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# AVALON'S COVID-19 TESTING AND LAB BENEFIT MANAGEMENT BRIEF

from Avalon Healthcare Solutions

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*Avalon is an expert in lab management with a foundation in science. Clinically-driven lab strategies are transforming lab testing into actionable intelligence for value-driven care. Avalon's core program includes a full delegation of Routine Testing Management, Genetic Testing Management, Independent Laboratory Network Management, and Medical Specialty Rx Management. You can learn more about our impact [here](#) and the latest news [here](#).*

# THE LATEST IN LAB BENEFIT MANAGEMENT AND IMPROVING HEALTHCARE OUTCOMES

On March 23, Avalon's CEO Bill Kerr was joined by Julie Barnes of Maverick Health Policy to discuss market trends and recent policy changes that impact lab testing and the greater healthcare industry. Their discussions touched upon some updates on COVID-19 lab tests in light of the Biden administration's new national pandemic-management strategies, reimbursement of lab testing, federal policy priorities as well as the transition of our healthcare system towards value-based care.

## UPDATES ON COVID-19 LAB TESTS

### *New COVID-19 Lab Tests in the Market*

Over the past year, the FDA has issued a record number of Emergency Use Authorizations (EUAs) due to the COVID-19 pandemic; at least 341 EUAs are allocated for in vitro COVID-19 diagnostic tests alone. Two new tests were recently granted EUAs:

#### **1) T-DETECT COVID TEST**

T-Detect COVID Test, developed by San Francisco-based company Adaptive Biotechnologies, utilizes next-generation sequencing to determine if individuals have been exposed to the SARS-CoV-2 virus by identifying the presence of adaptive T-cell immune response against the virus. Unlike current standardized COVID-19 PCR tests, which detects viral nucleic acid, this test analyzes DNA sequences from the body's own T-cells. Since T-cells contributes to immune memory, the T-Detect COVID Test is highly effective in detecting recent or prior SARS-CoV-2 infections. This is extremely useful for patients who may have experienced COVID-19 symptoms or believe they have been exposed to the virus but are not currently tested positive using the standardized tests.

#### **2) CUE™ COVID-19 TEST HOME AND OVER-THE-COUNTER (OTC) USE TEST**

Cue™ COVID-19 Test is developed by Cue Health Inc, a company based in San Diego, CA. It is the first COVID-19

PCR-type test authorized for at-home use. The OTC test does not require a prescription and is effective in detecting SARS-CoV-2 viral nucleic acid from nasal swab samples. The self-testing kit comes with a test cartridge, single-use 'Sample Wand' nasal swab and a battery-operated cartridge reader that connects to a Mobile App. Test results are available to the user within 20 minutes. This rapid, self-testing strategy is useful in increasing access to COVID-19 tests and achieving the goal of scaling up testing in the country.

### *Expanding the Nation's Testing Capacities - Biden's National Strategy for COVID-19 Response and Pandemic Preparedness*

As part of the Biden administration's National Strategy for COVID-19 Response and Pandemic Preparedness, the U.S. Department of Health and Human Services (HHS) will be allocating more than \$12 billion to scale up COVID-19 testing. In particular, this expansion of testing services will be largely focused on supporting larger-scale screening tests to facilitate the reopening of schools.

In addition, as part of the strategy, the FDA has released new guidelines to facilitate COVID-19 test development. These new guidelines include easing of requirements needed for tests to receive an EUA, such as removing the need for developers to first conduct testing on their COVID-19 tests on asymptomatic individuals. Home-based and point-of-care tests have especially benefitted from these new guidelines, drastically accelerating the process of these kits gaining authorization for public use. On top of that, test developers are receiving federal grants to scale up manufacturing and production of their tests. Cue Health, for example, received \$481 million from HHS and is expected to distribute 6 million COVID-19 tests by March 2021.

Collectively, these new changes are designed to increase access to COVID-19 tests and facilitate the reopening of schools and industries.

## REIMBURSEMENT OF LAB TESTING

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With the expansion of COVID-19 testing across the country, there are concerns about costs. The big question is who will be paying for the cost of testing? The federal government is committed to reimbursing for public health testing, particularly for the uninsured, to contain the spread of COVID-19. Congress designated billions in the American Rescue Plan to supporting the costs of testing for schools.

