



AS VACCINES ROLL OUT, TESTING STILL MATTERS

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BARELY A YEAR INTO the pandemic, we have good reason to hope that the several vaccines coming to market at unheard-of speeds will turn the tide. But we should temper optimism with realistic expectations and an awareness that we will need to employ other tools from the COVID-19 response toolbox for some time to come. Perhaps the most important of these is testing. Public health officials, test manufacturers, public and private clinical laboratories, and health care providers should all recognize the continuing need for robust testing capability and capacity.

With multiple vaccines in the market, many observers are asking whether the need for testing will decline. What are the implications of any decline in testing for diagnostics companies and clinical labs? In separate sets of research, BCG analyzed the outlook for testing volume in the US and in four big EU countries (France, Germany, Italy, and Spain). We developed three directional scenarios for each market: a base case, a more optimistic outlook that entails less testing, and a

more pessimistic stance that calls for more testing.

The bottom line for all three scenarios is that demand for testing is likely to follow similar trajectories in the US and the four European countries, with peak demand occurring in the seasonally affected first quarters of 2021 and 2022. Although we expect testing volumes to decline after 2021, we anticipate a continued need for testing in 2023 and 2024 as the disease enters a more endemic phase.

There are big spreads in projected levels of demand between the base case and the higher and lower testing scenarios. Several factors will determine the actual demand levels, the most important of which are the rates of vaccine uptake. The values for these variables will depend largely on the supply chain's efficacy and the population's willingness to get vaccinated. In the US, the extent of a federally coordinated testing response will also play a big role.

Here's more detail on what we found.

Five Reasons to Test and Their Associated Use Cases

Even if current and prospective vaccines prove to be highly effective, the need to test people for COVID-19 will continue, for at least five reasons (see Exhibit 1):

- **Diagnosis and Triage.** The recent spike in confirmed cases in many countries highlights multiple reasons for continuing to leverage the installed base of diagnostic testing instrumentation. These include diagnosing and triaging patients for medical response, informing clinical care, and monitoring disease levels in inpatient populations.
- **Population Screening.** In many countries, testing will remain part of a broader strategy to monitor the spread and prevalence of COVID-19, as well as to protect larger groups. This includes contact tracing and surveillance testing—the approaches to which are still evolving.
- **Safety Screening.** There are two priorities in this area. One is screening in public settings such as schools, airports, and sports arenas, so people feel safe returning to activities that involve public congregation. The other is screening in congregate living centers, especially senior housing and nursing homes, which have experienced high incidences of the disease and where many people remain at especially high risk.
- **Employer-Contracted Workforce Testing and Monitoring.** Some employers will need testing programs that can screen employees as they return to work. Companies’ requirements will differ depending on the extent to which employees can work remotely, the risk of exposure, and the extent to which protective “bubbles” must be maintained.
- **Testing for Immunity.** As vaccines reach more people and normal activities resume, we will need to test for immunity using antibodies or another technology. We will also need to monitor aggregate immunity by sampling broader populations and to satisfy private household concerns over particular individuals’ immunity status.

EXHIBIT 1 | An Overview of Testing Use Cases

	Diagnose and triage	Population screening	Safety screening	Workforce testing and monitoring	Test for immunity
Overview	Quickly diagnose and triage patients	Monitor spread and prevalence of disease, and protect larger groups during surges	Protect vulnerable populations, and perform screening in public settings	Enable return to work or maintain protective bubbles	Determine whether an individual is immune to COVID-19
Target	Presenting patients	General population	General population	Employees	General population
Examples	Symptomatic Inpatient testing	Surveillance testing	Congregate living (for example, nursing homes) Events and travel Students Private household	High risk/required at site (for example, health care) Required at site (for example, education, plants)	Private immunity testing Public health sampling

Source: BCG analysis.

The Key Drivers of Testing Demand

At the macro level, four factors will drive demand for testing. The first is the epidemiology of the COVID-19 coronavirus as it progresses from a pandemic to its endemic phase. We have seen a new, more highly contagious variation of the virus emerge, for example. Considerations that may influence the volume and type of testing needed include the infection and fatality rates, the speed of the spread (as indicated by the R-value, which is the average number of people that one infected person will transmit the virus to), the length of naturally acquired immunity, the share of asymptomatic patients, and the continued impact of comorbidities.

