

# LABORATORY ECONOMICS

*Competitive Market Analysis For Laboratory Management Decision Makers*

## Covid-19 Test Demand Surges Again

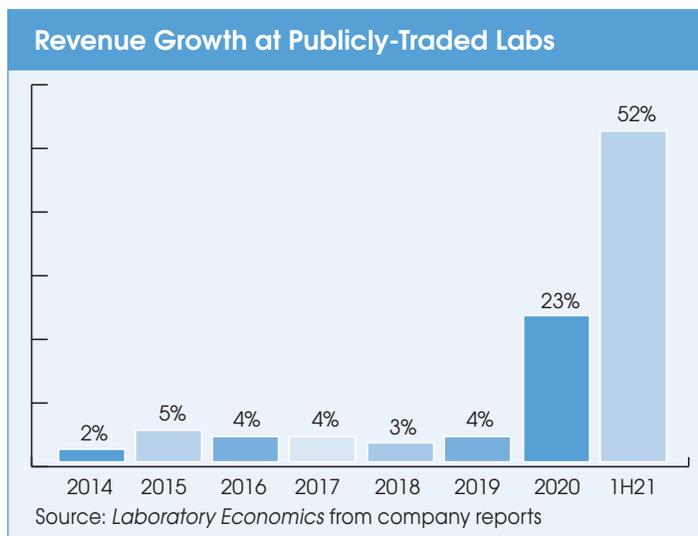
After a lull in the spring/early summer, Covid-19 PCR test volumes are surging again. Covid-19 PCR test volumes in the United States are currently averaging more than 1.5 million tests per day, according to the CDC. Strong demand for Covid-19 testing is expected to continue as President Biden’s new vaccination mandate covering employers with 100+ employees goes into effect. The mandate (affecting about 80 million Americans) will require a weekly negative test from employees who refuse to get vaccinated. As of mid-September, a total of 177 million Americans had been fully vaccinated, or 53% of the country’s population, according to the CDC’s data. *Continued on page 10.*

## At-Home Rapid Covid Tests Flying Off Store Shelves

CVS Health Corp. has stopped allowing customers to buy unlimited numbers of at-home Covid-19 antigen tests. The new purchasing limits apply to both Abbott Laboratories’ BinaxNOW test and a test from the startup Ellume, which are the only over-the-counter (OTC) Covid tests sold by CVS. Customers are now only allowed to purchase four of each of these tests in stores and six of each online. Both tests have been authorized by the FDA under an emergency use authorization. *Continued on page 8.*

## Record-Breaking Growth At Publicly-Traded Labs

Enormous demand for Covid-19 PCR testing has led to another period of record-smashing growth at the nation’s publicly-traded lab companies. On a combined basis, 21 publicly-traded labs reported a revenue increase of 52% to reach \$15 billion during the first six months of 2021 (after adjusting for acquisitions), according to financial reports collected by *Laboratory Economics*. This more than doubled the 23% growth these companies recorded last year, and contrasts with historical growth that has typically averaged between 2% and 5% per year. *Continued on page 2.*



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### Publicly-Traded Lab Revenue Jumps 52% In First-Half 2021 (cont'd from page 1)

Among five national clinical labs (Quest Diagnostics, LabCorp, Sonic Healthcare USA, BioReference and Enzo), combined revenue increased by 48% (after adjusting for acquisitions). BioReference had the strongest revenue growth, up 114% to \$904 million, driven by Covid testing. BioReference performed 6.9 million Covid-19 PCR tests and 300,000 serology antibody tests during the six months ended June 30, 2021, which represented 62% of the company's total lab testing volume for that period.

Among 16 specialty and genetic testing labs, combined pro-forma revenue increased by 73%. Pro-forma revenue growth was fastest at Fulgent Genetics, up 1,951% to \$513 million. Fulgent performed a total of 5.3 million billable tests during the six months ended June 30, 2021, up from 194,000 billable tests during the same period last year. Most of the increase was related to Covid-19 PCR testing; average price per billable test was \$96.

Biocept Inc. (San Diego, CA) posted the second-fastest revenue growth, up 1,161% to \$30 million, which included \$29 million attributable to Covid-19 PCR testing. The company processed 245,401 accessions during the six months ended June 30, 2021, up from 2,031 accessions during the same period last year.

