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The Missing Piece in the Fight Against the Pandemic is Finally Here:

The Evolution of Screening for COVID-19

by Dr. Mesfin Meshesha

OPTEEV™

Early Tools to Fight the COVID-19 Pandemic

Since the emergence of the novel corona virus (COVID-19) in Wuhan, China, around the end of 2019, the outbreak has developed into a pandemic and continues to present all kinds of health, economic and social challenges to humankind. A pandemic of such magnitude was only seen 100 years ago in 1918, which is commonly known as the 'Spanish flu'. Between now and then, we have made tremendous advances in science and technology; we have developed sophisticated healthcare infrastructure and stocked an array of armaments in our public health toolbox that include complex public and private laboratories equipped with sophisticated PCR and sequencing technologies and a repertoire of computational tools together that help track the pandemic and generate essential epidemiological data for strategic policy making. In addition to tools to track the trajectory of pandemics, we also have developed the capacity to make antivirals and vaccines at a record time. And yet, COVID-19 is still ravaging the globe, the death toll stands at a staggering 6 million people, and total cases have surpassed a half billion people.

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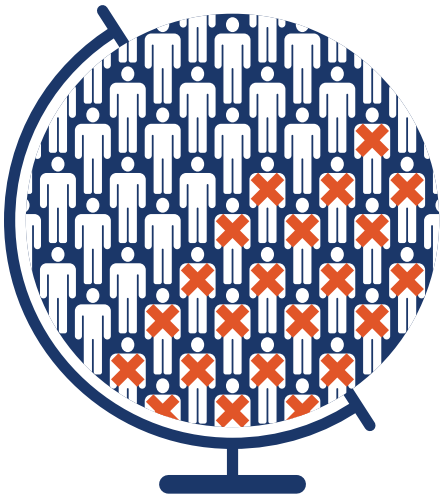
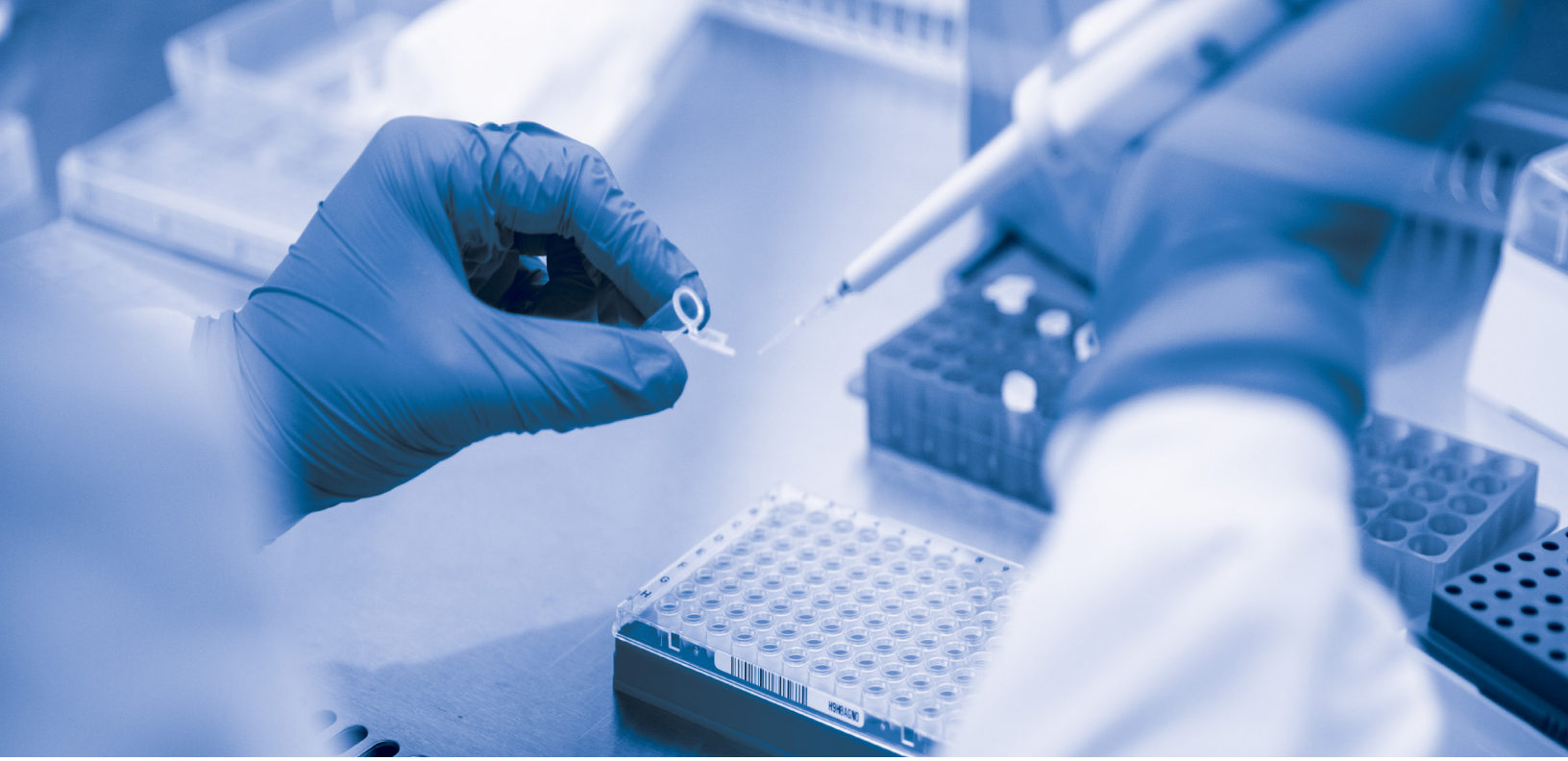


