cytiva

Research Report

The future of diagnostics

Advancements, challenges, and opportunities

cytiva.com

For diagnostics, the post-pandemic future is bright

Technological advances, innovative platforms, and decentralized test options are driving exciting developments and optimism across the diagnostics industry.

While the industry was put front and center during the COVID-19 pandemic, diagnostics have always played a critical role in treating illnesses and managing health. The ability to gain a fast, accurate understanding of a person's disease status helps to drive effective treatment in a timely manner and improve patient outcomes.

With new, more targeted and personalized therapies coming to the market quickly, and changing the way we treat complex conditions, it's increasingly important that diagnostics developers and manufacturers keep pace. Technological advancements, along with recent industry shifts and learnings, are setting the stage for exciting changes in diagnostics and clinical care.

To gain an understanding of where the diagnostics industry is at this pivotal time — and where it's going in the next 5 years — we surveyed a sample of people from the diagnostics industry. The objectives of this study were to:

- Gain an understanding of which external factors will have the most significant positive and negative impacts on the industry in the next 5 years
- Uncover and understand the challenges facing diagnostics customers, currently and in the next 5 years
- Learn what solutions and technologies diagnostics customers are seeking
- Find out how anticipated changes in key areas are likely to affect patients
- Identify growth areas for diagnostics development

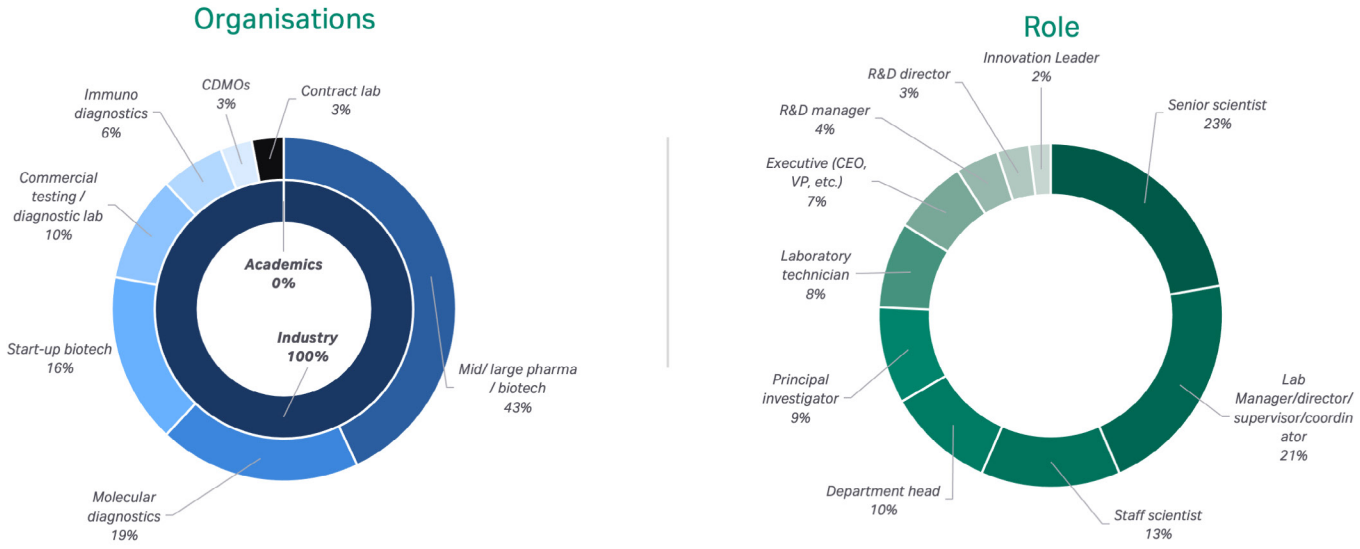
Who we spoke to for our diagnostics research

From March through April of 2023, we surveyed 175 members of the diagnostics industry, gathering information and insight on the current state of the diagnostics across three key regions: 41% of respondents came from the European Union (EU); 40% from the United States and Canada (USCAN); the remaining 19% were from the Asia Pacific region (APAC). This sample size and the respondent characteristics were selected to represent the broader, global diagnostics landscape.