### Revenue Growth at 21 Publicly-Traded Lab Companies (\$000)

| Company  | First-Half 2021 | First-Half 2020 | Reported Change | Pro Forma Change* |
|--|-----------------|-----------------|-----------------|-------------------|
| Labcorp (lab testing only)                         | \$5,123,300     | \$3,394,700     | 51%             | 50%               |
| Quest Diagnostics (lab testing only)               | 5,117,000       | 3,508,000       | 46%             | 42%               |
| Opko/Bio-Reference Labs                            | 904,149         | 421,811         | 114%            | 114%              |
| Sonic Healthcare USA <sup>1</sup>                  | 760,100         | 698,000         | 9%              | 30%               |
| Enzo Clinical Labs (lab testing only) <sup>2</sup> | 49,006          | 22,999          | 113%            | 113%              |
| Total, 5 National/Clinical Labs                    | 11,953,555      | 8,045,510       | 49%             | 48%               |
| Exact Sciences                                     | 836,896         | 616,689         | 36%             | 36%               |
| Fulgent Genetics                                   | 513,045         | 25,018          | 1,951%          | 1,951%            |
| Myriad Genetics                                    | 362,500         | 257,200         | 41%             | 41%               |
| Natera   | 294,342         | 180,484         | 63%             | 63%               |
| NeoGenomics  | 237,257         | 193,007         | 23%             | 23%               |
| Invitae Corp.                                      | 219,933         | 110,439         | 99%             | 99%               |
| Guardant Health                                    | 170,766         | 133,845         | 28%             | 28%               |
| CareDx   | 141,588         | 80,181          | 77%             | 77%               |
| Veracyte   | 91,808          | 51,826          | 77%             | 77%               |
| Castle Biosciences                                 | 45,571          | 30,133          | 51%             | 51%               |
| Progenity  | 42,601          | 34,094          | 25%             | 25%               |
| Biocept Inc.                                       | 29,803          | 2,364           | 1,161%          | 1,161%            |
| Exagen   | 23,359          | 18,532          | 26%             | 26%               |
| Psychemedics                                       | 11,800          | 10,851          | 9%              | 9%                |
| Dermtech   | 5,643           | 2,401           | 135%            | 135%              |
| Aspira Women's Health                              | 3,295           | 1,966           | 68%             | 68%               |
| Total, 16 Specialty/Genetic Labs                   | 3,030,207       | 1,749,030       | 73%             | 73%               |
| Grand Total, All 21 Lab Companies                  | \$14,983,762    | \$9,794,540     | 53%             | 52%               |

\*Pro forma change is estimated by *Laboratory Economics* after adjustments for acquisitions.

<sup>1</sup>Sonic Healthcare USA revenue for the six months ended June 30, 2021 at constant exchange rate of 1 Australian Dollar equal to 0.72 U.S. Dollar; pro forma change for Sonic is adjusted for exchange rate changes.

<sup>2</sup>Enzo's revenue is for lab services only for six months ended April 30, 2021.

Source: *Laboratory Economics* from company reports

## The Pandemic Intensified Chronic Lab Worker Shortage

There are approximately 338,000 clinical laboratory technologist and technician jobs in the U.S., according to the U.S. Bureau of Labor Statistics. Hospitals account for 47% of these jobs; independent labs, 20%; physician offices, 9%; schools and universities, 6%; and other settings, 18%. While the Covid-19 pandemic has increased the visibility of the clinical lab industry, it has also intensified the chronic shortage of lab workers. A new report (*The Clinical Laboratory Workforce: Understanding the Challenges to Meeting Current and Future Needs*) published by the American Society for Clinical Pathology (ASCP) and the Center for Health Workforce Studies at the University of Washington, provides an in-depth look at the lab worker shortage and strategies to increase the pool of qualified personnel. For more insight, *Laboratory Economics* spoke with the study's lead author Edna Garcia, MPH, Director, Scientific Engagement and Research at ASCP.



Edna Garcia,  
MPH

### How has the pandemic worsened the lab worker shortage?

It's made it difficult for students studying medical laboratory science to get onsite at clinical rotation sites. Many sites didn't want students due to Covid-19, and some programs turned away students weeks before they were scheduled to start rotations. As a result, the pipeline of new histotechnicians, medical laboratory technicians and phlebotomists entering the workforce has been disrupted.

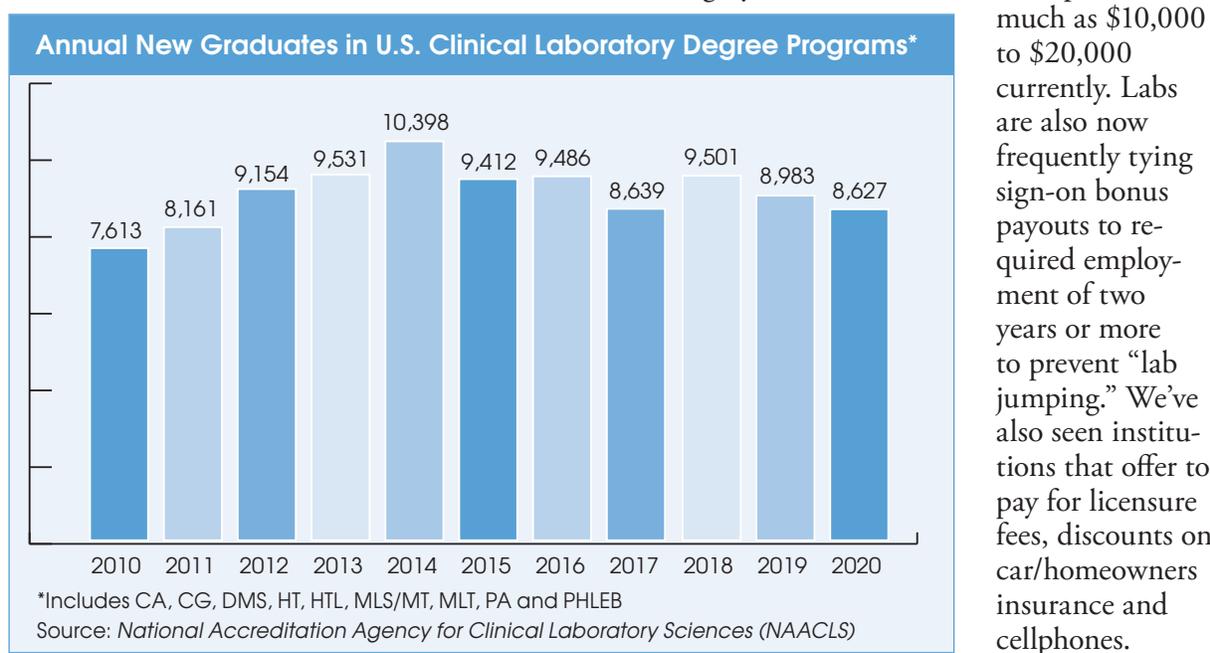
There were steep declines in the number of new histotechnicians, histotechnologists, medical lab technicians and especially phlebotomists last year [see table].