In the US alone, nearly a million people have died of COVID-19, a number close to double the size of people who died of flu one hundred years ago. So, what went wrong? **The purpose of my commentary** is not to address the entire problem in the fight against the pandemic but **to investigate and indicate solutions to what is missing in terms of diagnostics and screening that could have prevented some of the restrictions and lockdowns we had gone through and, perhaps, could have prevented some of the deaths, suffering, and economic setbacks.**



Eye Opening Moment

In early January 2020, the first draft genome sequence of SARS-CoV-2 was published in virological.com by Chinese researchers. In the following several days and weeks, a number of laboratories in different countries and organizations including the CDC developed polymerase chain reaction-based diagnostics for detecting the new virus. Multiple biotech companies such as Thermofisher prepared commercially available COVID-19 detection RT-PCR assays. Regardless of the rapid response to testing and tracking the pandemic, the supply of testing kits was not anywhere near the demand. Infrared thermometers were used almost everywhere including in hospitals and doctor's offices to screen for possible contagious people through elevated body detection. It was an eye-opening moment for companies like Opteev to search for new disruptive innovations in the areas of diagnostics and screening devices to fight pandemics.

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Current Screening/Diagnostic Tools and Their Limitations

RT-PCR

RT-PCR is a very good diagnostic tool. It identifies unique features of the virus in its genetic material, namely, the RNA of SARS-CoV-2. The method is very sensitive in that it can detect even a few copies of the virus present in a nasal swab sample. The average copy of virus in a nasal swab sample of an infected person is exceptionally higher than the sensitivity of RT-PCR. RT-PCR test is also highly specific. It can discriminate between different variants or sub variants such as the BA.1 and BA.2 subvariants of the omicron variant if properly designed.

During COVID surges, the **wait time** to receive a PCR test ranged from a **few days to over a week.**

Another advantage of a PCR test is that it has high throughput. It is possible to test up to 384 samples in a single run and multiple runs per day using a single PCR instrument; however, PCR also has limitations in its use. Operation of the system requires highly trained personnel. It needs expensive instrumentation and a long procedure that can possibly go wrong at any step. PCR is not a test for self-use and point of care diagnostics. Therefore, it leaves a large gap in terms of covering the level of testing required to fight the pandemic.

The major limitation of PCR in the fight against the pandemic is time: the time it takes to schedule a PCR test and the time it takes to receive a PCR result. During COVID surges, the wait time to receive a PCR test ranged from a few days to over a week. The time it takes to receive a result is usually 1 to 2 days, but during peak COVID surges could take even longer. When waiting to schedule a test of this nature and awaiting a result of infection, time is certainly of the essence.

