VIRAL SPIRAL

Marketing Plan*
I. Executive summary

Viral Spiral (VS) is a biotechnology company based in Taipei, Taiwan. We strive to produce an at-home detection test kit that will decrease the rate of infection, especially during this pandemic. VS has connected with a network of advisors with notable experience in their respective fields and has also established partnerships with factories and supply chain vendors. This will allow VS to advance in the research, development, and commercial fields.

Due to the COVID-19 pandemic, testing is high on demand in many countries around the world. Specifically, in the United States, California has the highest number of cases and deaths, which is why we plan on setting California as our market location. With the lack of test kits the United States has access to, the prices of those test kits become uncertain, making individual citizens hesitant to buy the test kits.

Some test kits already on the market include antigen, antibody, and molecular test kits. Antigen tests detect a specific antigen on the virus; antibody tests detect a specific antibody that is generated by the patients to combat the viral infection; molecular tests are ones that detect the nucleic acid of the virus. These are the three main categories of test kits that are being widely used in the pandemic, and thus effectively are competitors to VS. To put VS into perspective with these test kits already on the market, VS focuses on lateral flow antigen and antibody tests for our market analysis.

Besides being applicable to the detection of COVID-19, VS is also capable of detecting other viruses with known genetic sequences, which would be highly marketable. VS will come in the form of a syringe for saliva collection and purification, with a separate PCR test tube for our padlock probe rolling circle amplification (RCA) reaction. Rolling Circle Amplification is an isothermal method that amplifies target DNA/RNA when a padlock probe recognizes the target DNA/RNA and becomes circularized. The PCR tube will include all the reagents needed to run the RCA reaction. The reagents needed to run the procedure will need to be stored at -20 degree Celsius, so ice packs will be included when shipped.

There is a price range from $23 to $2300 for current test kits. Most test kits, however, fall into the range of $100. VS test kits will be $30 per package, with each package being able to run one test. We believe this is a reasonable price as VS does not require lab-based equipment to run or medical professionals to help interpret results. With VS set at this price, we believe that it will be competitive against current test kits.

VS also intends to collaborate with Formosa Biomedical Company, which is a Taiwanese government-regulated manufacturing company. By having VS made in Taiwan, it increases the credibility of our product as Taiwan has successfully managed to gain control of COVID-19 and has been able to prevent spread locally.

To stress the importance of getting tested during this pandemic, we plan to use digital advertising, social media, and ask media outlets to help get our point across. The reason is to highlight the benefits and reduced risks of testing at home, which allows for the consumer to neglect in person contact. VS plans to
expand our target market to states outside of California after the initial year. As different states follow different regulations, we plan to expand the use of VS one state at a time.

II. Business Description

VS’s management team consists of professionals with years of industry experience. In order to advance pipeline products, VS has teamed up with a network of advisors and consultants in legal, regulatory, business development, and commercial areas, among others. These advisors and consultants are industry veterans with notable experience and expertise in their respective fields. VS has also established long-term partnerships with factories and supply chain vendors. These meaningful partnerships provide the resources and flexibility VS require to rapidly advance an asset from research to development and finally, commercialization.

III. Market Analysis

Current Market Trends/ Situational Analysis

With the outbreak of SARS-CoV virus, there is a constantly high demand for test kits, especially in countries with soaring cases such as the United States and India (Gutiérrez & Clarke, 2020). In these countries, testing is crucially needed to suppress the virus outbreak. Despite the importance of testing, testing is not done for every individual due to several restraints. As our first target market is in the United States, we will perform our situational analysis for the U.S.. For lab-based tests, because of the long procedure involved with getting the test results, the test kits can stockpile in the hospitals, creating a delay in delivering testing results. The materials that are needed to run the test also put a strain on the hospital resource, causing the demand to overload. On the other hand, home test kits have been created, and eight home test kits have currently been authorized in the U.S. (Livingston, n.d.-a).

Another problem for testing in the U.S. is that individuals need to pay for test kits. The U.S. federal government has set aside $1 billion to pay the test kits for individuals who are not insured. However, the unorganized federal system coupled with the complicated billing system in the US causes test kits to have a wide range of prices. Adding onto the confusion, different states have different policies regarding testing (List of Coronavirus-Related Restrictions in Every State, n.d.). With uncertainty regarding the prices, individuals in the U.S. are hesitant to purchase the test kits.