At the same time, labs have experienced higher-than-average staff departures mainly due to early retirement taken by employees with health concerns. Some lab employees in the age range of 55-64 have retired early because of burnout and/or fear of catching Covid.

Finally, there has been increased demand for lab workers due to the high volume of Covid-19 testing, demand for rapid turnaround time, and the thousands of new Covid-19 testing labs that have been created over the past year.

### What's your take on the high sign-on bonuses being used to attract lab workers?

For more than 20 years, labs have competed for workers by offering sign-on bonuses. What's new is the size of the bonuses, which have increased from roughly \$1,000 to \$5,000 in the past, to as



much as \$10,000 to \$20,000 currently. Labs are also now frequently tying sign-on bonus payouts to required employment of two years or more to prevent "lab jumping." We've also seen institutions that offer to pay for licensure fees, discounts on car/homeowners insurance and cellphones.

### Which positions are in highest demand?

Medical lab technicians, histotechnicians, and phlebotomists have the highest vacancy rates. We also see many opportunities in molecular pathology departments, and the need for technologists with molecular biology (MB) and molecular pathology (MP) certifications.

### The long-term trend in new clinical laboratory science program graduates is flat.

Yes, the total number of new graduates for all lab degrees (HT, HTL, MLS/MT, MLT, etc.) has been stable for the past 10 years (see chart). But stable isn't good enough to keep up with the growing demand.

### Will increasing technology and automation alleviate the worker shortage in the lab?

From our data and conversations with lab staff and managers, the role of lab professionals is going to change with automation, but it's not going to reduce the number of techs required. There will be a need for staff who are knowledgeable in using and operating these machines in the near future.

### What can be done to increase the pool of qualified personnel?

Our report outlined three strategies. Number one, we've got to raise awareness of lab career opportunities at an earlier age. Specific activities and program content geared toward elementary and middle school students are needed. Incentives should be offered to encourage lab employees to participate in educational and awareness-building activities at elementary schools.

We've also got to do more to improve workforce retention. Too many lab employees leave the field to pursue new careers by enrolling in nursing or medical school. We need to keep existing employees by providing more opportunities for career growth through tier levels, increases in pay, and elevated titles.

Finally, we've got to encourage diversity in academic recruitment by partnering with STEM programs to recruit students from underrepresented groups, developing more scholarships, and recruiting more men, the non-dominant gender in this field.

### New Graduates in U.S. Clinical Laboratory Degree Programs

| Degree Type                          | Grads 2020 | Grads 2019 | Grads 2018 | Grads 2017 | 1-Year Change | 3-Year Change |
|--------------------------------------|------------|------------|------------|------------|---------------|---------------|
| Clinical Assistant (CA)              | 38         | 47         | 33         | 45         | -19%          | -16%          |
| Cytogenetic Technologist (CG)        | 30         | 23         | 30         | 16         | 30%           | 88%           |
| Diagnostic Molecular Scientist (DMS) | 89         | 88         | 163        | 67         | 1%            | 33%           |
| Histotechnician (HT)                 | 294        | 365        | 363        | 357        | -19%          | -18%          |
| Histotechnologist (HTL)              | 52         | 57         | 63         | 60         | -9%           | -13%          |
| Med Lab Scientist (MLS/MT)           | 3,964      | 3,899      | 3,772      | 3,894      | 2%            | 2%            |
| Med Lab Tech (MLT)                   | 2,848      | 2,932      | 3,160      | 2,453      | -3%           | 16%           |
| Pathology Assistant (PA)             | 154        | 151        | 134        | 132        | 2%            | 17%           |
| Phlebotomy (PHLEB)                   | 1,158      | 1,421      | 1,783      | 1,615      | -19%          | -28%          |
| Total Graduates                      | 8,627      | 8,983      | 9,501      | 8,639      | -4%           | 0%            |

Source: National Accreditation Agency for Clinical Laboratory Sciences (NAACLS)

## Labcorp Raises Minimum Hourly Wage To \$15

Labcorp (Burlington, NC) has announced it has increased the minimum hourly wage for U.S.-based, non-union employees to \$15 from \$10.95, effective September 2021. Labcorp has 38,693 non-union hourly workers in the United States. "Our frontline workers who are closest to our patients will see the most benefit from the rate increase," according to a Labcorp spokesman.

## Lighthouse Lab Services Acquires Burns Consulting Group

Lighthouse Lab Services (Charlotte, NC) acquired Burns Consulting Group (BCG-Houston, TX and Kansas City, MO) in August. BCG specializes in managed care contracting for independent clinical labs.

Lighthouse is a lab consulting firm focused on licensure and compliance with CLIA, COLA and CAP accreditation requirements, as well as new test development and validation. Earlier this year, Lighthouse expanded into pathology group auditing services through the acquisition of Vachette Pathology (see *LE*, April 2021).