Our industry representatives included a mix of senior and junior employees across various roles, company sizes, and diagnostic application areas (Fig 1). The majority of those surveyed worked for mid- to large-sized biotech or biopharma companies (43%), followed by molecular diagnostics organizations (19%) and start-up biotechs (16%). Nearly a quarter of respondents were senior scientists.

Most of those surveyed were working on the development or manufacturing of diagnostic kits (57%), with the rest involved in later stages of the process, closer to the patient, doing clinical diagnostics work (43%). When asked the area of research where they spent over 50% of their time, most responded with molecular diagnostics (58%) — where an assay's target is a nucleic acid — with the remainder working with immunodiagnostics that center around the identification and quantitation of proteins.

Fig 1. A breakdown of organizations and roles that are represented within our survey sample.



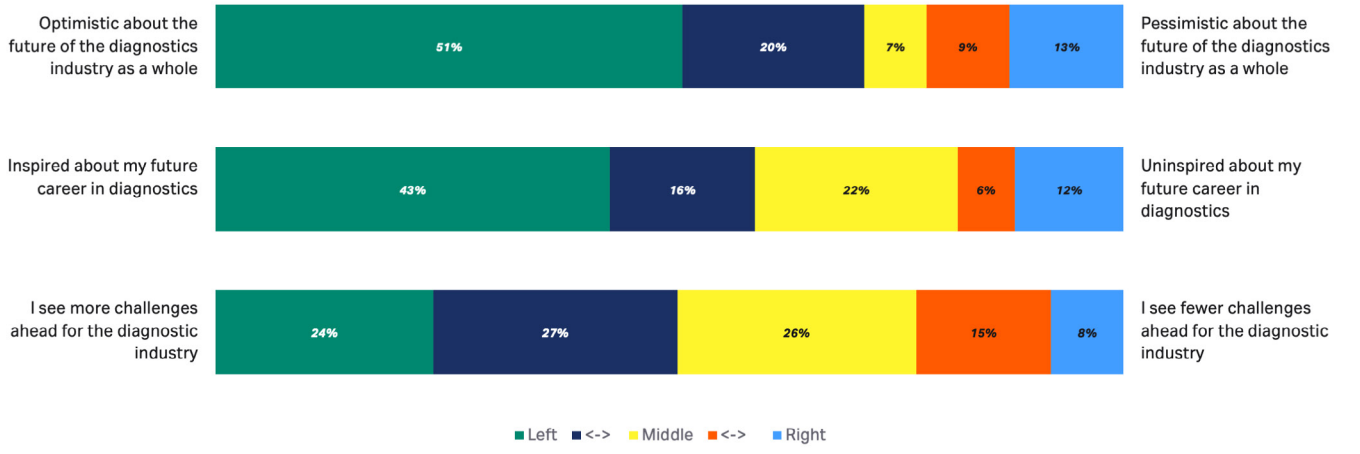
Optimism for the diagnostics industry is strong

Overall, the members of the diagnostics community who participated in our survey are feeling optimistic. When asked to rate their confidence about the industry's future on a five-point scale, more than half of those surveyed responded with the most optimistic outlook possible. Only 13% feel entirely pessimistic about the future of diagnostics, with all other responses falling somewhere in between (Fig 2).

With talent being an important driver of biopharma growth and resilience, checking in on how the diagnostics workforce is feeling about the future can help shed light on the industry's health and trajectory.

Reassuringly, there was a similarly positive distribution when people were asked if they felt inspired about their future careers in diagnostics. This result is good news for companies looking to grow their diagnostics business, as finding and retaining trained, knowledgeable employees is a known challenge in biopharma.

Fig 2. A measure of diagnostics customers' optimism about the industry and their careers, as well as expectations of challenges to come.