Private health plans also share reimbursement responsibility for COVID-19 testing. Following the new guidelines from the three federal agencies — Labor, Treasury and HHS, private plans are required to pay for COVID-19 diagnostic tests without cost-share, even when patients are asymptomatic. However, healthcare plans are unable to distinguish back-to-work or back-to-school testing from other purposes such as travel. So health plans may be at risk for paying for thousands of tests for which they are not legally required to cover.

Telehealth services have become increasingly popular in the past year due to the pandemic. It is important for plan providers to be aware that many referrals for diagnostic tests could be coming from those virtual visits, and make sure they have clear policies in place about reimbursing the appropriate tests. Plan providers will also need to be cognizant of the price transparency rules for both hospitals and healthcare plans, because the transparency regulations and the new surprise billing law will demand that patients have to be aware of the cost of their lab tests.

## FEDERAL POLICY PRIORITIES

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In Washington D.C., changes in the leadership of federal healthcare agencies are underway. The U.S. Senate recently confirmed Xavier Becerra as the new secretary of HHS. While the permanent positions for both Centers for Medicare & Medicaid Services (CMS) administrator and FDA commissioner are not yet filled, President Biden has nominated Chiquita Brooks-LaSure for CMS

Join us May 25  
for Avalon's webinar:

### Trends in Clinical Genetic Testing Impacting Health Plans Today

- Understand the many different genetic test panels
- Differentiate various gene coverage
- Overview of genetic testing standardization efforts

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administrator. If confirmed, Brooks-LaSure will be the first Black woman to be CMS administrator. Previously, she served as the deputy director for policy at CMS' Center for Consumer Information and Insurance Oversight, as well as the director of coverage policy at HHS where she played important roles in the implementation of the Affordable Care Act under the Obama administration.

POST-FIRESIDE CHAT UPATE: After her smooth confirmation hearing in April, members of the Senate Finance Committee voted along party lines -- a 14-14 split -- and ultimately delaying a full Senate vote on Brooks-LaSure's nomination. Republicans said their dissent was not due to the nominee's qualifications but in protest of the administration's revoking a previously approved Medicaid waiver for Texas. It is expected Brooks-LaSure will be confirmed sometime in May.

The Biden administration is prioritizing more equitable healthcare by focusing on disparities. Dr. Marcella Nunez-Smith, a doctor and public health specialist at Yale, will lead a 12-person health equity task force to address the disproportionate impact of COVID-19 on vulnerable communities. These efforts will continue throughout the Biden administration, even after the pandemic has ended.

# VALUE-BASED HEALTHCARE

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- **PARADIGM SHIFT FROM VOLUME-BASED TO VALUE-BASED HEALTHCARE**

As the country moves forward in the post-pandemic era, Avalon anticipates a transformative change — a shift from volume-based to value-based healthcare.

The pandemic exposed the weaknesses of a fee-for-service system. It continues to be a challenging method to finance medical care, especially during a public health crisis. When health provider offices were shut down during the pandemic due to state-wide lockdown policies, their revenue were dramatically reduced. Providers who had value-based contracts, however, did not have to rely on the number of patients seen or how many services are rendered, and were able to keep revenue flowing. With that, many were even able to easily shift to virtual care/telemedicine platforms. In addition, providers that had shifted to value-based care were also more likely to have data analytics platforms to support population health management and were better equipped to find patients most at risk of contracting the disease. Accordingly, providers who are accustomed to value-based contracts and who have invested in these systems were able to provide quality care in lower cost environments, despite a pandemic.

Moving forward, sweeping interoperability, information blocking, and price transparency rules will make health data and price data more available and accessible than ever before. Patients will be able to find and keep track of their own medical records so that they can make personal decisions on their treatment options and manage their medical conditions. They will also have information about where to go for the highest quality, yet most affordable care. There will even be electronic quality control measures in place so that patients will be able to provide timely feedback pertaining to their experiences. Because of these new rules and regulations, patients are able to gain access to information about any forms of medical services available in the market. They will even be able to

download this information onto an app of their choice on their smartphones to help them navigate all of the information.

- **AVALON'S LAB TREND REPORT**

How is Avalon responding with these transformative times? Avalon is currently in the midst of preparing a Lab Trend Report that will discuss our value-based initiatives, including some current policy issues and the many changes in healthcare, both at a federal and individual level. This insightful report will be the industry's first comprehensive lab trend report.