Brennan Burns

BCG was founded by its CEO Brian Burns, age 58, in 2017. He had previously spent 18 years at BCBS of Kansas City as Senior Vice President of Network Management. His son, Brennan Burns, age 29, joined BCG in 2018 after holding network contracting positions at BCBS of Texas and Gulf Stream Diagnostics. Below is a summary of *Laboratory Economics*' interview with Brennan Burns on hot topic managed care contracting issues.

### Why did BCG choose to join with Lighthouse?

Lighthouse had been referring us clients for several years, and the two companies believe we can achieve more as one company. My father has become Vice President of Managed Care Strategies at Lighthouse, while I am Vice President of Payer Contracting.

### What's the current managed care reimbursement environment like for clinical labs?

Nearly all Blue Cross Blue Shield and commercial insurers have now linked their fee schedules to the Medicare Clinical Laboratory Fee Schedule (CLFS). In-network independent lab rates range from as low as 45% of the current CLFS to as high as 110%, with most falling in a tighter range of between 80% and 100%, depending on the payer and the region of the country.

### So why not stay out-of-network and get paid more as a non-participating lab?

While out-of-network rates can average double or more those paid to in-network labs, payers have become stricter in terms of medical necessity and documentation requirements for out-of-network lab claims. This often results in non-payment. Claims denial rates for out-of-network labs average roughly 30% versus 5% for in-network labs.

In addition, being in-network is a huge selling point to physician office clients. Most physicians steer volume to in-network labs. They don't want to see their patients get hit with a huge balance bill from an out-of-network lab.

### Is there any room for independent labs to negotiate better rates with health insurers?

When it comes to lab contracts, most health insurers are only willing to spend time negotiating contracts with the big labs (Quest, Labcorp, Sonic/CPL and BioReference). Independent labs seeking in-network status are in a "take it or leave it" situation. Even so, independent labs are still better off being in-network.

However, one or two years after gaining an in-network contract there is the potential for labs to start up a conversation. Assuming there has been no fraud or abuse, it's possible for labs to seek a contract amendment that can raise their rates by 3% to 5%. This strategy has worked for our clients, especially if they offer a unique or proprietary test.

### Some out-of-network labs are having difficulty getting paid for Covid testing. What have you seen?

Labs charging reasonable rates (between \$75 and \$125 per Covid PCR test) are getting appropriately reimbursed. Those charging \$250 to \$300 and higher are having trouble.

### Have commercial lab rates finally bottomed out?

I'm optimistic that they have flattened out. There's simply no room for rates to go lower.

## PathGroup Buys DermLab

**P**athGroup has acquired DermLab (Birmingham, AL), an independent dermatopathology laboratory with four dermatopathologists. DermLab was founded by Charles Parrish, MD, Michael Jacobs, MD, and Stephen Mason, MD in 2013. PathGroup has stated that building out its dermatopathology business is a key strategic initiative. The DermLab deal follows PathGroup's acquisition of SkinDx (Birmingham, AL) in June (see *LE*, June 2021).

## BioReference Buys Roche's Ariosa Lab Testing Business

**O**pko Health subsidiary BioReference Laboratories (Elmwood Park, NJ) has acquired the U.S. Ariosa centralized lab prenatal testing business from Roche. The acquisition price has not been disclosed.

Ariosa's Harmony Prenatal Test (CPT 81507: \$795) has been performed in more than 1.5 million patients since being launched in 2012. The Harmony Prenatal Test is a blood test that is performed as early as 10 weeks into pregnancy. By evaluating fetal cfDNA found in maternal blood, the test is designed to assess the risk of Down syndrome and other genetic abnormalities.

The acquisition will complement BioReference's specialty health division GenPath, which currently offers the ClariTest Core. BioReference is transitioning U.S. Harmony customers over to their ClariTest Core test, which is run on the same core technology as Harmony at their lab in New Jersey.

Roche will maintain ownership of Ariosa's CAP/CLIA laboratory in San Jose for its ongoing oncology business as well as development projects. Roche will also continue to sell its test kit for NIPT, the Ariosa cell-free DNA System, to labs throughout the world, according to Roche.

Roche originally acquired Ariosa Diagnostics (San Jose, CA) for \$400 million in cash plus up to \$225 million in contingent consideration in December 2014.

## Quest Buys Nationwide Laboratory Services In South Florida

**E**ffective August 23, Quest Diagnostics acquired select assets of Nationwide Laboratory Services (NLS-Boca Raton, FL), an independent clinical lab founded by the late Mark Ginsburg, MD, in 1995. NLS specializes in testing services for end-stage renal disease (ESRD) patients through contracts with dialysis clinics throughout the country.

Testing services provided by NLS will transition to Quest's full-service lab in Miramar, Florida. Quest will also acquire select PSCs in South Florida. Quest currently has major labs in Tampa as well as Miramar and over 50 PSCs across Florida.

### Recent Acquisition History for Quest Diagnostics

| Date   | Laboratory Acquisition           | Notes   | Price (\$ mill) |
|--------|----------------------------------|---|-----------------|
| Aug-21 | Nationwide Laboratory Services   | Specializes in ESRD testing                             | NA              |
| Jun-21 | Mercy outreach lab               | Hospital lab outreach in AR, KS, MO, OK                 | \$225           |
| Aug-20 | Mid America Clinical Labs        | Acquired full ownership of joint venture lab in Indiana | \$198*          |
| Apr-20 | Memorial Hermann Diagnostic Labs | Hospital lab outreach in Houston area                   | \$120           |
| Jan-20 | Blueprint Genetics               | Genetic testing lab based in Finland                    | \$108           |

\*Quest acquired 100% ownership in deal that valued MAFL at \$198 million.