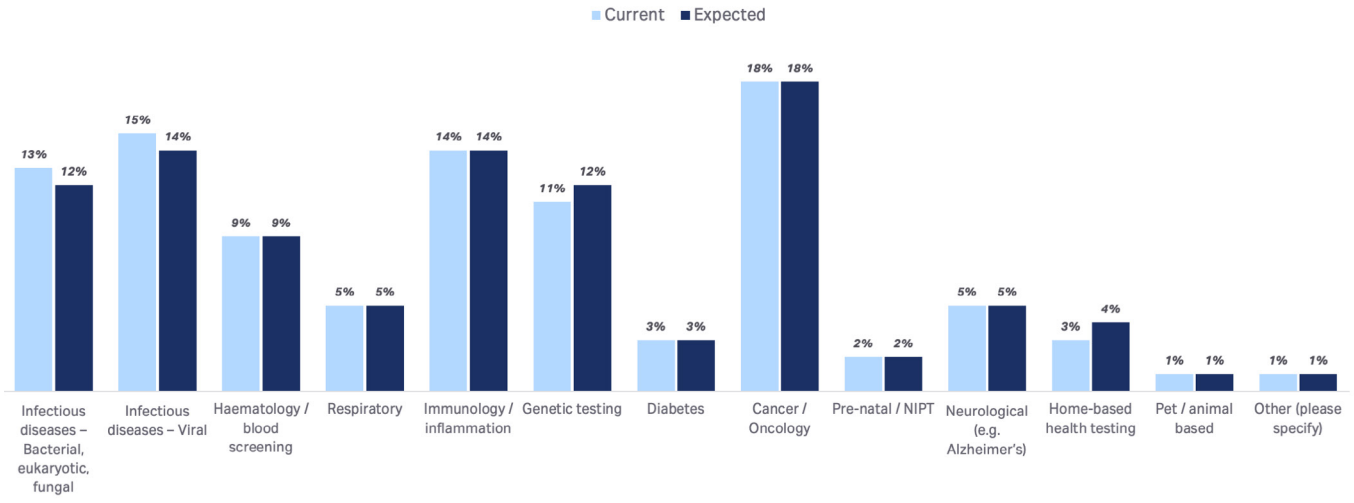


How customers spend their time on diagnostic activities

Our research participants focus on a wide range of clinical and across diagnostics applications. Based on survey results, there isn't expected to be a drastic change in how time is spent within the industry over the next 3 to 5 years (Fig 3).

There's expected to be a slight move away from infectious disease diagnostics, perhaps related to COVID-19 work slowing down. The anticipated increase in genetic testing can, in part, be explained by an increased focus on genetic biomarkers and companion diagnostics associated with novel therapeutics. A projected rise in time spent on home-based diagnostics aligns with a recent overall shift toward telehealth and more at-home services, catalyzed by the pandemic.

Fig 3. Across clinical and test application areas, a comparison of how time is currently spent within the diagnostics industry versus how diagnostics customers expect to allocate time in the next 3 to 5 years.



5 constructive changes from COVID-19

The COVID-19 pandemic has shaped the diagnostics industry in many ways over the past 3 years and will continue to influence its trajectory into the future. Respondents to our survey see many of the lessons learned from the pandemic as good ones. Below is a summary of five positive changes members of the diagnostics community identified as coming from COVID-19:

1. Access to telemedicine and remote healthcare
Because of COVID-19, the ability to deliver and receive care via telephone, video, and online chat gained traction. With patients staying home, payers began reimbursing for virtual consultations and remote monitoring. Diagnostics, being an integral part of the care process, is now being called upon to develop test platforms to support a more home-based care model.

In addition to providing exciting new test options for the industry to pursue, this shift also offers several advantages for patients. More continuous and convenient health insights can lead to increased compliance with medication use, testing, and follow-up and, ultimately, has the potential to improve outcomes (1).

2. Improved personal and public health practices
The pandemic increased the public's awareness and understanding of viral disease transmission and testing. This knowledge has led to increased concern for personal health and a proactive approach to preventing the spread of disease, including the adoption of effective hygiene practices such as mask-wearing, hand washing and sanitizing, and distancing when ill.

From a public health perspective, the pandemic also led to improved disease surveillance strategies, both locally and globally. These systems are now in place to respond more efficiently to future viral pandemics and health threats.

3. Investment in research and infrastructure
The need to rapidly deliver testing options, vaccines, and treatments for COVID-19 meant that facilities and laboratories needed to shift focus and scale operations quickly. This demand led to increased research funding for biopharma and investment in equipment and infrastructure — including improved cold chain solutions — that can now serve a wide range of applications into the future.

4. Rapid test development
For both molecular and antigen targets, "rapid" testing was a hot area of focus during COVID-19. Early in the pandemic, it became clear that the ability to get fast, reliable results — at home or at the point-of-care — was going to be key to stopping transmission and getting back to normal daily life, work, travel, and more. With time-sensitive antivirals in the mix, prompt answers become even more critical.