Competitor Analysis

Most test kits currently on the market can be categorized into 3 types: Antigen, Antibody, and Molecular. Antigen test is defined as a test that detects a specific antigen on the virus; Antibody test is defined as a test that detects a specific antibody that the patient’s body generates in response to a viral infection; and Molecular test is defined as a test that detects the nucleic acid of the virus. There are two types of test for antigen and antibody tests respectively: indirect ELISA and lateral flow. As home test kits use antigen/antibody lateral flow tests, we focus on lateral flow antigen/antibody tests for our market analysis. Since different types of test kits vary significantly in their performance and production, we analyze these three general test kit types for our market analysis.
**SWOT Analysis**
We performed a SWOT analysis of antigen test, antibody test, and molecular test, as well as our own.

### Antigen Lateral Flow Test

<table>
<thead>
<tr>
<th>Strength</th>
<th>Weaknesses</th>
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| ● Can test for active infection  
● Typically takes less time to produce a test result than PCR test | ● More likely to produce a false positive → FDA recommends a negative result to be reconfirmed with either another antigen test or rt-PCR test  
● Antigen test has a higher chance to detect other proteins, instead of the proteins of the targeted virus  
● Not a lot of scientific knowledge around antibody tests, which means that the results are less useful and accurate  
● Does not amplify the signal as PCR tests do → require higher concentration of sample for accurate detection |

<table>
<thead>
<tr>
<th>Opportunities</th>
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| ● Need for test kits due to COVID-19  
● Increased education and public awareness  
● Collecting data from social media for marketing advantage | ● Need to go through a series of regulations to put out into the market  
● Complication in distribution process due to substance preservation requirement |

### Antibody Lateral Flow Test

<table>
<thead>
<tr>
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</table>
| ● Easier to develop compared to other tests, making it easier to manufacture  
● Antibody ELISA tests typically can process multiple samples at once.  
● Antibody Immunoassay tests are instrument free, making it more accessible.  
● Antibody can be useful in tracking the spread of the viruses. However, this claim is still mostly debatable  
● Fast testing process | ● Can only identify the virus post-infection.  
● Typically has a lower sensitivity and specificity; makes the chance of getting a false positive and false negative extremely high when the infection is low.  
● Since scientists are not fully sure that the antibodies the tests detect are directly produced in response to the targeted virus infection, there’s a high chance that what the antibody tests detect are not even the targeted viruses, and thus making the information antibody tests provide not as useful.  
● Not a lot of scientific knowledge around antibody tests, which means that the results are less useful and accurate  
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<td>● CDC and FDA do not recommend antibody tests for COVID-19 diagnosis</td>
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<thead>
<tr>
<th>PCR</th>
<th>Weaknesses</th>
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</thead>
<tbody>
<tr>
<td>Strengths</td>
<td>● Medical professional help needed</td>
</tr>
<tr>
<td>● High specificity and sensitivity = accurate results</td>
<td>● Expensive medical equipment</td>
</tr>
<tr>
<td>● Test for active infections</td>
<td>○ Thermocycler</td>
</tr>
<tr>
<td>● Amplify the viral strains = require less viral load</td>
<td>● Reverse Transcriptase limits specificity</td>
</tr>
<tr>
<td>● A lot of scientific knowledge around PCR = PCR results are useful and trustworthy</td>
<td>● Expensive</td>
</tr>
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<td>● “Gold standard”- lots of companies use PCR</td>
<td>● Limited laboratory resources</td>
</tr>
<tr>
<td></td>
<td>● Could create delay in testing process</td>
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<tr>
<th>VS</th>
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<tbody>
<tr>
<td>Strengths</td>
<td>● Limited mass production</td>
</tr>
<tr>
<td>● Convenient -home based- no need for medical professional help and equipments</td>
<td>● Not quantitative</td>
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<tr>
<td>● Result is colorimetric, easy to interpret results</td>
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<td>● Fast, results under 2 hours</td>
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<tr>
<td>● In a portable kit, can be distributed easily</td>
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<td>● Prevent the need for in-person contact</td>
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<td>● Direct RNA-targeting increases specificity</td>
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<td>● Room temperature isothermal reaction</td>
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<tr>
<td>● High versatility- can design the RCA to target different viruses</td>
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<tr>
<td>● Connections established with hospitals</td>
<td>● Product might be labelled as “biohazardous”</td>
</tr>
<tr>
<td>● National Taiwan University hospital offers to collaborate with VS in</td>
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Market segmentation

VS’s product is designed to be applicable to all individuals who are experiencing virus-like symptoms or who want to confirm if they have been exposed to viral infection. Individuals over the age of 18. Though SARS-CoV-2 is a global pandemic, since the United States currently has one of the highest climbing infection rates (Gutiérrez & Clarke, 2020), the United States is VS’s target market, but the test kit can be marketed anywhere applicable.