Source: *Laboratory Economics*

## Spotlight Interview with Genetics Institute of America CEO Holly Magliochetti

Genetics Institute of America (GIA-Delray Beach, Fl.) was founded in 2019 by CEO Holly Magliochetti. The lab has 29 employees, including one pathologist, Lourdes M. Trigo, MD, who is the medical director. Magliochetti is the principal owner of GIA, which serves 4,000 clients across the United States. *Laboratory Economics* recently caught up with Magliochetti to discuss happenings at GIA.



Holly  
Magliochetti

### **Tell us about Genetics Institute of America.**

We started a technology company in 2015, Grace Health Technology, which offers pre-accessioning management for genetic testing. After years of sending out tests to other labs, we decided to start our own specialized high-complexity molecular lab. Genetics Institute of America was formed to balance clinical, research and education.

There is an awareness of the importance of genetics, but we realized there was a greater need for education. We developed a comprehensive educational program for physicians and payers. The culture here is steeped in servant leadership – saving lives, changing lives and giving back. Our philanthropic commitment has been a cornerstone from the beginning. Late last year we adopted a partnership in West Palm Beach to address homelessness. We've hired administrative staff successfully through that program. It's more than just donating money.

### **Who are your clients?**

Our primary clients are a broad spectrum of healthcare providers – primary care physicians, oncologists and other specialists. This year we are working on building relationships with large hospital groups. We have worked with nearly 2,000 physicians across the country. We are in every state except for New York and California.

### **What tests do you offer?**

We offer next-gen sequencing for pharmacogenomics, hereditary cancers, hereditary cardiac disease, Parkinson's, Alzheimer's and dementia, and diabetes. Clinically, we focus on germline testing. The research department is working on RNA and mRNA, in addition to genetic studies.

Next year we'll be adding testing in the OB/Gyn market, specifically carrier screening, including the ACOG/ACMG suggested panels, expanded panels and Ashkenazi Jewish panels. We're in the early stages working with a large hospital client to support somatic testing in formalin fixed, paraffin embedded tissue (FFPE), and we have plans to add next-gen sequencing for hematology.

### **Do you perform Covid-19 PCR testing?**

We do not. Initially we were involved in supporting it, but we felt it detracted from our core mission.

### **Are your volumes and revenues increasing?**

Our year-over-year revenue has increased by 235% year-to-date in 2021. In the fourth quarter, we are doubling the space of our lab from 4,000 square feet to 8,000 square feet. We had initially projected growth for next year of 50%. However, we now anticipate 2022 growth to continue at the same trajectory we've experienced this year.

### **Have non-Covid testing volumes bounced back to pre-pandemic levels?**

There was a short period of time in early 2020 when we had a small drop-off in testing. But we already had a non-contact model for specimen collection. Most of our tests are collected in-home with a buccal swab. Every test that we perform is reviewed by a genetic counselor, who consults with the physician.

In 2020 we thrived because we were already set up to work remotely. We were able to pivot very quickly.

The negative impact we had was related to supplies and staffing. We have partnered with our local medical technologist training program at Miami Dade College to bring in new MTs. We've also developed a fellowship program for new PhDs in preparation for expected growth.

#### **What supplies have you found difficult to get?**

In the beginning, PPE and some of the plastics were hard to get your hands on. Even now, it can be difficult to get pipette tips of certain sizes. But we have compensated. At no point did we ever have to stop or slow down operations, although we came close a few times.

#### **Tell us about the research side of the lab.**

Right now, our research testing makes up about 25% of revenue. We expect that to grow in 2022. One study is related to early detection of disease through urine, and one is focused on inflammation and genetic susceptibility to chronic disease. With our recent CAP accreditation, we offer a unique combination of research and clinical testing.

#### **What's the biggest challenge you have with commercial insurers?**

Getting them to understand the value of genetic testing. We have been working diligently to provide them with research data. Reimbursement is also challenging. It is a complex part of our model. We make it a practice to get all of our information for medical necessity prior to running the test to increase the likelihood the test will be covered.

#### **What do you see as your biggest challenges?**

I think our biggest challenge is to make sure we maintain a focus on our core competencies, because genetics is such a fast-growing field. We really want to be at the forefront of genetic testing. We also want to be sure our physicians and patients know they are not just a number to us. That is our greatest challenge as well as our greatest opportunity.

### **At-Home Rapid Covid Tests Flying Off Store Shelves** *(cont'd from page 1)*

CVS operates 9,900 retail stores across America.

This restriction was made "in order to serve our customers' OTC testing needs, and due to high demand," according to a CVS spokesperson. Covid at-home antigen tests are currently the top-selling item at CVS stores. As of mid-September, the CVS website showed that both the BinaxNOW and Ellume tests were out of stock at most CVS stores.

Both tests require self-collected anterior nasal swab samples with results provided within 15 minutes.

The BinaxNOW test package includes two antigen tests and costs \$24. After the first test, a second test is taken 36 hours later. The test has demonstrated 84.6% positive agreement (sensitivity) and 98.5% negative agreement (specificity).