Looking beyond the pandemic, the move toward developing tests that deliver quick, accurate results can continue to help streamline care across diagnoses. The faster a clinician can understand a patient's condition, the faster a treatment plan can be initiated.

5. Collaboration and adaptation
The diagnostics industry came together in extraordinary, unprecedented ways during the COVID-19 pandemic, and the effects are set to be long-lasting. For the sake of patients across the world, companies joined forces to accelerate test development and automate and scale diagnostics processes. Partnerships between public entities, private companies, and research institutions also helped improve access to testing. Regulatory agencies, for example, worked closely with test developers to streamline submission and approval processes.

Like most business sectors, the diagnostics industry also faced supply chain constraints in recent years due to travel restrictions, plant shutdowns, and project delays. In response, diagnostics companies have diversified suppliers and are now more discerningly stocking critical materials.

5 adverse effects of the pandemic

Not all of the COVID-19 related changes are seen as positive. Here are five ways respondents said change happened for the worse because of the pandemic.

1. Healthcare and workforce challenges
Medical institutions and research laboratories faced a range of challenges during the peak of the pandemic. High insurance, hospital, and healthcare costs put a strain on the system, and talent shortages limited institutional growth and operations, which, in some cases, affected quality.

2. Supply chain constraints
With an unanticipated need for tests and the logistical hurdles introduced by the pandemic, manufacturers were unable to keep up with demand. As a result, test equipment, materials, and reagents quickly fell into short supply, highlighting the vulnerability of global supply chains in the diagnostics area.

3. Funding allocation and financial impacts
The intense focus on COVID-19 may have led to the neglect of other important health issues, both in terms of attention and investment. With all eyes on developing and manufacturing solutions for the pandemic, funding for other programs and research into other disease states was, in many cases, deprioritized.

Price hikes have also increased overall financial risk within the diagnostics industry, and fluctuating investor interest has impacted market growth.

4. Environmental concerns
The diagnostics industry uses a large amount of plastic, bleach, and corrosive chemicals. When research and production activities ramped up during COVID-19, the increased use and disposal of these materials surely impacted the planet.

5. Quality issues and public perception
With tests being quickly developed using new diagnostic methods, there were instances of inaccurate results leading to overall quality concerns. As a result, the public's perception of diagnostic testing was negatively affected, leading to distrust of the industry as well as the FDA, CDC, and regulatory bodies. Particularly in the beginning of the pandemic, misinformation and political influences further compromised biopharma's reputation.

