**Executive Summary**

The desire to know oneself is quintessentially human, the measure of life is often how that initial mold is changed by everything we go through. The mold we are cast in is largely decided by our DNA, the blueprints to how our cells are built and function. This blueprint is one we know well with many people investing in it to understand how they are connected and what their genes say about them. The only issue is what is the next step, our DNA is largely set by the time you would be getting those results, while it can be important for understanding what precautions to take, it leaves very little room for direct intervention that can be readily seen or measured. This lack of feedback makes lasting changes harder to maintain, however what if there was a way to alter a significant portion of what defines our health and wellbeing and be able to measure how our lifestyle adjustments affect it. This is where your second genome takes the stage, that of your microbiome. The gut microbiome in particular has been shown to have effects on mood, depression, metabolism, and weight gain amongst others. This ‘second genome’ however is one that changes according to diet and lifestyle, so by knowing how yours is made up and by testing over time you can start to understand how it is affected and get that feedback on what works and how.

This is where our product MyCrobIQ comes into play, this is a personal sequencing kit for analyzing your gut microbiome and giving you back results specific to you. The MyCrobIQ kit allows for simple sample collection by the user, which is then sent to our lab facility where the sample and survey the user filled out with basic data are compared against the database to give them not only a report of what bacteria are present but also how that compares with our other users with similar demographics. The service is best when used as a recurring one, allowing the noise that can happen from a single test to be drowned out by the true data received over time. This area is where our competitors fall short, while they have solid accuracy that is muted by the lack of follow-up testing instead relying on a single sample. This single sample is bound to have alterations from the day-to-day fluctuations of the microbial community in the gut (Gurry et al., 2018). It also precludes the user from receiving feedback on how their adjustments have taken effect, specifically how their microbiome has changed or not changed in accordance with those changes. This comes at a time when many are dealing with increased weight issues and depression from the pandemic, many are unsure of how to proceed and what changes work. Even before the pandemic 80% of diets fail to achieve the user’s desired outcome (Engber, 2020). The lack of viable feedback beyond very superficial and volatile feelings about the diet make sticking to them harder, if the user knew they were actually changing how their gut acts and, if it’s in a healthier way, they can know that diet is worth sticking to. This is what MyCrobIQ is delivering in this time of need, a way for everyone to understand themselves better and offering them a way to adjust, change and grow with actual feedback into how their journey is going.

**Industry Description and Outlook**

Consumer awareness about health and hygiene is expanding especially after the onset of global COVID-19 pandemic and social distancing, giving an acceleration to the market for direct-to-consumer (DTC) testing kits. The positive impact of the pandemic on the health industry is a firm reason for the exponential industrial growth of the market. The advancement of diagnostic testing and sequence-based analysis of microbiome, also called gut flora testing, has witnessed a surge in demand and advancement over the last couple of years. Microbiome at-home test kits are becoming particularly popular because they provide actionable insight on how consumers can improve the quality of their lives. The companies offering the tests provide results based on various genetic and metabolic factors of the individual.

Even apart from the pandemic, cumbersome work schedules are leading the consumers to skip prescribed medical testing or other physical tests. Thus, as these kits are OTC (over the counter) based products, a gut microbiome kit is the best option for them as it provides simplicity, and it is handy. Apart from this, these tests are beneficial for people who are curious about their bodies and want to delve deeper into their gastrointestinal tract health or the ones monitoring their health or diet or some scientifically curious people.

This industry is very new and falls under the Education and Health Service Sector. The idea of personal sequencing being a market for use was originally developed by companies such as 23&Me and Ancestry.com using genomic data that was getting rapidly cheaper to sequence. The science of how the microbiome affects health is very much ongoing and as such its importance is varying in real-time as we learn. There are some companies working in this space at the moment, but none have reached name recognition to the average consumer.

The long-term outlook for the industry of microbiome testing is letting the laymen have the awareness about the importance of gut microbiome health and how important it is to monitor it as it portrays the overall metabolism of the body. The potential product for gut microbiome testing, named “**MyCrobIQ**”, exactly fits for this. The MyCrobIQ kit can be available OTC and is easy to use. The kit can be recollected for testing and the results can be then provided to the consumer via mail services.

The barrier of this industry is that there is less awareness among people as this is an upcoming industry. Along with it, the management of gut microbiome data is neither easy nor are the results much specific, with a wider reference range for the healthy microbiota. These products (kits) are generally expensive. Hence, with MyCrobIQ, using amplicon sequencing, which is a cost-effective method for testing and gives better results in terms of identification of taxonomies of the microbes, making MyCrobIQ a promising product, these obstacles can be overcome.

The global market for microbiome therapeutics should grow from USD 141.7 million in 2021 to USD 1.3 billion by 2026, at a compound annual growth rate (CAGR) of 56.4%. The infectious diseases segment of the market should grow from USD 53.8 million in 2021 to USD 191.8 million by 2026, at a CAGR of 28.9%.