The Ellume Covid-19 Home Test package includes a single antigen test and costs \$39. The test has demonstrated 96% sensitivity and 100% specificity in individuals with symptoms. In people without symptoms, the test correctly identifies 91% of positive samples and 96% of negative samples.

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## Cancer Diagnoses Declined Sharply During First Year of Pandemic

New diagnoses of eight common cancers (prostate, breast, colorectal, lung, pancreatic, cervical, gastric and esophageal) significantly declined during most of the first 13 months of the pandemic (March 2020-March 2021), according to a study by Quest Diagnostics published August 31 in *JAMA Network Open, Oncology*. It is believed to be the largest and most comprehensive analysis of cancer diagnosis rates during the pandemic.

Lockdown measures and fear of going to doctor's offices and hospitals are believed to have led many people to put off preventative care like routine screenings that could have resulted in diagnosis of cancer during the first year of the pandemic, the study suggests.

The Quest study included 799,496 patients (45% women/55% men) with an average age of 68. Data over four time periods was analyzed: prepandemic, March to May 2020, June to October 2020, and November 2020 to March 2021.

Prepandemic, January 2019 to February 2020, the average monthly number of new diagnoses for the eight cancers was 32,407. During March to May 2020, the monthly average fell by 30% to 22,748 cases. It fell by 10% to 29,304 cases in the next period, June to October 2020. Finally, new cancer diagnoses fell 19% to an average 26,204 cases in the last period, November 2020 to March 2021.

Delayed cancer diagnosis can lead to more advanced disease, more aggressive and costly treatment, and worse outcomes, noted the Quest study.

### Average Monthly Number of New Cancer Diagnoses

| Time Period                                   | Average monthly new cancer diagnoses | Decline in cancer diagnoses vs. prepandemic |
|---|--------------------------------------|---|
| Prepandemic:<br>January 2019 to February 2020 | 32,407                               | NA  |
| March to May 2020                             | 22,748                               | -29.8                                       |
| June to October 2020                          | 29,304                               | -9.6%                                       |
| November 2020 to March 2021                   | 26,204                               | -19.1%                                      |

Source: Quest Diagnostics Health Trends Study Published in *JAMA Network Open, Oncology*, Aug. 31, 2021

### ACLA Study Cites Emerging Crisis of Undiagnosed Diseases and Delayed Treatment

A separate study of Medicare claims data found that clinical lab test utilization overall fell by 18% from 2019 to 2020, even when taking into account the large volume of Covid-19 testing conducted in 2020. The study was sponsored by the American Clinical Laboratory Association and performed by Braid Forbes Research (Silver Spring, MD). The analysis compared the volume of CLFS tests for Medicare beneficiaries in the first nine months of 2020 to the volume of tests performed in the same period of 2019. Key findings included:

#### Cancer testing decreased by 31% on average across key tests, including:

- EGFR test volume for non-small cell lung cancer fell by 47%
- BRCA test volume for breast and ovarian cancer fell by 35%
- Prostate specific antigen (PSA) test volume fell by 16%

#### Diabetes testing decreased by 29% on average across key tests, including:

- A1c test volume fell by 20%
- Glucose test volume fell by 36%

Other tests seeing substantial volume declines included chronic kidney disease (-31%), liver disease (-23%), lipid panel (-22%) and drug testing (-21%).

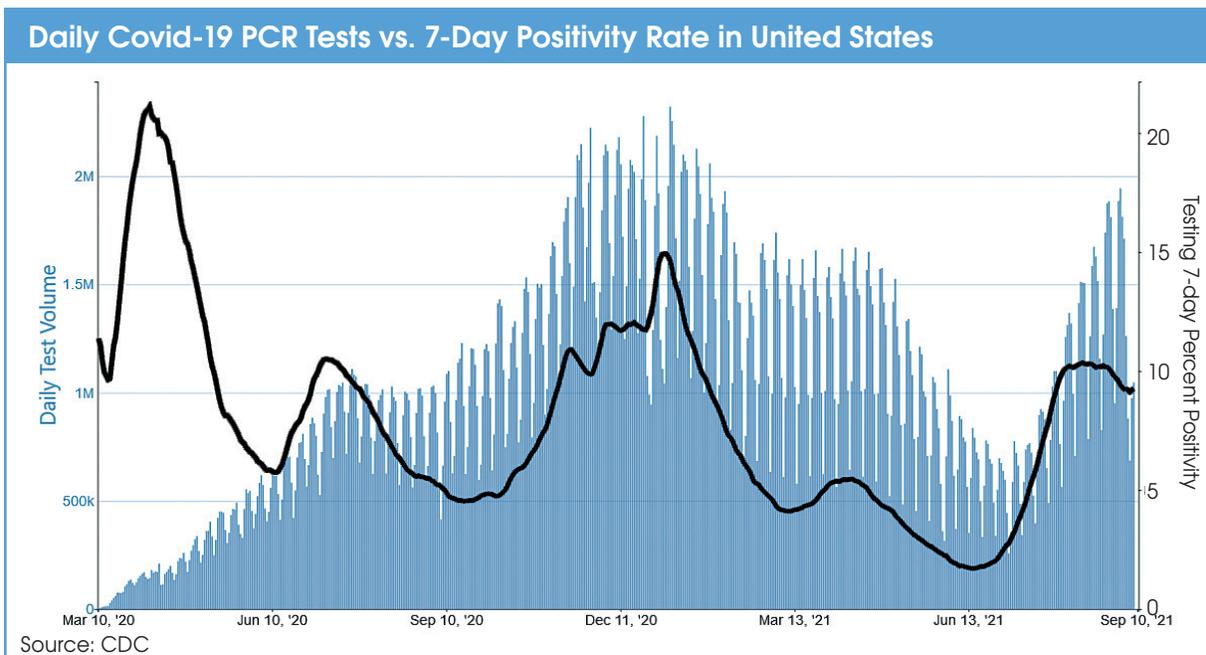
## Covid-19 Test Demand Surges Again *(cont'd from page 1)*

President Biden's new vaccine mandate is part of a broader plan announced on September 9. The key components of the plan are focused on increasing vaccinations and access to rapid Covid-19 antigen tests.