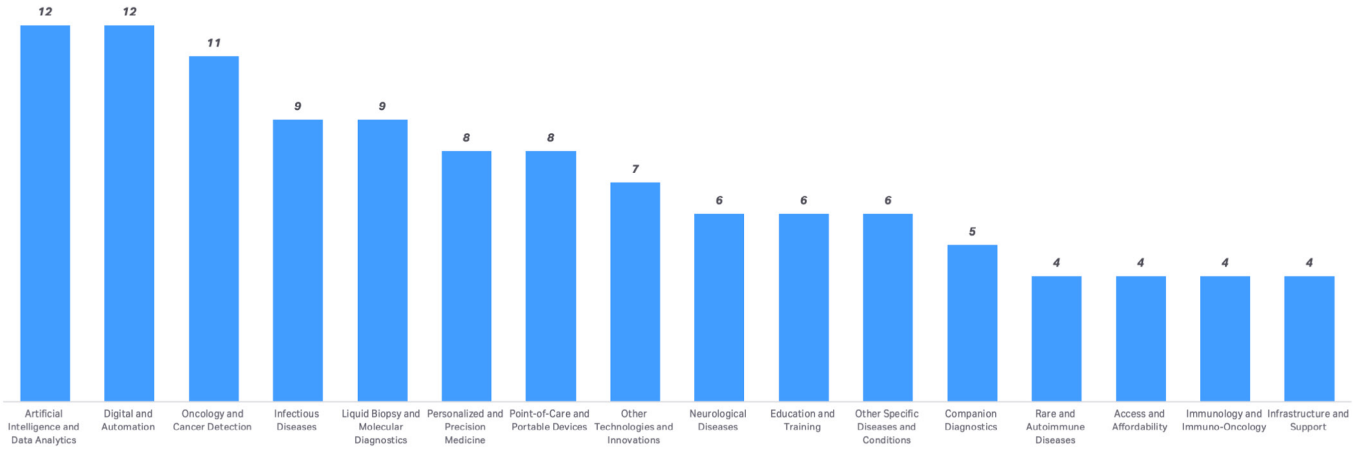
The future of diagnostics

Looking ahead, our research points to a rich, diverse future for the diagnostics industry. Tapping into the momentum gained and lessons learned during the pandemic, customers highlighted a wide range of areas they expect to evolve favorably over time. Over the next 3 to 5 years, these anticipated changes will help drive expanded and enhanced diagnostic capabilities, products, and processes so the industry can better serve patients.

Advancing the technology behind diagnostic development and application

Technological advances driven by artificial intelligence (AI) and digital solutions are sure to shape the future of the diagnostics industry. In fact, when respondents were asked what area they would choose to invest in if they had a blank check, AI tied as the top answer, along with digital and automation (Fig 4).

Fig 4. Results from asking respondents the following question: If you were given a blank check to invest in one area to improve the diagnostic industry, what area would you choose? (Note: This was an open verbatim question so the numbers equate to the number of mentions)



Progress in these areas has the potential to make diagnostics more informative, reliable, and efficient, especially with the influx of data from wearable health devices and genetic testing (2). Where humans might miss key trends, AI and machine learning can work together to identify signals within these large datasets. Patterns that are detected may help characterize or predict disease, helping to drive more informed diagnostic algorithms. AI algorithms can also be programmed to "see" details in diagnostic images that would otherwise be overlooked or misunderstood.

In parallel, faster, cheaper, and more efficient genetic assay techniques — such as long-read sequencing — will help to provide the genetic data needed to reap the most rewards from these digital tools.

Developing new tests and platforms for convenient, accessible, and more personalized care

Diagnostics customers expect to see several changes in the types of tests offered in the next 3 to 5 years, each of which promotes earlier detection and disease prevention in different ways.

- **Multiplexed testing:** Our survey population expects to see an increase in the development and adoption of multiplexed testing, which offers key benefits. By using a single sample to measure multiple targets, the diagnostic process is more efficient, cost-effective, informative, and, potentially less invasive due to the need to collect fewer samples.
- **Liquid biopsies:** In the next 3 to 5 years, respondents expect innovative detection markers and liquid biopsies to lead to earlier detection of cancer, easier monitoring of treatment response, and the ability to identify the emergence of drug resistance sooner.
- **Companion diagnostics:** With the development of more targeted therapies, companion diagnostics — which help characterize and differentiate diagnoses to identify effective treatments — are expected to become a more impactful part of disease screening and management.
- **Point-of-care testing:** Point-of-care (POC) tests provide the rapid results needed to initiate effective treatment without delay. Access to more solutions that promote faster diagnoses will help keep the aging global population healthy as susceptibility to disease increases.
- **Home-based kits:** Aligning with the pandemic-driven shift toward telemedicine, more diagnostics platforms designed for home use are expected in the future. Home-based testing adds convenience to the diagnostics process, particularly for patients who don't have access to transportation or who have mobility issues. It also means higher production volumes may be needed to meet the additional demand from patients versus clinicians.
- **Personal monitoring devices:** The influx of information available with the increased use of devices that offer health metric monitoring could revolutionize diagnostics over time. When combined with AI and machine learning, this data can provide more detailed insights into a person's health to identify patterns associated with disease and diagnose conditions sooner.

Changes to the business of diagnostics

Survey respondents see changes to the regulatory landscape as an ongoing challenge. The complexity of regulatory roadmaps can create a potential barrier for smaller business players, motivate companies to discontinue niche products, and drive a need for more time and resources to navigate new requirements. A rise in the demand and need for easier home testing may lead to a reduction in regulations.