Due to a rapid expansion in test kits and rising awareness about the developing technology, the North American region is expected to dominate the gut microbiome testing market in the coming years promising better patient outcomes. The increasing population, existence of prominent players, and regulatory approvals from the U.S. FDA is driving this market’s growth in the region. With this, Europe and Asia Pacific are expected to grow significantly during the forecast timeline due to the extensive research activity and rising investment in technologically advanced gut microbiome testing equipment in the region.

**Target market:**

For decades, microbiology has relied on traditional culture methods (TCMs) to identify bacteria involved in human health or disease. Majority of the time the samples are sent to a laboratory, and bacteria from these samples are cultured in broth and/or agar-based media, isolated and characterized for identification. This traditional culture methods classified bacteria based on species and strain level using the correct choice of incubation setting and media for possible selective growth of bacteria then evaluate for growth rate and antimicrobial susceptibility testing. This method requires a large amount of time to identify the organism for only a fraction of the diverse microbial population and provides only limited results (Gupta et al, 2019).

With Next Generation Sequencing (NGS), a method that commonly used for Microbiome Sequencing Kit, it is a game changer in which this method allows for rapid, sensitive, and cost efficient for patients/customers who are actively healthy to identify diverse microbiome in their digestive system based on similarity to reference 16S rRNA gene sequences available in public databases (Gupta et al, 2019). Based on research paper that had conduct studies on healthy children using collected fecal samples and hypopharyngeal samples, Next Generation Sequencing (NGS) represented 75.70% of the unique bacterial species cultured compared to traditional culture methods (TCMs) only identified 23.86% of the bacterial species (Gupta et al, 2019). Based on the results, this great Microbiome Sequencing Kit can be used by parents to help identify active microbial environments in the digestive tract and by keeping track of the healthy diet for their children in developing the right meal choice and healthy lifestyle from early age to young adulthood.

Microbiome sequencing kit has enabled researchers/customers/patients to study and understand the microbiome down to the genomic level and how microbes impact an individual's health. Since the microbiome testing uses Next Generation Sequencing to compare customers’ microbiome with a normal/healthy individual, it reveals the composition, balance, and level of bacteria and fungi inside the digestive tract from a stool sample. According to Weight Loss and Weight Management Diet Market Size, Share, and Trends from Market research, the weight loss and weight management diet market size was valued at 192.2 billion in 2019, and is projected reach $295.3 billion by 2027, registering a CAGR of 7.0% from 2021 to 2027 (Himanshu & Deshmurk,2021).

This kit used to assess the gut microbiome’s diversity and provide suggestions towards a healthier lifestyle. By understanding one’s health, individuals can start getting involved in improving quality of life, changing their diet and meal as well as modify their exercise and lifestyle plan based on results from microbiome sequencing reports. For instance, based on the test results and insight from the microbiome sequencing report, customers will have the tools and advice to personalize supplement choices, diet as well as lifestyle modification on how to balance microbiome. They can do the microbiome testing every week or month on a regular basis to track how dietary, lifestyle, and supplement changes affect the Gut Score as they make changes to their lifestyle.

Based on the global consumer testing market, it is valued at US$359.05 million in 2017 and is projected to expand at a CAGR of 15% over the forecast period to reach US$928.80 million by 2023 (Dublin,2018). Our target market would be those that are particularly health conscious, individuals who are potentially with health conditions that are linked with microbiome health, and/or healthy individuals who are wondering if their diet plans are effectively improving their health.

As we move forward in the future, we can easily imagine using Microbiome Sequencing Kit as analysis with Next Generation Sequencing to help define biomarkers and stratify patient populations, which may help identify new diseases like cancer and improve therapeutic outcomes in the future.

**Competitor Analysis**

The market space our product, personal gut microbiome sequencing kits (MicrobIQ), will be operating in is relatively new and nebulous but developing. There are some key competitors that have established in the same space, those include: Viome and Psomagen’s GutMicrobiome+. The company of Viome offers a microbiome sequencing kit using transcriptome sequencing for species and abundance recognition, as well as a lineup of health products. The GutMicrobiome+ kit from Psomagen uses Whole Genome Sequencing to identify which microbes are present and in what general quantities. The need for larger name recognition and reach is the main external factor on how the competitive market will be shaped, as of now all the companies are relatively new and niche. The changes in how sequencing technology continues to evolve will determine how each company's process works moving forward and what profits they can gain as the cost of sequencing decreases. The continuing decrease in sequencing costs will affect all the competitors as well as our own company in reducing costs as time goes on (Mullin, 2020). The companies we are competing against have the advantage of being established and their workflows set in place. The strengths and weaknesses of the main competitors will be addressed in the following paragraphs, as well as how the MicrobIQ kit stands to work in this market space.