The second factor in testing demand is the impact of the vaccines, including the efficacy of future vaccines (overall and in high-risk groups), duration of immunity, impact on transmission, and uptake (as noted earlier, in terms of peoples' willingness to take the vaccine and manufacturers' ability to supply sufficient quantities to meet demand). This factor is likely to have the greatest impact.

Third is the impact of therapeutics—both in terms of general efficacy and with regard to mild and severe cases. Therapeutics constitutes an important tool for improving overall health outcomes. The efficacy of different treatment options may also affect behaviors and people's willingness to take risks, thereby indirectly influencing disease levels and testing needs.

Fourth is government policy, which may directly affect people's ability to travel more widely or attend an event following a negative COVID-19 test, for example. Some governments could also require that individuals provide proof of vaccination under certain circumstances—a critical consideration in some use cases, such as screening for safety and employer testing. Governments have a range of policy levers available, and their approaches vary substantially and affect local testing demand levels. Each government has formulated its own policy regarding at-home testing re-

quirements and the types of tests its public health system will reimburse (irrespective of whether the labs that perform the work are public or private).

The dynamics of each use case and the specific attributes of each type of test will dictate the level of demand and the most appropriate testing site (central lab, near-patient, point-of-care, or at-home). Another important consideration involves the different requirements for testing symptomatic and asymptomatic patients. Relevant test characteristics include speed (the time from sample to answer), sensitivity (the ability to detect COVID-19 in all patients who have the disease), specificity (the ability to distinguish COVID-19 from similar viruses), cost, throughput (the rate at which tests that can be analyzed), and sample type (oral or nasal swab, for example). Each use case has specific testing requirements related to situations or circumstances that determine where and how the testing should be done. As circumstances evolve, more tests that have proven accuracy in asymptomatic cases may need to be authorized for emergency use.

Testing technology falls into three main categories. Molecular diagnostics consists of well-established lab-based tests that detect viral genetic material. Of the many versions on the market, the most common is quantitative polymerase chain reaction (qPCR). Antigen tests build on immunoassay technology. Antibody tests detect the presence of an immune response to the virus, indicating prior exposure to the virus, rather than serving as a diagnostic tool.

Of the various technologies, qPCR is currently the gold standard for high-throughput, high-accuracy testing, and it is likely to remain so. Although antigen tests are less expensive and have faster turnaround times, they produce more false negative results; as a result, debate continues about their best use. Various other molecular diagnostics technologies have entered the market, including loop-mediated isothermal amplification (LAMP), clustered regularly interspaced short palindromic repeats (CRISPR), and next-generation se-

quencing (NGS). These technologies are helpful additions to the testing arsenal, but some of them are better suited for more specific use cases. More time is needed to better understand where they can have maximum impact.

Three Directional Scenarios for Demand

Navigating the COVID-19 crisis involves dealing with the complex interplay of epidemic progression, medical response, government action, sector-specific impacts, and company actions. We have argued before that leaders need to develop a scenario-based approach to accurately derive implications and develop action plans. To this end, in separate efforts in October and November 2020, we assessed the spread and impact of COVID-19 in the US and in the four EU markets. Our goal was to make directional projections, not—given the rapidly evolving situation and the multitude of relevant variables—specific predictions of testing demand for the coronavirus. The scenarios provide a framework for thinking about the high degree of uncertainty that will remain a reality for decision makers. We did not attempt to model the progression of the disease or testing supply capacity. Our work covered the first four use cases identified in Exhibit 1—diagnose and triage, population screening, safety screening, and workforce testing and monitoring—but did not include any demand estimates for immunity testing. We developed our three scenarios as follows:

- **Base Case.** In this case, we assume that both vaccinations and therapeutics enjoy success. However, manufacturing and supply constraints, coupled with public concerns over long-term safety, limit full coverage and uptake until later in 2021-2022. Early and erroneous euphoria in 2021 over a “cure,” combined with general “COVID fatigue,” leads to a decline in mitigation efforts (in particular, masks and social distancing) in all markets, and local flare-ups continue into 2022 along with larger resurgences in individual geographies.
- **Lower Testing Demand.** In the more optimistic scenario, both vaccinations and therapeutics show widespread success in healthy adults. Manufacturing and supply rise to meet the increased demand for vaccinations. Mitigation strategies persevere to protect the most vulnerable while businesses and social institutions such as schools selectively and safely reopen.
- **Higher Testing Demand.** In the more dire, but less likely, scenario, vaccinations and therapeutics have limited success. The public remains on the fence regarding the benefits of vaccination, limiting uptake across markets. Virus mutations have an adverse impact on vaccine effectiveness. Social distancing continues to be embedded in everyday activities, and localized lockdowns become a norm. Testing demand is high.

