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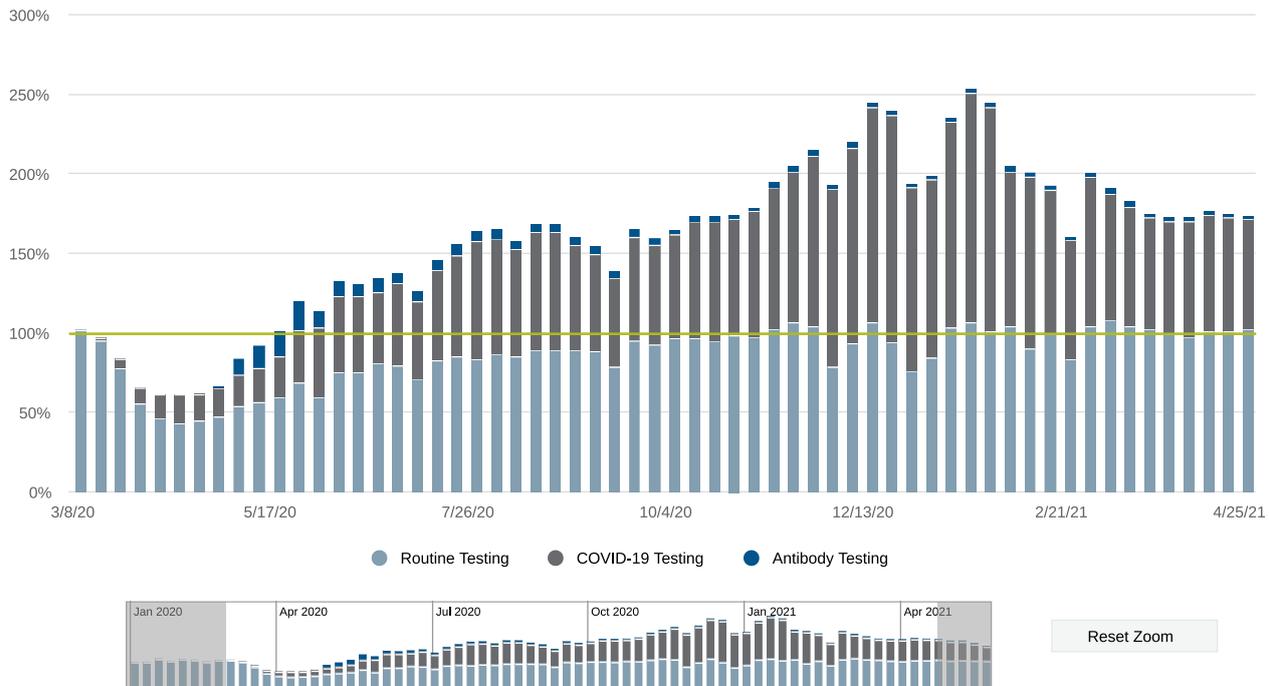
Opinions

What's next for diagnostic labs, a 'bright spot' during Covid-19?

Laboratory Volume Index
Total Lab Tests as % of Baseline Average



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By **Lâle White**

As U.S. diagnostic labs began confronting the Covid-19 pandemic in early March 2020, they faced monumental challenges to quickly build laboratory capacity. That included ramping up staffing and finding sources for the equipment and supplies needed to handle an unpredictable surge in the volume of Covid-19 testing.

Despite the vital role that labs play in providing diagnostic information, they have been running lean shops for years with little ability to increase their daily testing capacity. This behavior was borne out of a need for financial stability, largely because commercial and federal insurers like Medicare and Medicaid have been paying labs less and less for the same testing since well before the pandemic.

Labs must also adhere to regulations

that can reduce their bottom lines. In December of 2020, for example, the Trump administration announced that, starting Jan. 1, 2021, Medicare would pay the previously approved rate of \$100 only to labs that completed Covid-19 diagnostic tests within two days from the date of collection, as a nudge to get them to report and deliver test results in a more timely manner. Labs that don't complete the tests in two days' time are paid \$75.

