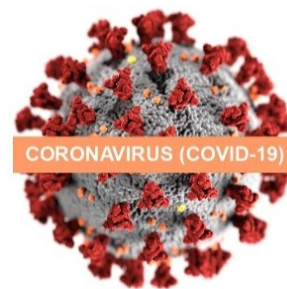




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E25Bio has developed and preparing to bring to market a Paper-based Lateral Flow Antigen Test Strip for Detecting Active COVID-19 Infection faster, simpler and cheaper than today's Gold Standard



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Interview conducted by:
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CEOCFO: *Dr. Herrera, what is the vision behind E25Bio today?*

Dr. Herrera: The vision of E25Bio is to make outbreak prediction a reality, such that we are able to identify an outbreak before it ever occurs. The way that we envision accomplishing this is by rapid detection of infectious diseases using affordable, rapid diagnostics that are digitally integrated to the cloud.

CEOCFO: *When did the concept start?*

Dr. Herrera: The vision started with three of our co-founders; myself, Dr. Herrera, second, Dr. Irene Bosch, and third, Dr. Lee Gehrke. These three co-founders have spent and dedicated their professional careers to the study of infectious disease immunology and how to mitigate viral outbreaks throughout the world, and particularly in low resource regions. In the case of Dr. Irene Bosch and Dr. Herrera, executives at the company, we started developing technologies to diagnose infections early, and as fast as we could. While at MIT and Harvard, we developed these rapid diagnostic tests in such a way that they require no moving parts and no machinery. Our paper-based tests are similar to pregnancy tests and provide visual results in 15 minutes or less. You apply a small input of blood or in the case of coronavirus, a respiratory sample, such as a Nasopharyngeal swab (NP), and then in a matter of ten to fifteen minutes you have a result. You are able to see it by eye just like a pregnancy test and that either indicated are positive (with the presence of a visual band on the test) or you are negative (absence of the band).

CEOCFO: *What is the typical way of diagnosing viruses? How does your approach differ? What is the science that enables the rapid test?*

Dr. Herrera: The current standard of diagnosis and the gold standard is a methodology called PCR or Polymerase Chain Reaction. Polymerase Chain Reaction is a very specific way of diagnosing infectious diseases and that is detection by nucleic acids. However, while it is quite specific and sensitive, it also has a lot of setbacks that we are witnessing today with regard to the coronavirus pandemic. One is that it is not affordable. It costs anywhere from one hundred to three hundred dollars per patient. And it is not scalable. You can typically diagnose one hundred to five hundred at a single facility per day. Also, it requires logistical support. It requires an extraction of sample out of the human body, extraction of RNA in pristine condition and then you need a trained technician or a trained experimentalist to do the experiment on a machine that requires power. Therefore, this is not applicable and it is not tenable in low resource regions such as those where we work in Africa and Latin America. Even in developed countries, like the United States, we find ourselves in a tricky situation.

Because we realized that early on, part of our goal was then to develop something that was much simpler than the current gold standard. We sought to miniaturize that type of technology into a paper-based lateral flow test strip. The way that we did that was by developing molecules known as monoclonal antibodies. These monoclonal antibodies are sort of like hooks at the end of a fishing rod. Those molecules are the ones that actually recognize viral targets - the virus itself. Or when you are infected with the virus; the virus produces proteins that are secreted into bodily fluids. Our monoclonal antibodies can detect those viral proteins.

Part of the technology at E25Bio is the development of these monoclonal antibodies, but then moreover, identifying, through a high throughput screening methodology, the best antibodies with the highest sensitivities and specificities for the virus or the viral proteins. Once we have identified these antibodies, then we apply them to development of these lateral flow tests that resemble pregnancy tests, that fit in the palm of your hand, that gives a visual readout in fifteen minutes or less, and that makes diagnosis much faster, simpler, and cheaper.

CEOCFO: *Have similar approaches been tried?*

Dr. Herrera: Similar approaches have been tried. There are many, many paper-based lateral flow tests that detect something else, what we call human antibodies. When a person is infected by a virus, you are acutely infected for 5-7 days at which point you are able to be diagnosed by PCR or an antigen-based tests, like those produced by E25Bio. However, after 7 days, your body's immune system produced antibodies that can neutralize or kill the virus. There are rapid diagnostics to diagnose the convalescent phase of infection. These tend to be less specific.