### Key Points to President Biden's New Covid-19 Plan

- The Department of Labor's Occupational Safety and Health Administration (OSHA) is developing an Emergency Temporary Standard (ETS) that will require all employers with 100 or more employees to ensure that their workforce is fully vaccinated or to require any workers who remain unvaccinated to produce a negative test result at least weekly before coming to work. The rule is expected to be issued within weeks and will affect roughly 80 million American workers.
- The Centers for Medicare & Medicaid Services (CMS) will require Covid-19 vaccinations for workers in most healthcare settings that receive Medicare or Medicaid reimbursement, including but not limited to hospitals, dialysis facilities, ambulatory surgical settings and home health agencies. This rule will affect nearly 17 million healthcare workers.
- A new Executive Order requires vaccinations for nearly 4 million federal workers and the employees of companies that contract with the federal government.
- President Biden reached an agreement for three top retailers that sell at-home, rapid Covid-19 antigen tests—Walmart, Amazon, and Kroger—to sell these tests at-cost for the next three months. The three big retailers are expected to soon offer these tests for up to 35% less. In addition, Medicaid plans must now cover at-home tests for free to beneficiaries.
- President Biden's plan also urged entertainment venues like sports arenas, large concert halls, and other places where large groups of people gather, to require that their patrons be vaccinated or show a negative test before entry.

Meanwhile, the recent increase in Covid-19 PCR test volumes has pushed the total volume to 544 million tests since the start of the pandemic. Assuming an average reimbursement rate of \$90 per test would indicate that the U.S. has spent a total of nearly \$50 billion on Covid-19 PCR testing to date.



## Invitae Is America's Fastest-Growing Independent Lab

**Invitae Corp.** (San Francisco, CA) grew its Medicare Part B allowed payments the most during the three-year period from 2016-2019, according to newly released data from CMS. Invitae, which specializes in genetic testing, grew its Part B allowed payments from \$3 million to \$57 million during the three-year period for a compound annual growth rate (CAGR) of 167%.

**Caris MPI** (Phoenix, AZ), which specializes in next-gen sequencing for cancer, grew by 84% per year to reach \$39 million of Part B allowed payments in 2019.

**CareDx** (Brisbane, CA), which specializes in genetic testing for transplant patients, grew by 77% per year to reach \$72 million of Part B allowed payments in 2019.

Overall, some 2,800 independent clinical labs saw their Medicare Part B allowed payments increase from \$4.806 billion to \$5.808 billion for a CAGR of 7% during the three years, 2016-2019.

### Top 25 Fastest-Growing Labs by Medicare Part B Allowed Payments\*

| Laboratory Name                          | City                  | 2019 Medicare Allowed Payments | 2016 Medicare Allowed Payments | 3-year CAGR |
|--|-----------------------|--------------------------------|--------------------------------|-------------|
| Invitae Corp.                            | San Francisco, CA     | \$56,541,578                   | \$2,955,775                    | 167%        |
| Caris MPI, Inc.                          | Phoenix, AZ           | 39,320,180                     | 6,265,487                      | 84%         |
| CareDx, Inc.                             | Brisbane, CA          | 71,713,104                     | 12,923,901                     | 77%         |
| Quest Diagnostics/Med Fusion             | Lewisville, TX        | 9,959,040                      | 2,089,936                      | 68%         |
| Exact Sciences                           | Madison, WI           | 240,161,797                    | 61,657,028                     | 57%         |
| LabSolutions LLC.                        | Atlanta, GA           | 26,325,458                     | 7,028,611                      | 55%         |
| Mako Medical Laboratories                | Raleigh, NC           | 8,340,079                      | 2,351,228                      | 53%         |
| MD Spine Solutions                       | Reno, NV              | 19,330,999                     | 5,506,986                      | 52%         |
| Spectrum Diagnostic Labs                 | Arlington, TX         | 8,347,745                      | 2,389,433                      | 52%         |
| Precision Toxicology                     | San Diego, CA         | 15,240,737                     | 4,669,837                      | 48%         |
| Phlebexpress                             | Temecula, CA          | 6,636,562                      | 2,308,853                      | 42%         |
| NeoGenomics Laboratories                 | Aliso Viejo, CA       | 29,539,683                     | 10,288,558                     | 42%         |
| Realtox Labs                             | Reisterstown, MD      | 9,005,695                      | 3,212,209                      | 41%         |
| Labcorp                                  | Seattle, WA           | 28,739,757                     | 11,517,510                     | 36%         |
| siParadigm LLC.                          | Pine Brook, NJ        | 10,811,430                     | 4,336,465                      | 36%         |
| Regional Toxicology Services             | Tacoma, WA            | 5,003,315                      | 2,222,251                      | 31%         |
| Brookside Clinical Laboratory            | Aston, PA             | 6,443,132                      | 2,905,162                      | 30%         |
| Medscan Laboratory Inc.                  | Williston, ND         | 8,927,802                      | 4,068,035                      | 30%         |
| Medical Diagnostic Laboratory            | La Verne, CA          | 4,698,814                      | 2,287,947                      | 27%         |
| National Labs Inc.                       | Hayward, CA           | 5,941,017                      | 2,935,127                      | 26%         |
| Quest Diagnostics                        | Seattle, WA           | 11,602,010                     | 5,955,371                      | 25%         |
| Interpace Biosciences                    | Pittsburgh, PA        | 9,901,869                      | 5,194,677                      | 24%         |
| Texas Digestive Disease Consultants      | Southlake, TX         | 5,330,447                      | 2,827,076                      | 24%         |
| Veracyte, Inc.                           | So. San Francisco, CA | 31,517,754                     | 17,043,231                     | 23%         |
| Labcorp                                  | Overland Park, KS     | 5,485,867                      | 3,037,969                      | 22%         |
| <b>Total for all 2,836 clinical labs</b> |                       | <b>\$5,808,100,308</b>         | <b>\$4,806,415,863</b>         | <b>7%</b>   |