The company Viome is a competitor that also sells gut microbiome sequencing kits to consumers. They use transcriptome technology which will show more detail than the amplicon sequencing our company uses; however, this comes with greater costs which are passed on to the consumers (Laudadio et al., 2018). They also have a synergy with their other products, selling probiotics and supplements that are supposed to be aligned with the results received in the microbiome sequencing (Viome, 2021). This gives them an avenue to keep customers beyond the initial kit by getting them to buy products in line with those results. This is their main advantage, while they do not have widespread name recognition, they attempt to keep customers with the renewable supplement subscriptions. The weakness of this strategy is by keeping all the supplements and probiotics in-house it allows the skeptical consumer reasons to doubt some of their results as it would behoove them to encourage buying their products. They also rely on a more detailed sequencing process with transcriptome sequencing, but this detail is limited as it is still only a single data point which is vulnerable to the day-to-day variations in the microbiome that obscure the larger trends (Gurry et al., 2018).

The company Psomagen is another competitor that offers a gut microbiome sequencing kit. Their process involves the use of whole genome sequencing to determine the microbial community in the consumer’s gut. This allows them to get results for more than just bacteria, including viruses and protists (Brumfield et al., 2020). The company has the advantage of being lab certified and HIPPA compliant allowing for more consumer confidence and trust in their product as well as a feeling of data privacy (Psomagen, 2021). This competitor once again struggles reaching new customers as they aren’t well known or easy to find with google without specific search terms. They also mention the potential for using more than one kit, but it is not a main selling point they advertise. The whole genome sequencing platform offers more detail than the amplicon sequencing but at the cost of higher costs and longer analysis times. The problem with day-to-day fluctuations in the microbiome once again is an issue for singular kits that have no repeat testing.

In comparison to the competitors, the MicrobIQ kit is designed to track how the consumers microbiome changes over time by having them collect samples on multiple occasions and sequence those samples over that respective period of time. This helps to remove the day-to-day fluctuations obscuring the true makeup of the microbiome, while also providing a tool to see how changes might be impacting the consumer’s microbiome over time. With this model and the use of amplicon sequencing it allows us to provide a lower cost to the consumer per kit. The company also provides a simple, easy to understand report of the findings and gives you updates on what your results may mean as the science changes over time with your renewing kits. This connectivity to the kits and the users over time provide for an in-depth look at how their microbiome is changing over time and when compared with survey results from all the users of the system can help elucidate trends in what the microbiome results may mean for similar users. This means as the user base grows so does the value of the results to each user and opens the possibility of use by medical researchers to develop new analyses with the user-protected database we acquire.

**Regulatory restrictions and requirements**

Since MicrobIQ is not marketed as a medicinal device, it should not fall under regulations by the FDA. The FDA defines a medical device as “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.” Because MicrobIQ is not intended for the treatment or diagnosis of any diseases, and it does not affect the body in a significant way after use, it should not qualify for FDA regulation. MicrobIQ is not designed to test for pathogenic species of bacteria and does not have the technology to differentiate between virulent and non-virulent strains since it only searches for 16S rRNA sequences.

However, MicrobIQ could have its classification changed due to earlier precedent set by 23andMe. In that company’s situation, it filed a De Novo Classification Request to test for genetic diseases such as Parkinson’s and Celiac disease, subjecting it to FDA premarket review. If MicrobIQ were to evolve and land into a similar situation, where the technology would be used to detect gut microbiome related disorders, we would follow in a similar suit to 23andMe. MicrobIQ most closely resembles a medical device, so we would file a De Novo Classification Request for a novel medical device. Since this device is low risk, we would apply as a Class I device, which subjects us to general controls, which are applied to most medical devices on the market. However, the FDA may subject us to special controls, as there is not a predicate device to MicrobIQ, and special regulations may be put in place for our product. The ultimate decision lies with the FDA, so there is uncertainty on how our device will be regulated.

MicrobIQ samples will be sent to a laboratory for NGS genomic testing, but bacteria in the samples could become pathogenic and would count as biohazards. Our laboratories will comply with OSHA standards to reduce the risk of disease transmission. This includes everything listed under the Occupational Exposure to Hazardous Chemicals in Laboratories standard (29 CFR 1910.1450). Since we are based in North Carolina, we will also follow the Clinical Laboratory Improvement Amendments of 1988 as stated by the NC Division of Health Service Regulation to obtain CLIA registration.

**Team Member Contributions**

The team divided up the work into sections, with one team member taking each of the core sections and Stevie Clemens taking the executive summary. The industry description and outlook section was done by [Drashti Mehta](mailto:dmehta12@uncc.edu). The target market section was done by [Thao My Nguyen](mailto:mnguye39@uncc.edu). The competitor analysis section was done by Stevie Clemens. The regulatory restrictions and requirements section was done by Michael Rosenfeld. The compilation of the paper and references was done by Stevie Clemens.