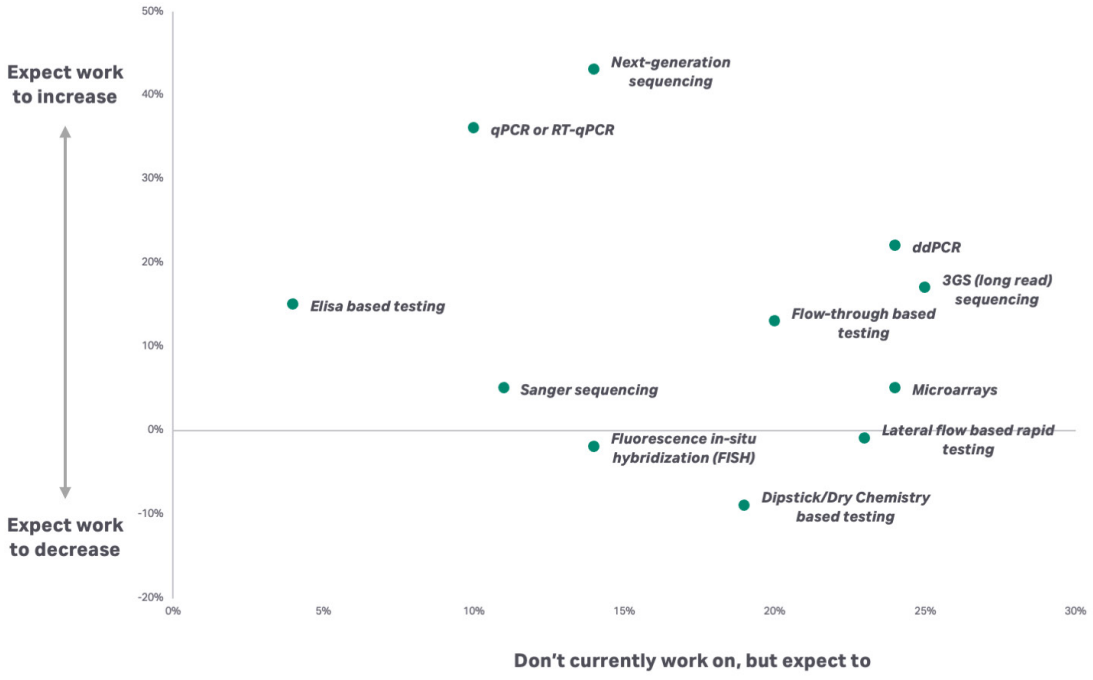
Competition across the diagnostics industry is also expected to increase with the rise of domestic alternatives. This competition has the potential to drive lower prices, reduce gross profit margin, and cause particular financial challenges for small companies.

Technology platforms that are driving the industry forward

With certain diagnostic technologies growing in popularity during the pandemic, we wanted to gain an understanding of which platforms diagnostics customers are currently working with, as well as how those platforms may change in the future.

At present, qPCR, ELISA-based testing, and next-generation sequencing (NGS) are ranked as the top three most used technology platforms within our survey sample. Work in all three of these areas is expected to increase in the future, along with ddPCR, flow-through testing, Sanger and 3GS sequencing, and microarrays. Conversely, customers expect to work less with dip-stick/dry chemistry testing in the next 3 to 5 years (Fig 5).

Fig 5. Prediction of technology platforms respondents expect to be working with in 3 to 5 years.