The opening of California's pric-

ey state-run Covid-19 testing facility in late October 2020 and the operational problems it experienced caused some of the state's existing labs to compete with their own government for limited supplies of test kits and personnel — a clear example that the state didn't need more labs, but rather that the existing labs needed increased testing capacity.

U.S. labs have risen to the challenge of Covid-19 by leveraging the already established, complex testing infrastructure despite having to work in crisis mode with constant supply shortages, shifting testing requirements, and disparate insurance coverage. Their efforts are a reminder that diagnostic labs comprise a collaborative network across regions that is integral to sustaining the U.S. health care system.

My company, XIFIN, has been tracking diagnostic testing across the country since April 2020, and provides a snapshot of the results in our weekly Laboratory Volume Index. After a high of nearly 2 million Covid-19 tests recorded in the U.S. per day in January 2021, as recorded by the Johns Hopkins Coronavirus Resource Center, the total number dropped to about 1.3 million per day by mid-March. We're also starting to see volumes for routine testing — diagnostic tests not related to Covid-19 — increase and trend slightly above pre-pandemic levels, a sign that people are returning to regular medical visits.

Now that U.S. diagnostic labs have expanded their capacity for testing — and with Covid-19 testing volumes on the decline — here's how the country can capitalize on their capacity and the newfound awareness of the role diagnostic labs play in America's collective health.

Don't underestimate the need for continued Covid-19 testing

Though there is hope that the dark-

est days of the pandemic are behind us, the threat of Covid-19 variants loom, making it evident that continued diagnostic testing is integral to the country's return to a sense of pre-pandemic normalcy.

As I write this, nearly 200 million U.S. residents have been vaccinated with one of the three available vaccines, and daily Covid-19 cases are fluctuating. Even so, public health agencies must continue to work hand in hand with diagnostic labs to understand more specifics around continuing Covid-19 cases. In the near term, excess capacity in diagnostic labs should be used to track viral loads in test samples, as well as to identify and monitor the prevalence of SARS-CoV-2 variants and antibody resistance to the virus.

Without such real-time and real-world data, public health experts will lack the information they need to determine herd immunity thresholds.

Embrace diagnostics' emerging growth areas

Labs are beginning to strategize about how to redirect molecular PCR testing capacity that is no longer being used for Covid-19 toward other areas, such as genetic and direct-to-consumer (DTC) testing. Many labs that previously outsourced a portion of their molecular testing to another lab because they lacked the volume to invest in greater capacity will now likely use some of their freed-up Covid-19 capacity to run those tests in-house.

The DTC testing market is anticipated to continue growing by approximately 13% between now and 2028, an indication that consumer appetite to access health care from home will continue to grow beyond the telehealth boom. And a recent analysis of the infectious disease diagnostics market — which supports

doctors and clinicians with early diagnostic information — shows it's also expected to grow in the coming years.

Some people embraced DTC testing in response to decreased in-person doctor visits and the huge rise in telehealth visits following the imposition of strict social distancing measures at the start of the pandemic. As DTC testing shifts the location at which specimens are collected from medical offices to homes, offering more convenient access to health care and testing, it's also a pivotal moment for diagnostic labs to collaborate to get insurance providers across the country to agree on more equitable and uniform reimbursement policies. This can help ensure that labs are compensated similar amounts when they're running the same tests, instead of receiving varying compensation depending on patients' insurance carriers.

It's also important that reimbursement adequately covers the cost to labs for running tests — some are inadequately reimbursed, meaning they lose money performing tests. As DTC testing is likely to make up part of their daily capacity in the future, this issue must be addressed now.

Covid-19 has tested the U.S. health system, revealing many weaknesses and some strengths. The national laboratory network component has proven to be a resilient and logistically efficient bright spot. To capitalize on the momentum it has built, industry leaders, diagnostic professionals, and policy makers need to work together to help set the course for a strengthened health care system better positioned to care for all Americans.

Lâle White is the CEO and a founder of XIFIN, a San Diego-based health information technology company.