

New Technology, Vaccine Availability Reshaping Hospital Care

Pandemic Speeds Up Innovation, Aids in Movement to Decentralize

■ By NATALLIE ROCHA

When **Ingo Chakravarty** was in his 20s he remembers taking a camera and a big roll of film on his travels. He recalled the extra time and costly development of film, as a way of illustrating what's next in healthcare.

What once required extra steps and extra expenses can all be done on his phone — he believes the same can be said for simplifying diagnostic testing in the future.

"It's an interesting example of where you don't have to be an expert anymore," Chakravarty said. "And while that's not a healthcare example, it is for me."

As the president and CEO of **Mesa Biotech**, Chakravarty is convinced that if people can easily test themselves at home for a variety of diseases or infections, it won't be a big deal anymore. Its rapid-PCR COVID-19 test, Accula SARS-CoV-2, received Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) and provides visual results within about 30 minutes.

The San Diego-based company started the development of its technology at **Los Alamos National Lab** in New Mexico and has since focused on manufacturing and commercializing next generation molecular diagnostic tests.

Local biotech companies like Mesa Biotech are leading the way in Point of Care (POC) technology that would eventually enable consumers to take these tests and get results without ever visiting a doctor's office.

Like many things, the COVID-19 pandemic has a way of revealing cracks in the old way of doing things and thrusting the new normal into the spotlight.

Consumers Taking Control

President and CEO of **Truvian Sciences**, **Jeff Hawkins** believes there are healthcare "trends" from 2020 that won't just come and go, but rather change and decentralize healthcare moving forward.

"I think when we look at 2021, there's several healthcare trends that have emerged in 2020 that are going to continue, such as consumers seeking out and taking more control over their health care," Hawkins said of the increased interest in telemedicine and POC options.

Since 2015, Truvian's core technology has focused on POC blood diagnostic testing that requires just a few drops of blood and a benchtop diagnostic system to provide lab-accurate results in 20 minutes for a comprehensive suite of health tests.

Over the past year, Hawkins expected that companies and larger entities would want access to healthcare tools and rapid diagnostic tests, but what it really showed him was an overwhelming consumer appetite for accessible health data and POC testing options.

Hawkins expected companies and larger entities would want access to their rapid antibody test, but what it really showed him was an overwhelming consumer appetite for accessible, POC testing options.

"I think in that regard, the other thing the pandemic did was put a bright spotlight on the broader diagnostic industry, and that there really isn't a Point of Care infrastructure," Hawkins said. "And that's where our core strategy fits, as we have built an instrument to bring diagnostic testing into this highly distributed market."

What's Next?

Hawkins foresees investors paying more attention to diagnostic testing which in turn will spark more innovation within the space of POC options.

"I think you're going to see a renewed interest from investors in investing in diagnostic tools," Hawkins said. "I've been in this field for a little over 20 years, and over the last decade or so diagnostics has not necessarily been a prime sort of a priority."

"I think we're going to see a broader startup community from an investment to drive this industry, I think you're going to see quite a bit of investing activity in some of these alternative approaches, you know, at home testing, or a decentralized platform like we're building that



Jeff Hawkins
President & CEO
Truvian Sciences

can be in retail clinics."

He believes this trend will extend beyond 2021, as the consumer interest in the technology of these platforms signals longevity in healthcare beyond the pandemic.

Rapid Tests

Another key feature of these POC technologies now and moving forward is time, Hawkins explained, is the ability to have a quick turnaround time of results. This is a broader market trend that allows people to make better informed healthcare decisions when it comes to managing the pandemic now or a person's well-being in the future.

While Truvian said it plans to focus more on its core technology in 2021, other companies like **Quidel Corporation** (NASDAQ: QDEL) are honing in on the market for rapid COVID-19 diagnostic tests.

The publicly-traded company specializes in molecular diagnostics, cellular-based virology assays and in May 2020, Quidel received the FDA's first EUA for a COVID-19 antigen test, Sofia 2 SARS Antigen FIA. In December, Quidel received EUA for its new QuickVue SARS Antigen test for use in physician offices and pharmacies.

Quidel's president and CEO, **Douglas Bryant**, said that the publicly-traded company anticipates FDA emergency use authorization to market its latest, QuickVue AT-Home COVID-19 Test in the coming weeks.

"We see At-Home testing as the ultimate empowerment of people to know their current health status and make prudent decisions to protect themselves and their loved ones," Bryant said. "The 'new normal' calls for routine testing and Quidel is determined to answer that call."