Antigen Test

Another great diagnostic that can be used at home and as a personal screen is the antigen test, which is also known as a rapid test or quick test. These tests work by identifying a certain protein that is unique to SARS-CoV-2 using specific antibodies. The turnaround time for antigen test is about 15 to 20 minutes. Antigen tests are very specific. It is unlikely that you will get a false positive result; however, antigen tests are not very sensitive, which creates the potential for a false negative result. The best antigen test, so far tested, has a sensitivity of 82% according to some studies. In actuality, the sensitivity of these tests is much lower because the procedure is multi-step and prone to user error. A self-nasal swab is not a pleasant procedure and people tend to just scrub the tip of their nose for a sample, which can also result in a false negative.

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Antigen tests may, also, not detect all variants or new emerging variants. Recently the FDA warned that several types of rapid tests failed to detect the Omicron variant, resulting in false readings. This is because antigen tests seek out, and grab ahold of, specific proteins on the outer shell of the virus particle. When a mutation occurs, the resulting variant can have altered proteins that differ from the specific proteins that the test was designed for, causing a false negative result.

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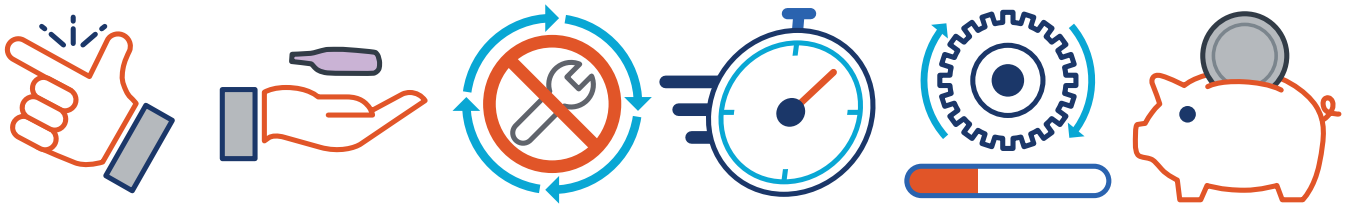
A false negative result can be very dangerous because it informs the user that they are not infectious when, in fact, they are infectious and can lead them to potentially infect others with their false sense of confidence. Another limitation of antigen testing is that an individual is not apt to use it multiple times during the day due to the lack of simplicity in performing the test as well as the time it takes to wait for a result. **Performing an antigen test requires a multistep operation that needs to be done on a flat surface and is not easy to use while someone is conducting their routine activities throughout the day.**

In addition, 15 to 20 minutes of waiting for a result prevents a busy individual from performing the test every time they enter a new indoor area during their busy day. Cost is also a factor that limits multiple usage throughout the day. Even with government subsidies, frequent antigen testing throughout the day is just not feasible from an affordability standpoint.

The Ideal Screening Device

An ideal personal screening device must fulfill the following. It must be very simple to use so that anyone can do it correctly. It should not be a multistep procedure where an untrained user could make a mistake at any of the steps such as procuring a sample through a nasal swab or creating a component of the test by adding a buffer or other reagents. It should also be portable, small, and accessible for use as needed, such as something you can carry in your pocket or handbag or even a wearable device. Portability and accessibility are imperative so that it can be used as you move around and make multiple stops to see people in your daily activities. An exposed person can start breathing out viruses at any time given enough incubation period. Access to such a portable personal device can give you a superior advantage to test yourself and protect your loved ones, while a wearable or personal space protector can protect you by notifying you of the presence of a contagious person in your vicinity.

Key Takeaways



Should be very easy to use.

Should be portable.

Should work multiple times without the need to replace parts.

Results should be quick, within a minute or two.

Should not have to be reprogrammed for new, emerging variants.