With FDA having authorized eight home test kits as of October 2020, representing a growing market for home test kits, the United States stands as an ideal market for VS’s home-based test kit (Livingston, n.d.-b). Home test kits allow the individual to test whether he/she has a viral infection without having to do doctors’ visits, which could potentially result in infection. VS’s test kit further enables the user to immediately get the results so that he/she can get early treatment and lower the chance of developing later complications. On top of these benefits for the user, by being a completely at-home test kit with no need for lab-based equipment or medical training, VS’s test kits could help relieve the strain on hospitals caused by the surge in coronavirus cases. Besides being applicable for detection of SARS-CoV-2, VS’s RCA technology can be applied to other viruses with known genetic sequence, making VS’s test kit highly versatile. Considering all these factors, we conclude that VS’s test kit would be highly marketable in the United States with demands from both non-medical and medical populations.

Within the United States, as there are different state laws regarding test kits, we decide to target the state of California first due to several factors. In terms of the severity of SARS-CoV-2 infection across the states, California currently has one of the highest climbing infection rates, thus generating a high demand for test kits. In addition, the California state government has a high incentive for buying test kits (What to Know About California’s Coronavirus Testing Expansion - The New York Times, n.d.). The California state government, to allow the multiple businesses to reopen, has been active in expanding testing capability in an attempt to suppress infection. Not only just testing symptomatic people, the state government also stresses the importance of testing asymptomatic people (What to Know About California’s Coronavirus Testing Expansion - The New York Times, n.d.). Besides the government's active effort in pushing for testing, which increases the target market size and creates a possible collaboration of VS with the state government, California also has a population that is able to afford buying test kits. California's high Asian population means there will be a guaranteed source of buyers for VS’s test kits, considering that Asians generally have been more vigilant in terms of Covid prevention and testing (COVID-19 Deaths Analyzed by Race and Ethnicity, n.d., p. 19). Thus, we think that California would be the model market for VS’s test kit.
IV. Marketing Program

Product

As of October 24th, COVID-19 has caused 1.1 million deaths across the world, with 218 K deaths alone in the U.S (Coronavirus Update (Live), n.d.). A big problem across the test-kit market is that the antibody and antigen rapid lateral flow tests are not sensitive enough to test for accurate results. This leads to the identification of false positives and false negatives which could create strain on the limited resource hospitals have. PCR tests are currently the gold standard due to its high sensitivity and specificity. However, PCR requires trained professionals and specialized medical equipment to operate. As we have seen with the COVID situation, this could also put a huge strain on medical resources and create a delay in the testing process.

With more than 75% of our 2000 surveyed population expressing support for home test kit, VS decided to develop home test kit. In March, the U.S. Food and Drug Administration (FDA) approved the first home test kit developed by LabCorps (Commissioner, 2020), allowing for sample collection done at home, which was previously disallowed by the FDA (“Updated FDA COVID-19 Testing Guidelines Specifically Disallow at-Home Sample Collection,” n.d.). With the unfolding of COVID-19 pandemic, the FDA also expresses support for telehealth, health services that incorporates technology for patients to be able connect with medical personnel over long distances, to help enforce social distancing (FDA and CDC Promote Telemedicine during COVID-19 Outbreak - Regulatory, 2020). With this trend, we believe that the development of home test kits would be beneficial to both patients and medical facilities, as well as generate a high demand.

VS’s product is a detection device that will come in the form of a syringe for saliva collection and purification, with a separate test tube for the RCA (rolling circle amplification) reaction. To allow the consumer to easily administer their own home test kit, the saliva collection syringe will have all testing reagents needed for RNA purification prefilled for immediate use. The PCR tube will also include all the reagents needed to run the RCA.

