.co.uk/products/microbi ome-test	N	Devon, United Kingdom
Carbiotix https://carbiotix.com	N	Two addresses registered for the business; one in California and one in Sweden. All reports refer to Carbiotix as a " <b>Sweden-based</b> " business. Carbiotix's website confirms they were founded in Sweden
Daye https://www.yourdaye.co m/products/vaginal- screening/	N	London, United Kingdom
Diagnostic Solutions Laboratory https://www.diagnosticsol utionslab.com/tests/gi- map	Y	

Table 3: Location of DTC Microbiome-Based Testing Companies

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 https://www.gdx.net/prod ucts/gi-effects	Y	
i-screen https://www.i- screen.com.au/	Ν	Australia
Juno Bio https://www.juno.bio/	Y	
Machemehl Method Institute https://www.m2institute.c om/	Y	
Microba https://insight.microba.co m	N	Australia
MyDiagnostics https://mydiagnostics.in/pr oducts/gut-dysbiosis-test- at- home?variant=334017658 22563		Bengaluru, India

Myota https://myotahealth.com/p roducts/gut-microYbiome- test-kit	N	Conflicting information as to whether they are based in the U.K. or Germany. Myota currently only ships within the U.K.
OME https://ome.health	N	London, U.K.
Thorne https://www.thorne.com/	Y	
Psomagen https://www.keanhealth.co m/guthealth	Y	
smartDNA https://www.smartdna.co m.au	N	Australia
Smart Nutrition https://smartnutrition.co.u k/	N	Notts, U.K.
Sova https://www.sova.health/p roducts/gut-microbiome- test	N	Haryana, India
TinyHealth https://www.tinyhealth.co m/store/adult-gut-health- test	Y	
Ombre https://www.ombrelab.co m/	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		Several reports, and Zoe's own website, list Zoe as based in both Boston and London. All current job postings are for UK or a "compatible time zone". From Zoe's privacy policy, <b>"ZOE is based in the United Kingdom, but also</b> has operations in the United States."