



Industry Outlook Report

Laboratory Market Trends: A View to 2021





Introduction

2020 has caused dramatic changes in laboratory-based diagnostics, healthcare, and medicine beyond what anyone could have imagined one year ago. As 2021 approaches, we expect the diagnostic laboratory testing market to experience both unique opportunities for growth and profitability, as well as challenges due to potential changes to reimbursement – a common theme as of late.

Within the COVID-19 diagnostic testing segment, we see a steady increase in the number of tests performed and in the diversity of testing options. Reimbursement incentives for high throughput and fast turnaround times will favor laboratories that have streamlined their processes and adopted technology to drive automation and other high throughput strategies. Laboratories will need to continue to invest in technology within the lab as well as in automation that facilitates efficient communication with physicians, patients, and public health agencies. The pandemic has incited some laboratories to invest in molecular diagnostics testing platforms, and these labs are likely to expand their molecular diagnostic testing menus in 2021 and beyond to include syndromic infectious disease panels in order to ensure efficient utilization of those systems over time.

Also, in 2021, the Centers for Medicare and Medicaid Services (CMS) has proposed significant cuts in reimbursement to pathologists and clinical diagnostic laboratories that perform certain tests. This will drive laboratories impacted by these cuts to seek ways to reduce costs through new technologies that streamline workflows. Under this same plan, molecular pathology interpretation services will be reimbursed at more than twice the current rate. This increase should drive momentum within the molecular pathology testing market and have a positive impact on personalized medicine.



Reimbursement incentives for high throughput and fast turnaround times will favor laboratories that have streamlined their processes and adopted technology to drive automation and other high throughput strategies.”



COVID-19 Testing

Laboratories will continue to find a strong market for testing symptomatic and asymptomatic individuals for COVID-19 using high-sensitivity methods such as qPCR and loop-mediated isothermal amplification (LAMP). These tests will remain in high demand in 2021 as more people return to work and to travel. Routine screening of asymptomatic individuals will still be needed for those in assisted living facilities, attending universities and schools, entering pre-surgical care, and working in high-risk professions.

In addition to high-sensitivity molecular tests, we foresee new trends emerging in the COVID-19 laboratory testing market in 2021, such as:

- **Serology Tests for SARS-CoV-2:** Clinically meaningful antibody-based tests will complement the COVID-19 testing menu of many diagnostic testing labs. For example, in November 2020 the U.S. FDA issued the first Emergency Use Authorization (EUA)¹ for a serology test that detects neutralizing antibodies from recent or prior infection with SARS-CoV-2.
- **High Throughput, Fast Turnaround:** CMS will modify reimbursement² for COVID-19 testing to \$100 per test for laboratories that:
 - issue test results within two days of specimen collection, and
 - complete the majority of COVID-19 diagnostic tests using high-throughput technology within two days for all patients (not just Medicare patients) in the previous month.

Laboratories that take longer than two days to release COVID-19 diagnostic test results will be reimbursed at a rate of \$75 per test.

In order to meet anticipated demand for COVID-19 testing, many laboratories have invested significantly in automation equipment and software to increase throughput and improve result turnaround time. These labs should reap the benefits of this investment in 2021 given the CMS reimbursement changes.

- **Increased Testing at Regional Labs:** COVID-19 reimbursement incentives, as well as the need for increased testing capacity and fast turnaround times, will continue to drive testing toward independent, regional labs. This trend will open up an opportunity for these labs to capture market share within the larger testing market.

1 <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-test-detects-neutralizing-antibodies-recent-or>

2 <https://www.cms.gov/newsroom/press-releases/cms-changes-medicare-payment-support-faster-covid-19-diagnostic-testing>



Technology to Drive Automation

The demand for faster test results will push laboratories to increasingly adopt technology that drives a higher degree of automation, both within the lab and with important external stakeholders in the diagnostic testing process.

Internal Automation

The demand for rapid testing will increase the use of advanced instrumentation in labs to support high-throughput testing in 2021. This instrumentation can include: liquid handlers, fully or partially automated analyzers, and other types of robotics – all aimed at improving diagnostic testing quality, increasing lab throughput, decreasing manual intervention, and standardizing lab workflows.

In parallel, it will be essential for labs in 2021 to have a laboratory information management system (LIMS) that automates the entire workflow by managing samples and associated data, to improve lab operations and efficiency. Labs will demand flexible and configurable LIMS applications that can handle high-volume accessioning and support instrument interfacing across multiple testing lines to ensure reliable data processing and fast turnaround times.