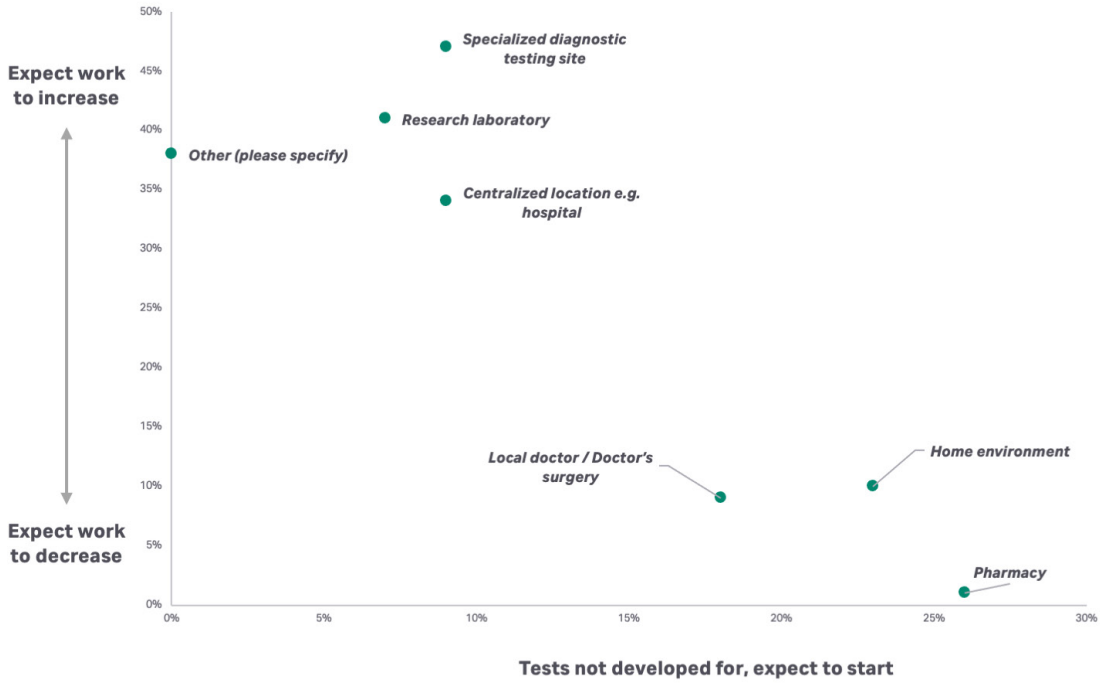


These anticipated changes align with molecular and genetic testing platforms playing an increasingly important role in clinical diagnostics (3). While the pandemic accelerated this shift, its applications expand far beyond infectious disease diagnosis to improved understanding and characterization of cancer, inherited conditions, and more.

Where diagnostic testing is happening, now and in the future

More than half of the diagnostics customers surveyed are currently working with tests intended for specialized diagnostic sites (83%), research laboratories (81%), centralized locations such as hospitals (79%), and doctors' offices (56%).

Fig 6. Prediction of where tests developed by respondents in the next 3 to 5 years will be used.



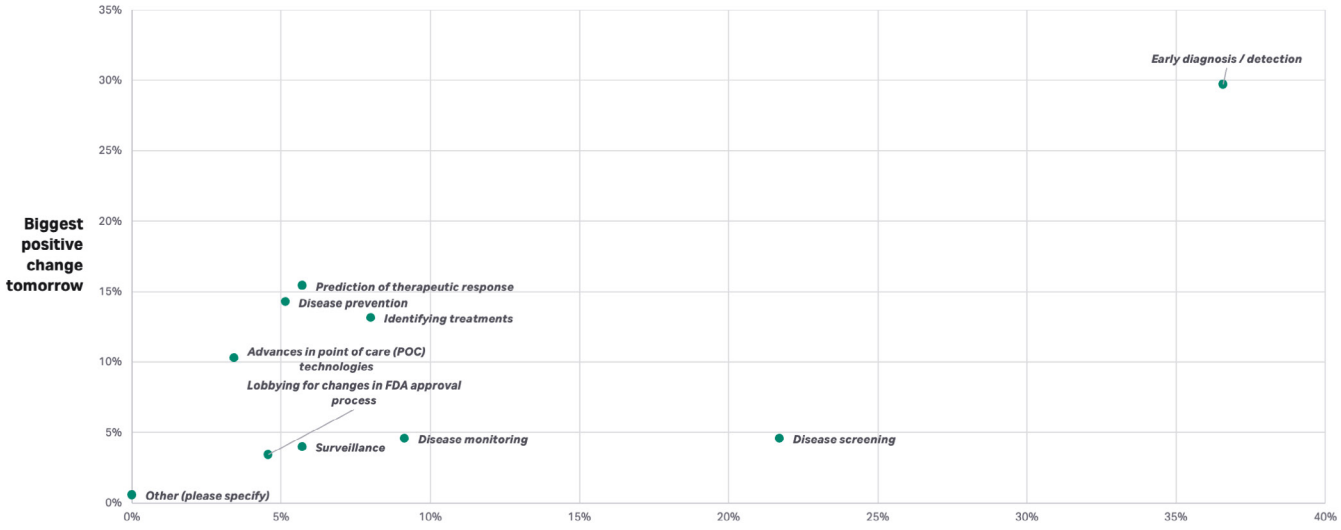
While less than half of the diagnostics customers surveyed are currently working with tests intended for pharmacies and home use, looking to the future, more than half expect to. More than 20% of customers who aren't currently working with these types of test platforms think that they will be in the next 3 to 5 years (Fig 6). Also speaking to the future decentralization of testing, some of the "Other" responses pointed to an increase in work on tests designed for public areas (i.e., cruise ships) and remote locations.