"The vision of E25Bio is to make outbreak prediction a reality, such that we are able to identify an outbreak before it ever occurs."- Bobby Brooke Herrera, PhD

At E25Bio, our bread and butter, what our proprietary technology really aims to do, is to provide rapid detection of acute infections. We are among the few companies around the world that have been able to prove ourselves to create products to diagnose active dengue infection, active Zika infection, active Chikungunya infection and now, in record timing, we produced a test to detect active coronavirus infection.

CEOCFO: *Where is that test today? What is happening right now?*

Dr. Herrera: I want to step back, just to illustrate the power of E25Bio. There was a mysterious respiratory illness that was brought to the world's attention in December, late 2019. By January 30th, the World Health Organization deemed the current epidemic a public health emergency of international concern. That is when E25Bio decided to turn on its engines and to find the best monoclonal antibodies that recognize this virus and in a matter of two weeks, we had a paper-based antigen test for detection of active COVID-19 infection.

In order to validate that test you have to do a couple of things; one is the make sure that it works in your lab, in the E25Bio lab. However, we then sent the test off and we first asked the question, "Does this test pick up virus, meaning SARS-CoV-2. An independent lab confirmed that our test detects the novel coronavirus. Great! Next! Does it actually pick active viral infections? Working with top academic hospitals in Boston, we are now starting to validate the test on human samples. All of our data thus far has suggested that we are in the high sensitive and high specificity range. That means that we are able to detect people when they are infected and when people are not infected.

Now that we have established ourselves, both in the laboratory as well as clinically, we are now transferring our technology to our manufacturers. This is part of the beauty of our type of technology; these tests are scalable. We hope to scale to production of 150,000+ per day by end of April and early May, such that we can distribute as many tests across the United States as well as across the world, to help the current testing situation.

CEOCFO: *How will the recent funding help you do that? What are the barriers, even in the situation that we all find ourselves in today, to having people pick up on it as there may be many people claiming they have things that will work but do not?*

Dr. Herrera: The funding be being used on scale up. I had mentioned that we are now at a phase where we are transferring our technology to our manufacturer. That is where they are able to produce hundreds of thousands of tests per day. In order to do that it requires a significant amount of capital. Therefore, we are using our resources to bring in

all of the necessary components that go into high scale production of these lateral flow tests. In addition to that, we continue to perform research in our laboratories, such that we can improve our results over time.

CEOCFO: *So many people are coming up with ways to test. How do you stand out so that E25Bio receives the attention you deserve?*

Dr. Herrera: There are a couple of ways. One; I do not want to discourage any types of technology. PCR technology is great technology, antigen-based technology is great technology and human antibody detectors are also great technologies, but they are all used in different situations. However, what I will say is that E25Bio produced antigen-based diagnostics. Our tests are scalable and affordable. Therefore, our technology allows us to reach the masses very quickly. Second; An antigen-based test can actively be used in the hospital for triage. That means that because our test results occur in fifteen minutes, we can distinguish severely ill patients from those that are pre-symptomatic or asymptomatic and that is very important in the age of Coronavirus, where pre-symptomatic and asymptomatic are also infectious.

Third; which is a very important point, is that if a person is infected with Coronavirus, they report to the hospital and the hospital does a PCR test. That PCR performed and results are delivered within a couple of days. Regardless, only one test is ever done on a single patient. However, with an antigen-based test, that is affordable and provides rapid results, you can track the evolution of the viral infection over time, because these things are so affordable. For example, you can do a test on day one, day two, day three, day four, and so on, such that you are able to track whether the patient's immune system is clearing the virus over time. That has important implications for, not only transmission of the disease, but also for epidemiology.

CEOCFO: *Really overwhelming! What is the takeaway for our readers and for the medical community, for the world, about the E25Bio solution?*

Dr. Herrera: What we have now realized is that infectious diseases not only cause human harm, but they cause social harm, they cause economic harm, extreme economic harm in the case of Coronavirus, and they do not respect borders. That means that they can infect any person in any country, despite what you look like and where you live and how much money you have. I think what is important is that we one, invest resources into the life sciences, both in the academic sciences as well as in biotech sciences, and two, we prepare for outbreaks. That means, governments, in the future, should pay attention to infectious diseases, because they have drastic implications for the way that we live

Finally, more resources should go towards helping fund biotech companies, like E25Bio, Inc., that have the capacity to bring to market diagnostics and vaccines when it actually matters.