Directional Demand Volumes and Swing Factors

Under all three scenarios, testing demand follows similar trajectories in both the US and the four European countries that we modeled. (See Exhibits 2 and 3.) For example, in our European work, peak quarterly demand in the base case—which occurs in the seasonally affected first quarters of 2021 and 2022, when more patients present with COVID-19-like upper respiratory symptoms—approaches 100 million tests. Peak quarterly demand in the higher demand case exceeds 100 million tests, and in the lower demand case projects to about 90 million tests.

After following a peak-valley-peak path through 2021, demand for testing progressively declines from the first quarter of 2022 onward. A fairly steady spread of about 30 million tests a quarter separates the optimistic and pessimistic scenarios in Europe. Our first two use cases (diagnosis and triage and population screening) drive more than half of the demand, followed by the third case (safety screening), which represents another material segment.

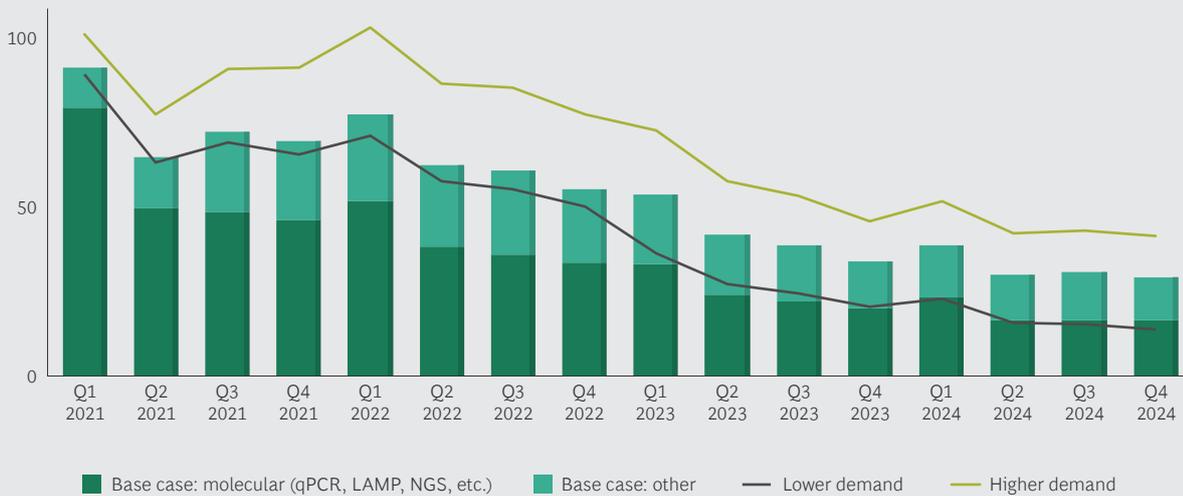
The level of peak demand and the rate of decrease over time will vary in response to a few factors, but by far the most important of these are vaccine efficacy and local rates of vaccine uptake. Concerns about the effectiveness of the first vaccines are fast receding, but questions remain around the efficiency of the supply chain and logistics (given the need to maintain the vaccines at subzero temperatures), particularly for the more complex mRNA vaccines. The broad-

er scenario range shown in the US reflects a set of more country-specific assumptions, especially the extent to which a federally coordinated testing response governs the vaccine rollout.

In all markets, our three scenarios don't cover the full range of possible outcomes, such as the population rapidly reaching herd immunity or vaccine rollouts fundamentally failing. Nor did we model mass