\*The top 25 was calculated from all independent clinical labs that had a Medicare allowed payment amount of at least \$2 million in 2016.

Source: *Laboratory Economics* from Medicare Part B Provider Utilization files, 2016 & 2019

## Lab Stocks Up 15% Year To Date

Twenty-three lab stocks have risen by an unweighted average of 15% year to date through September 10. In comparison, the S&P 500 Index is up 22% thus far in 2021. The top-performing lab stocks so far have been Interpace Biosciences, up 197%; Fulgent Genetics, up 80%; and Myriad Genetics, up 68%. Labcorp is up 48%, Quest Diagnostics is up 30%, and Sonic Healthcare is up 29%.

| Company (ticker)             | Stock Price 9/10/21 | Stock Price 12/31/20 | 2021 Price Change | Enterprise Value (\$ mill) | Enterprise Value/Revenue | Enterprise Value/EBITDA |
|------------------------------|---------------------|----------------------|-------------------|----------------------------|--------------------------|-------------------------|
| Labcorp (LH)                 | \$300.95            | \$203.55             | 48%               | \$33,410                   | 2.0                      | 7.0                     |
| Quest Diagnostics (DGX)      | 154.94              | 119.17               | 30%               | 23,020                     | 2.1                      | 6.6                     |
| Sonic Healthcare (SHL.AX)*   | 41.63               | 32.15                | 29%               | 22,570                     | 2.6                      | 8.8                     |
| Exact Sciences (EXAS)        | 103.65              | 132.49               | -22%              | 19,270                     | 39.6                     | NA                      |
| Guardant Health (GH)         | 129.09              | 128.88               | 0%                | 12,820                     | 31.2                     | NA                      |
| Natera (NTRA)                | 120.15              | 99.52                | 21%               | 11,070                     | 21.9                     | NA                      |
| Invitae (NVTA)               | 31.17               | 41.81                | -25%              | 7,070                      | 18.2                     | NA                      |
| NeoGenomics (NEO)            | 52.52               | 53.84                | -2%               | 6,330                      | 13.0                     | 59.0                    |
| Veracyte (VCYT)              | 48.66               | 48.94                | -1%               | 3,320                      | 21.1                     | NA                      |
| CareDx (CDNA)                | 69.47               | 72.45                | -4%               | 3,310                      | 13.0                     | NA                      |
| Myriad Genetics (MYGN)       | 33.23               | 19.77                | 68%               | 2,780                      | 5.0                      | NA                      |
| Opko Health (OPK)            | 3.56                | 3.95                 | -10%              | 2,680                      | 1.4                      | 14.2                    |
| Fulgent Genetics (FLGT)      | 93.69               | 52.10                | 80%               | 2,400                      | 2.6                      | 3.6                     |
| Castle Biosciences (CSTL)    | 74.48               | 67.15                | 11%               | 1,750                      | 22.4                     | NA                      |
| DermTech Inc. (DMTK)         | 35.33               | 32.44                | 9%                | 778                        | 85.3                     | NA                      |
| Aspira Women's Hlth (AWH)    | 3.49                | 6.71                 | -48%              | 342                        | 57.2                     | NA                      |
| Biodesix (BDSX)              | 9.66                | 20.16                | -37%              | 235                        | 3.1                      | NA                      |
| Progenity (PROG)             | 1.02                | 5.31                 | -81%              | 215                        | 2.9                      | NA                      |
| Enzo Biochem (ENZ)           | 3.49                | 2.52                 | 38%               | 163                        | 1.5                      | 21.8                    |
| Exagen (XGN)                 | 13.30               | 13.20                | 1%                | 130                        | 2.8                      | NA                      |
| Interpace Biosciences (IDXG) | 9.33                | 3.14                 | 197%              | 91                         | 2.3                      | NA                      |
| Biocept (BIOC)               | 3.79                | 4.44                 | -15%              | 49                         | 0.9                      | NA                      |
| Psychemedics (PMD)           | 7.79                | 5.09                 | 53%               | 49                         | 2.2                      | 33.4                    |
| Unweighted Averages          |                     |                      | 15%               | \$153,852                  | 15.4                     | 19.3                    |

\*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from company reports and Capital IQ

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