- **LAB COALITION**

For better or for worse, the public health emergency shone a bright spotlight on how lab tests are manufactured, how they get to market, the different types of tests that are available, and how much they cost. With all of this attention, particularly on the challenges of our country's poor public health infrastructure, federal policymakers are eager to make fundamental changes to the oversight of the lab testing industry. With policy changes so likely to change dramatically in the years ahead, Avalon Healthcare Solutions is launching a new coalition -- it is called the LAB Coalition, "Laboratory Access and Benefits Coalition." The purpose of the coalition is to make sure that policymakers create a regulatory infrastructure that will ensure better access, value, and trust in our diagnostics industry.

So the LAB Coalition is going to lobby Congress and anyone else in a position to change federal policy so it makes more sense. Avalon is leading this effort, putting together a diverse group of healthcare industry leaders who care about lab testing. The point is to capitalize on the positive developments and lessons learned during COVID to transform lab services for the future. Avalon invites anyone reading this to inquire about the LAB Coalition - which will bring together payer, manufacturer, patient, consumer, provider, laboratory professionals, and health care thought leaders to advocate for legislative and regulatory solutions for better lab testing policy.

## AVALON LABORATORY NETWORK CAPACITY & TURNAROUND TIME REPORT

LAB	RT-PCR Y/N	MULTIPLE PLATFORMS	CAPACITY (PER DAY)	TAT
Quest	Y	Y	300,000	1-2 days
LabCorp	Y	Y	275,000	1-2 days
Aegis	Y	Y	110,000	1-2 days
BioReference	Y	Y	100,000	1 day
Premier Medical Lab	Y	Y	100,000	1-2 days
Eurofins-Diatherix	Y	N	60,000	1-3 days
Mako Medical Lab	Y	Y	50,000	1-2 days
GenetWorx	Y	Y	40,000	2 days
AIT (American Institute of Tox)	Y	Y	20,000	1-2 days
PathGroup	Y	Y	20,000	1-2 days
Sonic-CPL	Y	Y	20,000	1-3 days
Genesis DX	Y	Y	16,000	1-2 days
MDL (Medical Diagnostic Lab)	Y	N	12,000	1-3 days
AccuReference	Y	N	10,000	2 days
LabTech	Y	Y	10,000	2 days
Inform Diagnostics	Y	N	5,000	1-2 days
Luxor	Y	Y	5,000	1 day
Neogenomics	Y	Y	5,000	1-4 days
Transplant Genomics	Y	N	5,000	1-2 days
Precision Genetics	Y	N	4,000	1-2 days
BAKO	Y	N	2,500	1-2 days
Radeas	Y	Y	2,400	1-2 days
NephronPharm	Y	Y	2,000	2-3 days
Wake Medical Lab Consultants	Y	Y	1,500	1 day
Andor Labs	Y	N	500	1-2 days
SMA	Y	Y	500	1-2 days



Attendees of the April 20th webinar had a sneak peek of Avalon's Lab Trend Report, the laboratory industry's first-ever comprehensive trend report that consolidates and analyzes various forms of claims and laboratory data. Set to be released in May 2021, the report aims to provide valuable insights into the trajectory of lab diagnostics to the community by critically evaluating historical patterns, events, past and current health, and federal policies as well as scientific advances in diagnostic technologies. With Avalon's vast industry experiences, the report will contain expert perspectives that will aid in predicting and understanding future trends.

Avalon's Lab Trend Report is particularly useful in today's context as the COVID-19 pandemic has raised global awareness about the importance of lab testing in managing diseases as well as exposed issues on industry-government dynamics. Because of the advent of diagnostic technologies, there are more lab tests (that also more complex) available than ever before. Also, medical care is heavily reliant on lab tests, therefore, knowing how to facilitate test management (i.e., costs, types, claims, regulations, market forces) has become increasingly important.

## ***What can one expect from the Lab Trend Report?***

- Lessons learned from the COVID-19 pandemic.
- Market forces influencing the industry and healthcare plans.
- Avalon's Lab Management Benefit program and services.
- A forward-looking message from Avalon's Clinical Advisory Board Chair Geoff Baird, Professor and Acting Chair of Laboratory Medicine and Pathology at the University of Washington.

- Other major concerns include managing genetics tests and unit price trends, the importance of government regulations and increasing patient focus.
- Avalon's transition from volume-based to value-based care with the emphasis on integrating lab results.

Ultimately, the Lab Trend Report will be a useful tool to help decision-making processes that will benefit businesses, customers and patients. To watch the April 20th webinar, read past newsletters, and learn more about Avalon Healthcare Solutions please visit our website: [www.avalonhcs.com](http://www.avalonhcs.com). In the latter half of the year, we will also delve deeper into and expand on topics covered in the Lab Trend Report.

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