Douglas stated that the anticipated demand for an at-home testing option — that could provide 60-second results of a COVID-19 infection — means investing in manufacturing. The company said that to meet demand, Quidel is opening a new production facility in Carlsbad and plans

to hire 400 new employees with a goal to produce 600 million QuickVue tests per year.

Types of Tests

These days, there is so much talk of tests and vaccines, that it is important to understand the different types of tests local companies are developing to detect COVID-19 infections.

To find out if a person has COVID-19, people are looking at either a molecular or antigen test to detect an infection.

Rapid antigen tests, such as Quidel's Sofia 2 SARS Antigen FIA, detect one or more specific proteins from a virus particle. According to the FDA, all currently-authorized antigen tests are POC tests and provide results in less than an hour.

"Antigen tests tend to be highly specific but are typically less sensitive than molecular tests," states the FDA website. "However, because antigen tests can generally be produced at a lower cost than molecular tests and have a simpler design, antigen tests could scale to test millions of individuals per day."

No test is perfect and rapid antigen tests can produce inconsistent results because they require a larger amount of the active virus to be present to produce a positive at the time of testing.

To name a few of the diagnostic companies in San Diego producing PCR COVID-19 test, that would include **Hologic** (Panther Fusion SARS-CoV-2 assay), **Helix** (Helix COVID-19 Test) and **Thermo-Fisher Scientific** (TaqPath COVID-19 Multiplex Diagnostic Solution).

Mesa Biotech's molecular COVID-19 test is a combination of a rapid-PCR test; the company has made deals with the National Football League (NFL) and the National Basketball Association (NBA) to provide its 30-minute test.

Healthcare Tools for 2021



Jane Finley
Senior Vice President
& Area Manager
Kaiser Permanente
San Diego



Douglas Bryant
President & CEO
Quidel Corporation



Truvian's core technology is a POC blood diagnostic testing that requires just a few drops of blood and a benchtop diagnostic system.



Chris Howard
CEO
Sharp Healthcare

Healthcare Tools for 2021

Last year saw a turning point with the innovation of diagnostic tests in the effort to mitigate the spread of COVID-19. While the distribution of COVID-19 vaccines in 2021 is a top priority for

healthcare leaders, a variety of POC options continue to help the industry meet the needs of patients.

"Even though it's a new year, COVID-19 is still very much with us, and will continue to be well into 2021," said **Jane Finley**, senior vice president & area manager for **Kaiser Permanente San Diego**.

"We encourage San Diegans not to avoid seeking the care they need during the pandemic and are hopeful that with the projected pace of vaccinations we will return to more normal times soon."

Going into the new year, Kaiser Permanente is focused on the rollout of the COVID vaccines, while continuing to test and treat those affected by the disease.

Currently, California is authorized to administer COVID-19 vaccines in three phases, with the first doses going to healthcare workers and long-term care residents.

UC San Diego Health has so far received shipments of both the **Pfizer** and **Moderna** vaccines.

"With two vaccines in hand, we can redouble our efforts to provide protection from infection by the SARS-CoV-2 virus," said **Patty Maysent**, CEO, UC San Diego Health. "These are still early days, however. We must continue to mask, distance, wash our hands and follow all public health measures until everyone has been offered the chance to vaccinate and we have gained significant immunity. That day will come."

Kaiser's continued care for San Diegans is underscored by the many ways the healthcare industry has adapted to the needs of patients through options like telehealth.

The company shared that by April of last year more than 86% of patient visits were virtual. More recently, in-person visits have slowly increased over the past several months and as of December 2020 in-person and virtual visits were evenly split at about 50% each.

Masks have become a wardrobe staple, and back in December at a San Diego County press briefing, **Sharp Healthcare** CEO, **Chris Howard** emphasized the necessity of wearing a mask for the sake of not only his hospital staff, but all San Diegans.

"My only request is this," Howard said while holding a mask. "This is a simple thing to do...wear a mask, maintain your social distance, wash your hands, and if you don't have to go out, don't — stay home."

As of Jan. 12, the county reported that the intensive care unit (ICU) bed availability for the Southern California region was 0.0%.

Additionally, the Regional Stay at Home Order, which includes San Diego County, prohibits gatherings of any size with people from other households and adds restrictions to multiple sectors.

The state's order remains in effect until the region's ICU availability meets or exceeds 15%.

Scripps Health President and CEO **Chris Van Gorder** echoed the importance of everyone continuing to wear masks and staying away from crowds, adding that this is the "key to getting us through the pandemic."