In parallel, it will be essential for labs in 2021 to have a laboratory information management system (LIMS) that automates the entire workflow by managing samples and associated data, to improve lab operations and efficiency.

External Automation

In 2021, labs will also demand additional technology to further automate communication with external stakeholders. They will need to automate both front-end and back-end processes and streamline ordering and reporting through their LIMS, or a tightly integrated provider portal, to support communication with physicians and patients. At the same time, more labs will require integration with their LIMS and other key systems, such as billing software, to expedite reimbursement. Finally, we expect there will be a greater demand for robust public health reporting via LIMS integration with public health systems in 2021.



Test Menu Expansion

The pandemic has caused fluctuations in routine diagnostic testing in 2020, with volumes now beginning to return to pre-COVID levels. This will continue into 2021 as more people return to providers for in-person treatment related to chronic conditions or routine medical care.

Clinical laboratories that have built a solid customer base in COVID-19 testing may see a jump in testing for other analytes in 2021. To adapt to these demands, many diagnostic testing labs will expand their test menus. They are likely to introduce molecular diagnostic panels for upper respiratory pathogens, including influenza A, influenza B, and tuberculosis. And the capital equipment expenditure to support COVID-19 testing will prompt laboratories to move into other areas of syndromic infectious disease testing using molecular techniques (e.g., sexually transmitted infections, gastrointestinal illnesses, chronic wounds, etc.).



Proposed CMS Reimbursement Cuts

CMS has released a Physician Fee Schedule (PFS) Proposed Rule that proposes significant payment cuts for pathologists and clinical laboratories that bill under the Clinical Laboratory Fee Schedule (CLFS). The agency estimates payments to pathologists will decrease by 9% (\$1.1 billion over 10 years), while payments to clinical laboratories will decrease by ~5%. Additionally, several cytopathology codes will be cut by nearly 22%. However, molecular pathology interpretation will be reimbursed at a higher rate under these changes (increasing from \$19.13 to \$42.91).

These proposed cuts represent a significant impact to the overall diagnostic industry in 2021 and beyond. Laboratories performing diagnostic testing will need to find creative solutions to reduce costs. Many will turn to technology first, creating opportunities for collaboration with core vendors, such as their LIMS provider, to assist with automation and workflow efficiencies.



Advancement of Personalized Medicine

The push for personalized medicine via genomic- and proteomic-specific diagnostics will continue in 2021, as the decreased costs associated with next-generation sequencing (NGS) and other genomics-based techniques have made this class of test more accessible. Further, the increase in reimbursement for molecular pathology will likely contribute to the strong performance of this market segment in 2021.

The companion diagnostics market has seen significant advances in 2020, with a total of ten therapeutics receiving FDA approval in combination with one or more companion diagnostics. We anticipate this market will maintain steady growth throughout 2021. Also, we predict NGS panels for oncology will increase in value, with a greater emphasis on panels that monitor for disease progression and those that assist with therapeutic selection based on patient tumor profiles.



Conclusion

In sum, 2020 has been a rollercoaster of a year for laboratories (and virtually every other area of health-care), that brought on quick, dramatic changes. There's no sign of these changes slowing down over the next year, and we expect labs to face new opportunities and challenges in 2021.

Now is the time to focus on how to capitalize on the opportunities, and effectively manage any headwinds that may arise. Technology will be the key. Should your laboratory need a solution to improve automation, streamline your workflow, or extend your customer reach, [contact the ApolloLIMS team](#). Our team of lab professionals will work with you to ensure your lab is prepared for all that may come in 2021.



Now is the time to focus on how to capitalize on the opportunities, and effectively manage any headwinds that may arise. Technology will be the key.

[ApolloLIMS.com/contact](https://www.apollolims.com/contact)

About

ApolloLIMS offers a comprehensive, configurable platform to streamline the operations of a diverse array of laboratory environments. The company began in the 1990s as a laboratory technology consulting firm. Today, ApolloLIMS provides its extensive and trusted laboratory information management system to effectively assist its customers in navigating the reimbursement, regulatory, and competitive pressures that animate the current laboratory marketplace.

The company extends its Apollo Alliance commitment of deep expertise, data-driven best practices, and unparalleled support to more than 80 toxicology, molecular, clinical and public health laboratories across the country, the majority of which turned to Apollo to set up Covid-19 testing and reporting in 2020.



www.apollolims.com