**References**

Brumfield, K. D., Huq, A., Colwell, R. R., Olds, J. L., & Leddy, M. B. (2020). Microbial resolution of whole genome shotgun and 16s amplicon metagenomic sequencing using publicly available Neon Data. *PLOS ONE*, *15*(2). https://doi.org/10.1371/journal.pone.0228899

Dublin (2018). Global $928 Million Consumer DNA (Genetic) Testing Market 2018-2023 with 23andMe, Ancestry, Color Genomics and Gene by Gene Dominating. *Research andMarkets,*from[*https://www.prnewswire.com/news-releases/global-928-million-consumer-dna-genetic-testing-market-2018-2023-with-23andme-ancestry-color-genomics-and-gene-by-gene-dominating-300640236.html*](https://www.prnewswire.com/news-releases/global-928-million-consumer-dna-genetic-testing-market-2018-2023-with-23andme-ancestry-color-genomics-and-gene-by-gene-dominating-300640236.html)

Emergen Research, https://www.emergenresearch.com/. (n.d.). *Gut microbiome test market*. Gut Microbiome Test Market Size | Share | Trend Analysis Report by 2027. Retrieved November 7, 2021, from https://www.emergenresearch.com/industry-report/gut-microbiome-test-market.

Engber, D. (2020, January 13). *Unexpected clues emerge about why diets fail*. Scientific American. Retrieved November 7, 2021, from https://www.scientificamerican.com/article/unexpected-clues-emerge-about-why-diets-fail/.

Greenberg, S. (n.d.). *DIY Microbiome Testing: Market Trends You Need to know-with interview*. DIY Microbiome Testing: Market Trends You Need To Know-With Interview. Retrieved November 7, 2021, from https://blog.bccresearch.com/diy-microbiome-testing-market-trends-you-need-to-know-with-interview.

Guarner, F. (2015). The gut microbiome: What do we know? *Clinical Liver Disease*, *5*(4), 86–90. https://doi.org/10.1002/cld.454

Gupta, S., Mortensen, M.S., Schjørring, S. *et al.,*(2019). Amplicon sequencing provides more accurate microbiome information in healthy children compared to culturing. *Community Biology* (2), 291. https://doi.org/10.1038/s42003-019-0540-1

Gurry, T., HSY Microbiome Consortium, Gibbons, S. M., Nguyen, L. T., Kearney, S. M., Ananthakrishnan, A., Jiang, X., Duvallet, C., Kassam, Z., & Alm, E. J. (2018). Predictability and persistence of Prebiotic dietary supplementation in a healthy human cohort. *Scientific Reports*, *8*(1). https://doi.org/10.1038/s41598-018-30783-1

Himanshu,V and Deshmukh, R (2021). “Weight Loss and Weight Management Diet Market Size, Share,and Trends.” *Allied Market Research,*from<https://www.alliedmarketresearch.com/weight-loss-management-diet-market>.

Laudadio, I., Fulci, V., Palone, F., Stronati, L., Cucchiara, S., & Carissimi, C. (2018). Quantitative assessment of shotgun metagenomics and 16S rdna amplicon sequencing in the study of human gut microbiome. *OMICS: A Journal of Integrative Biology*, *22*(4), 248–254. https://doi.org/10.1089/omi.2018.0013

Mullin, E. (2020, February 20). *The price of DNA sequencing dropped from $2.7 billion to $300 in less than 20 years*. Medium. Retrieved November 7, 2021, from https://onezero.medium.com/the-price-of-dna-sequencing-dropped-from-2-7-billion-to-300-in-less-than-20-years-f5e07c2f18b4.

Psomagen. (n.d.). *Gut microbiome testing at-home: Gutbiome+*. Psomagen. Retrieved November 7, 2021, from https://psomagen.com/delete/gutbiome/.

Razzauti, M., Galan, M., Bernard, M., Maman, S., Klopp, C., Charbonnel, N., Vayssier-Taussat, M., Eloit, M., & Cosson, J.-F. (2015). A comparison between transcriptome sequencing and 16s metagenomics for detection of bacterial pathogens in wildlife. *PLOS Neglected Tropical Diseases*, *9*(8). https://doi.org/10.1371/journal.pntd.0003929

Shreiner, A. B., Kao, J. Y., & Young, V. B. (2015). The gut microbiome in health and in disease. *Current Opinion in Gastroenterology*, *31*(1), 69–75. https://doi.org/10.1097/mog.0000000000000139

Viome. (n.d.). *Gut Health Test Kit*. Viome.com. Retrieved November 7, 2021, from https://www.viome.com/products/gut-intelligence.