EXHIBIT 2 | Projected Directional Quarterly Demand in Four EU Countries

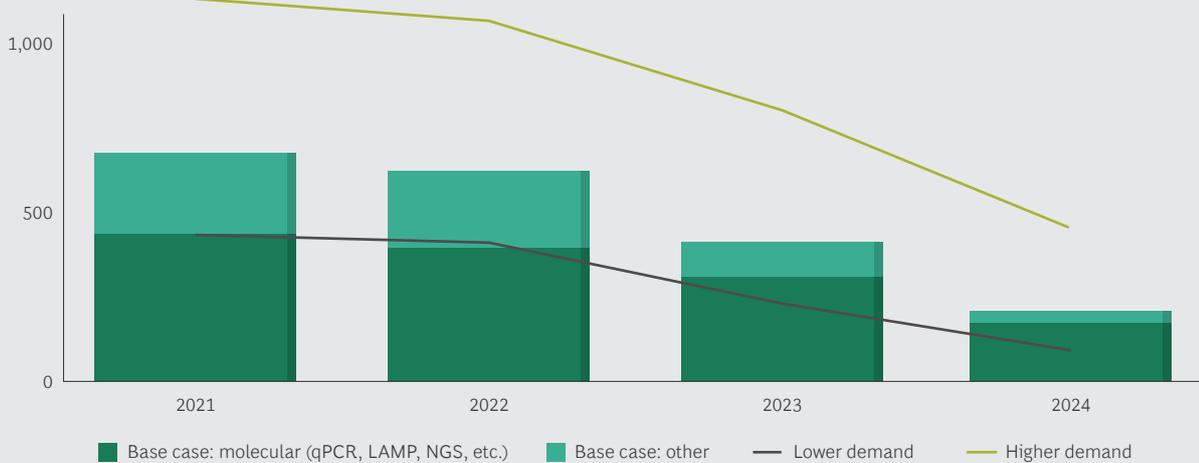
Quarterly testing volume in France, Germany, Italy, and Spain (millions)



Source: BCG market model.

EXHIBIT 3 | Projected Directional Annual Demand in the US

Annual US testing volume (millions)



Source: BCG market model.

screening of the full population in any of the countries we modeled.

Implications

Even assuming that the vaccines now on the market prove highly effective and rapidly gain uptake, the future is full of uncertainty. All participants in the health care ecosystem must be agile in their ways of working and prepared to quickly adapt their strategic and operational focus in response to shifting demand signals and patient needs. In addition to pure testing capacity, the pandemic has highlighted the importance of turnaround time and the critical need for skilled lab technicians. We must address these issues as we maintain enough capacity to meet testing needs.

Looking toward a brighter future raises the question of how to use in vitro diagnostics (IVD) capacity most effectively after COVID-19 testing levels drop, especially given the substantial investment in increased capacity across multiple technologies in central labs and the expansion of at-home and point-of-care testing. We should also address backlogs in non-COVID-19-related testing and consider the degree to which we ought to maintain increased capacity as a hedge against future pandemics.

In the near term, qPCR capacity could support COVID-19 testing levels beyond the ranges that we have modeled. Many of these tests will be broader respiratory multiplex panels that test one patient sample for several respiratory illnesses simultaneously (combining, for example, COVID-19 with influenza A/B and respiratory syncytial virus). This is just one example of how assay portfolios are likely to evolve as innovation accelerates more broadly. Several countries are also looking at strategies to boost point-of-care, at-home, and direct-to-consumer testing—especially for testing asymptomatic patients.

New entrants to the IVD market may become more firmly established in the ecosystem. Technology evolution will continue,

in qPCR and beyond, as evidenced by investments in point-of-care solutions, NGS, and CRISPR.

IVD manufacturers, boosted by COVID-19 testing demand, have incentives to develop novel content that will use their new molecular installed base in the future. Besides filling gaps in their menus of infectious disease tests, they may be able to expand into areas such as autoimmune disorders and oncology. We may also see greater awareness of the potential downstream benefits of screening as a preventive tool for a broader range of diseases.

Labs may choose to use their molecular diagnostics capacity to expand their testing capabilities beyond traditional applications. Compared with microbiology and immunoassay tests, molecular diagnostics in certain situations can provide novel clinically relevant information in such areas as STDs, respiratory illnesses, hepatitis, HIV, and hospital-acquired infections.

Changes will go beyond testing equipment and assays. In the short term, labs must manage a more fragmented installed base of testing platforms. In the medium term, shifts in sample collection sites—for example, to a greater share of samples being collected in pharmacies or in the home—may have an effect on operations.

TESTING IN PRIVATE and public labs continues to be a crucial pillar of any comprehensive response to the pandemic. Since COVID-19 isn't going to be eradicated any time soon, we will need to maintain a significant testing capacity and capability for a number of years after a highly efficacious vaccine has become commonly available.

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