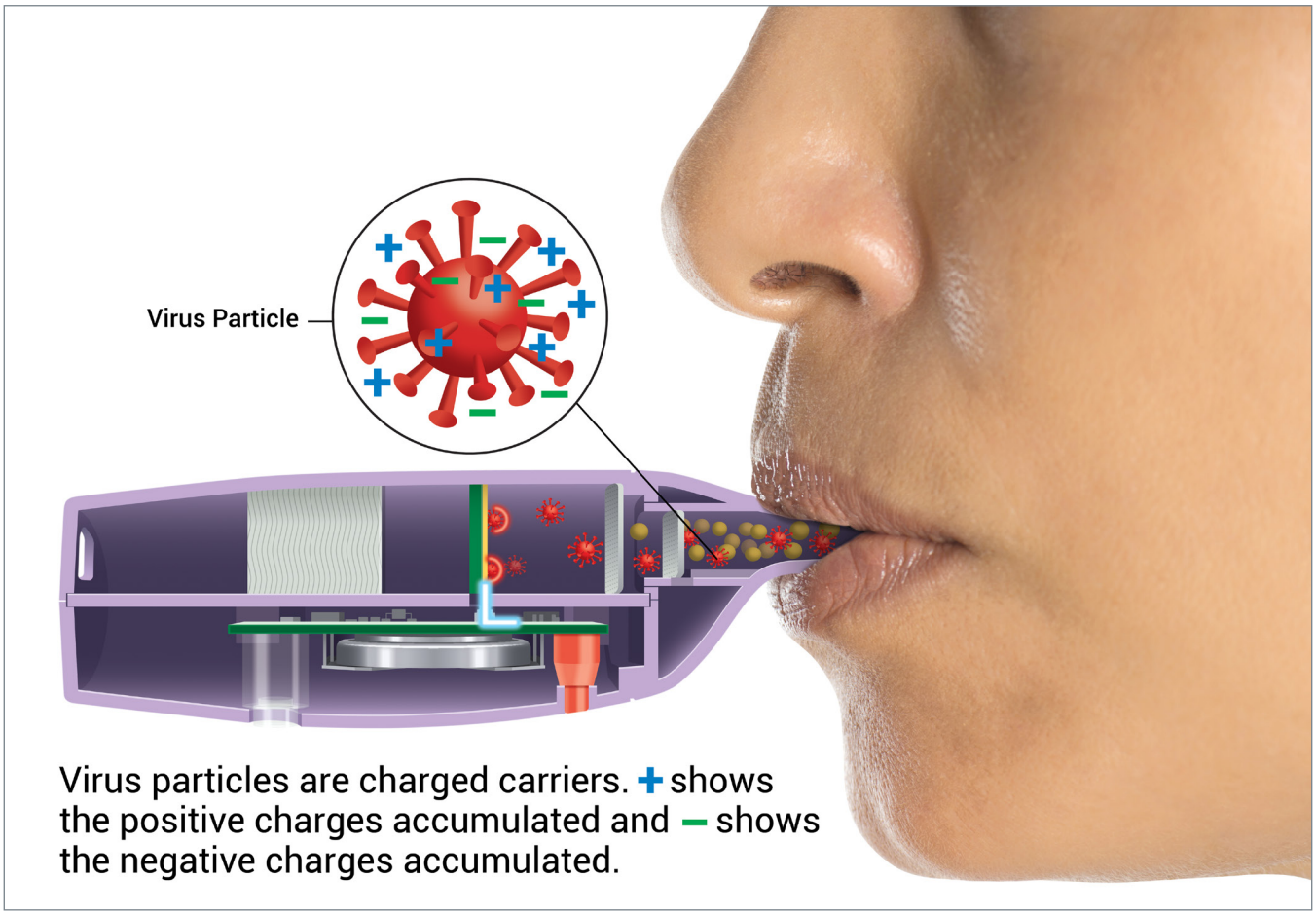
Should be inexpensive, so that everyone can have access to it.

Another important feature of a personal screening device is that it should be designed to be used multiple times as needed without the need to replace parts so that you can continuously monitor your personal space and yourself. The results should also be available as quickly as possible, such as within a minute or two so that people won't be discouraged to continuously monitor because of longer waiting time for the results. It should also not have to be reset or reprogrammed for new, emerging variants.

The ability for a screening device to be variant agnostic is very important as new mutations are frequently occurring. It would not be ideal to have a screening device that is effective one week but then does not detect infection the following week. Finally, it should be inexpensive so that everyone can have access to it which consequentially benefits efforts to control transmission of the virus in your community.