"While we have high hopes the vaccine will put an end to this pandemic, we must continue to do what we already know has a positive effect on reducing the spread: wear a mask, wash your hands, sanitize and physically distance. It's a big sacrifice for all of us to avoid family and friend gatherings, but it's the most important thing we can do to save lives and get everyone back to work and school as soon as possible," said **Diane Hansen**, president and CEO of **Palomar Health**.

Working together within the local business community is essential to creating solutions that will bring San Diego out of the pandemic, as no single person or company alone holds the answer.

Location for Innovation

"Our close work and relationships with a wide range of companies and suppliers, including those here in the San Diego region and across the country, have been crucial in supporting the care we continue to deliver every day to COVID-19 patients in our hospitals and clinics," said Van Gorder.

Scripps Health includes five hospitals and 19 outpatient facilities, and offers laboratory services throughout the region.

"Amidst shortages of COVID-19 diagnostics and reagents, the rapid response and exceptional support by locally headquartered companies has been critical to Scripps Health's response," said **Johan Otter**, **Scripps Health** assistant vice president, ancillary services.

For example, Otter said that despite manufacturing and distribution uncertainties experienced by all diagnostic vendors during this pandemic, Hologic helped his lab keep its testing operation stable.

"Despite manufacturing and distribution uncertainties experienced by all diagnostic vendors during this pandemic, Hologic went above and beyond to keep our testing operation stable by providing predictable supplies of reagents and frequent updates on anticipated supply forecasts," Otter said. "This exceptional service helped facilitate our strategy to optimize patient care by minimizing result turnaround time."

Hawkins describes the San Diego business, academic and healthcare community as a symbiotic relationship that mutually benefits from each other.



Diane Hansen
President and CEO
Palomar Health

"I think being in San Diego, you have the three high quality academic medical centers here, whether it's **UCSD**, whether it's **Scripps** or **Sharp**," Hawkins said. "But you also have the local talent in terms of building your company, because there's so many sorts of diagnostic and medical device companies here in San Diego. So, I think it's a bit of a mix of both being near each other, it easier to build a company and develop a technology to be successful."

Quidel's top executive agreed that the talent within San Diego's workforce fueled the industries innovation over the past year.

"Thanks to our extraordinary workforce, the San Diego business community has emerged as the world's epicenter of innovation against COVID-19," said Bryant. "From testing to treatments, the pace and scale of research and development here has been extraordinary and has tapped the full spectrum of talent housed within our community."

Vaccine Distribution

Rady Children's Hospital, the largest children's hospital in California, was the first hospital in the region to deliver the COVID-19 vaccine to frontline hospital workers in December.

But, as it will take some time before the general population can receive vaccines, healthcare leaders are relying on every tool at hand, from diagnostic tests to vaccines, to keep people healthy. Rady has also opened its doors to treat COVID-19 patients up to the age of 30.

But just this past week, San Diego has led the way on vaccine distribution innovation as it comes up with new ways to distribute the COVID-19 vaccines. Healthcare workers are currently being mass vaccinated at **Petco Park** as the facility has partnered with the county and **UCSD Health** to create a "Vaccination Super Station" in an effort to get as many as 5,000 healthcare workers vaccinated daily.

The ultimate goal is to roll out the vaccine and administer as many shots as possible to eligible residents. Currently, those considered to be in Phase 1A-Tier of the state's vaccine priority list are able to get their shots at the Petco Park Tailgate Lot. ■



Johan Otter
Assistant Vice
President, Ancillary
Services
Scripps Health



Chris Van Gorder
President and CEO
Scripps Health

PHASES FOR COVID-19 VACCINE DISTRIBUTION

PHASE 1A

About 3 million people

- Healthcare workers
- Long-term care residents

PHASE 1B

1B TIER ONE:

- Individuals 75 and older
- Those at risk of exposure at work in the following sectors:
 - Education
 - Emergency services
 - Childcare
 - Food and agriculture

1B TIER TWO:

- Individuals 65-74 years of age
- Those at risk of exposure at work in the following sectors:
 - Transportation and logistics
 - Industrial, commercial,
 - Congregates settings with outbreak risk:
 - Incarcerated
 - Homeless
 - residential, and sheltering facilities and services
 - Critical manufacturing

PHASE 1C

- Individuals 50-64 years of age
- People 16-49 years of age and have an underlying health condition or disability which increases their risk of severe COVID-19

- Those at risk of exposure at work in the following sectors:
 - Water and wastewater
 - Defense
 - Energy
 - Chemical and hazardous materials
 - Communications and IT
 - Financial services
 - Government operations/community-based essential functions