These anticipated shifts suggest more accessible and convenient testing options are coming to benefit patients, particularly those who live in rural areas that aren't close to large medical institutions or specialized diagnostics testing sites.

Diagnostics' biggest impact on patient outcomes, today and tomorrow

When asked about the biggest ways the diagnostics industry is positively affecting patient outcomes today, early disease diagnosis and detection and, along the same lines, disease screening were ranked at the top (Fig 7). By searching for and accurately identifying conditions, reliable diagnostic tests allow clinicians to develop appropriate treatment plans in a timely manner.

Fig 7. A graphical representation of results from the following survey question: Where can the diagnostics industry make the biggest positive change in patient outcomes today and over the next 3-5 years?



Looking ahead, early diagnosis and detection remain an important priority for the industry, with capabilities likely to be enhanced by new technologies, platform development, and AI.

Survey respondents also anticipate a more impactful role in predicting therapeutic response and, similarly, identifying treatments in the future. Advances in precision medicine and pharmacogenomics — powered by assays — are helping to move medicine away from a "trial-and-error" approach to treatment and more towards targeted, personalized, and predictable prescribing. The benefits of getting the right therapy to the right patient the first time are many (4):

- Diseases can be effectively managed sooner
- Progression due to treatment delay is prevented
- Side effects from ineffective, unnecessary medications are avoided
- Costs associated with failed treatment plans are reduced.

The diagnostics industry will play a significant role in driving these critical improvements in care .

Lastly, members of the diagnostics community expect continued advances in POC technology to have a strong positive impact on patients. POC tests offer direct benefits to patients in terms of accessibility and by delivering results quickly, which allows for faster initiation of treatment (5).

Conclusions

The diagnostics industry has seen a lot of change since the start of the pandemic, and our research suggests it will continue to evolve in the future. Challenges remain, but — tapping into the momentum from this recent transformation — customers are feeling optimistic as they look to AI, technological advances, and regulatory cooperation to drive continued progress.

Key advances expected in the future include:

- Incorporating digital tools into diagnostic test development and algorithms to help shed new light on how disease characteristics present and drive innovation across the industry.
- Using diagnostic platforms that are faster and more reliable to help clinicians predict, evaluate, and deliver more personalized, effective, and timely care, as well as monitor outcomes.
- An increase in multiplexed, at-home, and POC test options will make diagnostics more convenient, informative, efficient, cost effective, and accessible.

Our research shows that diagnostic capabilities are only set to grow in impact and influence. With revolutionary treatments changing the way we tackle diseases, the diagnostics industry will continue to play a key role in providing access to the critical information that's needed for people to get and stay healthy.

Find out more about the diagnostic components, services and solutions from Cytiva [https://www.cytivalifesciences.com/solutions/diagnostics]

References

1. Gajarawala SN, Pelkowski JN. Telehealth Benefits and Barriers. J Nurse Pract. 2021;17(2):218-221. doi:10.1016/j.nurpra.2020.09.013
2. Walter W, Haferlach C, Nadarajah N, et al. How artificial intelligence might disrupt diagnostics in hematology in the near future. Oncogene. 2021;40(25):4271-4280. doi:10.1038/s41388-021-01861-y
3. Alamri AM, Alkhilaiwi FA, Ullah Khan N. Era of Molecular Diagnostics Techniques before and after the COVID-19 Pandemic. Curr Issues Mol Biol. 2022;44(10):4769-4789. Published 2022 Oct 11. doi:10.3390/cimb44100325
4. T P A, M SS, Jose A, Chandran L, Zachariah SM. Pharmacogenomics: the right drug to the right person. J Clin Med Res. 2009;1(4):191-194. doi:10.4021/jocmr2009.08.1255
5. Clerc O, Greub G. Routine use of point-of-care tests: usefulness and application in clinical microbiology. Clin Microbiol Infect. 2010;16(8):1054-1061. doi:10.1111/j.1469-0691.2010.03281.x.

cytiva

cytiva.com

For local office contact information, visit cytiva.com/contact

CY34331-14Jul23-EB