Creating the Next Generation of COVID Screening Devices

Opteev was born out of necessity from its sister companies that have extensive experience in sensor technology for various engineering applications. When the pandemic hit hard in early 2020s, Opteev set out to develop electrical biosensor based instantaneous screening devices to help the fight against the COVID-19 pandemic. Opteev took advantage of semiconductor-based biosensors and the nature of viruses as charge carriers. Viruses have genetic material made of nucleic acids, DNA or RNA wrapped in protein cover. SARS-CoV-2 has an RNA genome. Nucleic acids have a partial negative charge because of their phosphodiester bonds and the protein coat is made up of amino acids that can be neutral, negative, or positive in charge. Therefore, the net charge of the virus is the cumulative charges of the genetic material and the protein. The interaction of the virus with a specially designed liquid semiconductive medium or a solid polymer semiconductor generates changes in the conductivity of the electrical biosensor which can then be picked by electrodes. Such electrical data can be analyzed using algorithms to decide threshold values and make a positive or negative call.



Virus particles are charged carriers. + shows the positive charges accumulated and – shows the negative charges accumulated.

ViraWarn Plus – Available Now

Applying this technology, Opteev has developed several ViraWarn™ screening devices. ViraWarn Plus is based on a specially designed liquid conductive medium, which, upon interaction with the virus, generates fluctuation in conductivity. The fluctuation in the electrical properties of the semiconductive medium is collected by electrodes and data is processed by Edge Artificial Intelligence algorithms to determine detection of the virus. **ViraWarn Plus is used to monitor one's personal space such as at your desk at work or on your coffee table/dining table at home. It is also a great screening tool to have near clerks who interact with many people in a day at close distance.** ViraWarn Plus has been independently tested, both in laboratory conditions in the US and in hospital wards in India, and has been demonstrated to work at a near 100% accuracy.

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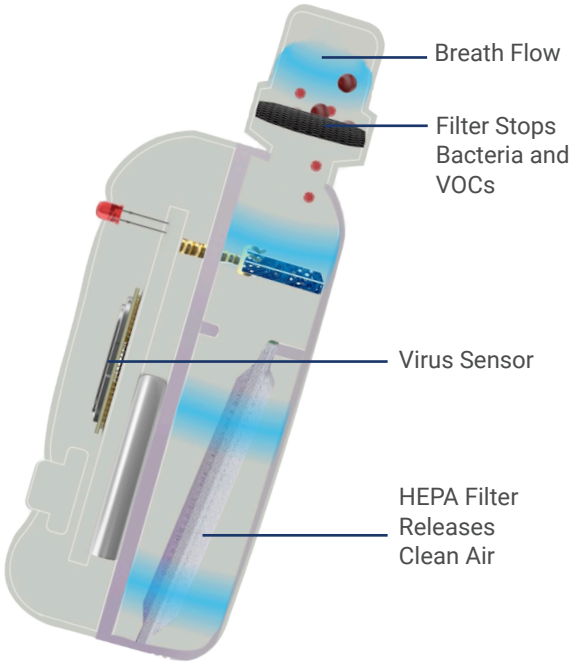
ViraWarn Plus is currently available to purchase on Opteev's website at **www.opteev.com.**

ViraWarn – Coming Soon

ViraWarn is the first breathalyzer screening device for COVID-19 that uses a semiconductive polymer biosensor. Breath is one of the most non-invasive sample types and is also extremely easy to provide. Your breath contains biomarkers that can identify different ailments including volatile organic compounds (VOCs), viruses, bacteria, antigens, and nucleic acid. ViraWarn is small, fits in the palm of your hand, is portable and can be used multiple times as required. It is an incredible tool that gives you the freedom of mobility in such risky pandemic times. With ViraWarn, you can check yourself before you walk into your home, before or after work, or when you visit your friends, loved ones, or high-risk people. The results are available instantaneously which encourages people to frequently monitor.



Your breath contains biomarkers that can identify different ailments including volatile organic compounds (VOCs), viruses, bacteria, antigens, and nucleic acid.