We use RCA (rolling circle amplification) to detect the presence of virus RNA. Rolling Circle Amplification is an isothermal method that amplifies target DNA/RNA when the designed padlock probe recognizes the target DNA/RNA and becomes circularized. We have done studies regarding the use of RCA, and have chosen to implement it as a huge part of our project because of RCA’s instrument free nature and its ability to amplify RNA and DNA.

We have consulted National Taiwan University (NTU)’s Molecular Biology professor and lead epidemiologist, Dr. Sui Yuan Chang, regarding our use of RCA in our test kit. Dr. Chang confirmed that the test kit should be molecular-based. We also talked with Dr. Wen Jian Chou, the head of NTU hospital’s Department of Pathology, who offered that NTU hospital could collaborate with VS in developing our RCA technology. In addition, we talked to another professor from NTU’s Molecular Biology department, Huang Fore Lien. He validates our approach with RCA by describing it as a “powerful, simple and cheaper diagnostic method for a variety of RNA viruses including SARS-COV19, H1N1pdm09 and Influenza B Victoria lineage.” With these experts’ validation of our technology, we are confident in using RCA for our test kit.
Packaging

VS’s product is a detection device that will come in the form of a set for a specific target virus. The set contains a syringe for saliva collection and purification and a separate test tube for RCA reaction. The syringe, specially designed by VS, contains all the reagents needed for extraction of RNA from the collected saliva. The syringe has three parts in total: the plunger, the barrel with the special mouthpiece, filter, and stopper. All parts of the syringe will come in an assembled form with the reagents solution in the barrel. As for the test tube for RCA reaction, the tube will contain a solution mixture with everything necessary for the RCA reaction, including but not limited to the DNA probes, phi29 DNA Polymerase, and SplintR ligase. As the reagents need to be stored at -20 degree Celsius, ice packs will be included in the set when shipped or taken out of ideal stored condition.

Figure 1: CAD model for VS’s saliva collection/purification device. The plunger, the barrel, and the stopper (in red) are shown

(Livingston, n.d.-b)

Figure 2: Example of what VS’s collection device would look like

To prevent liquid spillage, the assembled syringe and the RCA reaction tube will be wrapped tightly with plastic and placed in a styrofoam rack. A detailed procedural manual for how to run the experiment and discard the sample will also be included. Then, every component will be packaged in a 15x5x3 box with clear labeling on the box.
As the sample is a possible source of biological hazard, the procedural manual will include detailed plans regarding how to discard the sample. The set will include biohazard ziplock bags and other materials needed for discarding the sample after use. As the used test kit is considered to be biohazard waste, the manual will come with instructions regarding how to correctly throw away VS after use. There are three steps to which customers should follow with the disposal of VS. The customers should first put VS in a disinfecting solution for three hours, wash VS thoroughly with soap and water, and lastly microwave the device to ensure safety (Disinfection Technology and Strategies for COVID-19 Hospital and Bio-Medical Waste Management, n.d.) Since no elements in the VS package is biologically hazardous, the package label does not need to follow CDC’s guideline of biologically hazardous objects (CDC LC Quick Learn: Recognize the Four Biosafety Levels, n.d.).

**Pricing**

VS’s test kit will be priced at $30 per package.

With the widespread reach of the test kits, there are a lot of factors to be considered for pricing VS’s test kits. In the United States, the current price for test kits ranges from $23 to $2300. However, New York Times found that most test kits are around $100, with the $1000 to $2300 range test kits being outliers (Kliff, 2020). Still, the price of $20 to $100 for test kits is still a wide one. To determine where VS’s test kit price lies on the spectrum, we looked into the reasons for the wide range of prices.

One reason is the fact that the three different types of test kit vary in the amount of resources needed to produce and run the test as well as the difficulty in producing the test kits. As different test kits target different sites of the virus, antibody tests are the easiest to invent, with antigen following, and PCR test being the hardest. In addition, antibody and antigen tests do not require lab-based equipment and medical knowledge to run while PCR tests can only run in a lab setting. Thus, antibody and antigen tests are usually priced between $20-$50, and PCR tests priced between $60 and $300 (Covid-19 Tests: Answers on Cost, Accuracy and Turnaround Time - WSJ, n.d.). Although VS’s test kit is molecular based like PCR, VS’s RCA reaction does not require lab-based testing, which takes away a lot of the price makeup for PCR tests. Meanwhile, as molecular tests are more specific and sensitive than antibody and antigen tests, we decide that VS’s test kit can be priced higher than the cheapest antibody test at $20. Adding onto the consideration is that our current home test kits are priced from $100 to $150 (Livingston,
n.d.-b). We price VS’s test kit to be at $30, which is 70% lower than most test kits. We believe that, with this price and the integrity of our product, VS’s test kits are competitive against other current test kits.

Having set a price for VS’s test kit, we also considered the fact, in the void of an organized federal support system for testing and the existing problem of American billing system (Kliff, 2020), different state governments offer different degrees of financial support in covering the cost of getting a test kit, which results in price variation of test kits in different states. We picked the state of California specifically for its government’s support in covering test kit costs. The price of $30 for VS’s test kit includes the consideration of VS getting a subsidy from the California state government, which will be further discussed in the “Distribution Strategy” section and “Challenges and Solutions” section.

**Distribution Strategy**

VS intends to partner with a Taiwan-based, government-regulated manufacturing company and marketing company for the test kit distribution. VS would be in charge of the research development of our RCA technology. The manufacturing company, such as Formosa Biomedical Company, would produce and assemble the test kits in Taiwan with the protocols that VS has given, and outsource the test for outside quality control. As Taiwan has a provenance in the biomedical field, VS’s test kits being made in Taiwan increases the credibility of our product (*Taiwan Emerges as Pioneer in Strengthening Global Healthcare*, n.d.). Once the quality of the test kits is validated, the marketing company would distribute the kits to the California government in a potential partnership.

As we believe that our test kits will have a widespread application, VS aims to make the test kits as commercially available to the buyers as possible by partnering with California’s state government. The California government has been active with promoting and expanding testing. In August, California state government formed a new partnership with PerkinElmer in the effort to expand testing (*What to Know About California’s Coronavirus Testing Expansion - The New York Times*, n.d.). With this partnership, the PerkinElmer test can be priced as low as $31. We could follow PerkinElmer’s model for our test kit.

Considering the buying power and support of the California government, we believe that the California state government could sufficiently subsidize VS’s test kit and make the test kit to be able be priced at our ideal price of $30. Through the Californian government, VS’s test kits can be distributed to medical facilities.

**Promotional Strategy**

In collaboration with a marketing company, VS will primarily promote our product through the California state government to medical facilities, where people might be the most attentive to medical news. To spread our VS test kit, with California’s government’s certification, we also plan to incorporate digital advertising, social media, and ask media outlets to help advertise our product. We strive to emphasize the importance of test kits and getting tested, especially during this pandemic. The purpose of this is to encourage self-testing and highlight the reduced risk of testing at home, as there is no need for in-person contact. VS and test kits in general allow the infection rate to be decreased, as people will be more aware of the circumstances and quarantine themselves properly if they tested positive. Some places we can distribute information brochures about VS would be clinics, universities, pharmacies, and
convenient stores. This can potentially increase our market size and allow consumers to learn about VS and the impacts it can bring.

V. Financial Landscape

The price positioning of VS’s test kit is currently at $30 based on our price analysis of the current test kit in the “Price” section. Based on this price positioning, we believe that enough people will buy VS’s test kit.

As VS’s RCA technology is still at the prototype stage, we are currently unable to do a Profit and Loss statement for VS’s product. Detailed commercialization of VS’s test kit will need to be made before VS can do an accurate Profit and Loss statement. However, based on the integrity of VS’s test kit and the potential to collaborate with the California state government, we trust that VS will make a profit.

VI. Challenges and Solutions

Product Certification

VS will have to be verified and approved by FDA before going into the consumer market. However, EUA (Emergency Use Authorization) allows VS to be passed at a faster rate, since the global pandemic elevates the situation at hand and effectively makes it an emergency for test kits to be in use.

Distribution Expansion and Pricing In Different States

We plan to expand our target market to other states in the United States after the initial 12 months of this marketing plan. As there are different regulations within each state and US health care prices are unregulated, opaque, and unpredictable, the distribution method and the pricing of test kits in each state will be different (Kliff, 2020). We will tackle this problem by expanding our test kit distribution one state at a time. By collaborating with state governments like we plan to with the California state government, we could better alleviate the problem with the faulty billing system in the US to ensure an affordable price of VS’s test kits in each state.
References