ViraWarn Clip – Coming Soon

ViraWarn Clip is the first wearable COVID-19 screening device that easily fastens to your shirt or jacket like a pin and monitors for coronaviruses in your personal space. Similar to ViraWarn, ViraWarn Clip uses a solid conductive polymer biosensor with enhanced filtration systems to remove moisture, electrolytes and particulate matter from entering the biosensors. The conductive polymer is func-tionalized with an organic layer that immobilizes viruses and, upon binding, alters the electrical property of the conductive polymer. That generated electrical data is used to determine the detection of COVID-19 or Flu virus. ViraWarn Clip is designed to alert a person of exposure within one's personal space, such as in situations when you are having conversation with someone at close distance.

Besides providing ultra-fast detection and being affordable, convenient, discreet, and extremely easy to use, ViraWarn, ViraWarn Plus, and ViraWarn Clip are all variant agnostic. This means that all three of these devices do not need to be reprogrammed, reset, or recalibrated to detect new and emerging variants. ViraWarn and ViraWarn Clip are currently involved in clinical trials and will be available to purchase soon. To reserve your ViraWarn Clip or ViraWarn device you can sign up for the reservation list here: https://opteev.com/reserve-now/. ViraWarn Plus is available to order now.

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To get email updates on **ViraWarn** and **ViraWarn CLIP** release dates, sign up here at **www.opteev.com**. **ViraWarn Plus** is available to order now.

Shifting to a 'Screen to Test to Treat' Initiative

President Biden announced a plan for the next phase of pandemic response during his State of the Union address in March, **which focuses on a 'Test to Treat' program to allow for easier treatment options for people infected with COVID-19.** The program has been established at pharmacy-based clinics, health centers, assisted living and long-term care facilities and Department of Veterans Affairs facilities. **This program is a great step towards providing quicker treatment options for infected individuals but does not solve the root problem, which is COVID transmission in the first place.**

It can take anywhere from 36 hours to 6 days to become symptomatic with COVID-19 and many individuals never even become symptomatic. This means that the majority of infected individuals are spreading COVID-19 unknowingly for extensive periods of their illness. Opteev's remarkable innovations are designed to target the root cause of the pandemic, which is human-to-human transmission. Even with all the tools in the public health armament, it has become clear that **the only way to truly reduce the spread of COVID-19 is through normalizing frequent screening** in addition to normalizing the use of wearable passive monitoring devices.

Normalizing Frequent Screening

If every American can pull an affordable, multi-use screening device from their pocket and discreetly screen themselves prior to entering an indoor space, then we can drastically reduce human-to-human infection nationwide, which typically occurs indoors. Adding a wearable monitoring device to each of those individuals will reduce the rate of infection even further.

Normalizing frequent screening could turn an unpredictable pandemic that is currently ravaging the world into an amenable endemic. This is why **shifting to a 'Screen to Test to Treat' program is so important.** Frequent screening with Opteev's new products will offer the potential to catch the virus before it has a chance to infect others. After receiving a positive result from ViraWarn or ViraWarn Plus, the user should then confirm whether that infection is caused by COVID-19 by taking a PCR test or antigen test but will know that they are infected with coronavirus and can take the necessary precautions to not infect others.

Currently, the majority of people only test themselves if they are symptomatic, have been exposed to a known infected individual, or are forced to for travel or to attend an event. For this reason, COVID-19 is able to spread even easier. Catching the virus early on through frequent and convenient screening is imperative in the fight to turn the pandemic into a manageable endemic and we finally have the means to achieve this with Opteev's ViraWarn Plus and ViraWarn.

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Screen Test Treat

ViraWarn and **ViraWarn CLIP** are not yet approved for sale and the details contained in this Whitepaper are for information purposes only. Sign up for email updates on these products at **www.opteev.com**. **ViraWarn Plus** is currently available to order and can be purchased at **https://opteev.com/virawarnplus**.

About Dr. Meshesha

Dr. Mesfin Meshesha is the Head of Virology and Diagnostics at Opteev Technologies and oversees the multiple subgroups of Opteev's Virology Department, pathogen research, and molecular diagnostic technology development. Dr. Meshesha received his PhD from Ben Gurion University in Israel and was a Postdoctoral Research Fellow at The Johns Hopkins University. As an expert in RNA viruses, Dr. Meshesha was integral in developing the remarkable ViraWarn technology.

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