

Workplace diagnostic testing for COVID-19

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EY

Building a better
working world

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01 | Executive summary

In December 2019, the first reported case of a severe acute respiratory syndrome illness related to the novel coronavirus (SARS-CoV-2) was identified in Wuhan, China.¹ The World Health Organization (WHO) declared the disease caused by SARS-CoV-2 a public health emergency in January 2020 and designated it as COVID-19 in February 2020.² In March 2020, the WHO escalated COVID-19 to pandemic status.³

Since then, despite lockdown measures across the world during the peak of the pandemic waves, countries have demonstrated varying degrees of success in flattening the curve of COVID-19.⁴ Resurgences have continued in many countries depending on factors such as widespread testing capabilities (critical for disease identification and isolation), and the general public's acceptance of and adherence to risk mitigation strategies. As of October 2020, more than 33 million confirmed cases of COVID-19 have been reported globally, with deaths in the US exceeding 205,000 and more than 1 million in 213 of the world's countries and territories,⁵ spanning all continents except Antarctica.⁶ Predictive models indicate that global deaths could exceed 2.8 million by 1 January 2021.⁷

The impact on the global economy from workplace closures and workforce instability due to the COVID-19 pandemic has been severe. Across industries, there have been disruptions in global manufacturing and supply chain networks, with severe repercussions to global financial markets.⁸ With these and other macroeconomic variables under siege, political stability across the world is being tested.⁹ Vaccine approval and availability are projected to occur between Q1 and Q3 2021, though it will likely take until the end of the 2021 calendar year for most eligible people to get vaccinated. This will likely bring ongoing logistical and operational challenges that will impact business continuity.¹⁰

Risk of transmission of the virus is increased in congregate settings such as the workplace and universities, and persons who are COVID-19 positive appear more likely to be infectious in the earlier stages of the virus, even prior to the development of symptoms. Additionally, some infected persons never develop symptoms.

While the U.S. Centers for Disease Control and Prevention (CDC) and other countries' public health authorities have provided guidance on returning to work for critical infrastructure employees during the pandemic,¹¹ guidance for non-critical workers across all industries is less clear.

Globally, several industries, including education, professional sports, manufacturing and tourism (among others), are experiencing significant business continuity challenges.¹² Many are seeking to implement workplace re-entry strategies to drive business recovery and avoid permanent disruption. To be effective, these strategies must go beyond subjective risk measures (e.g., symptom questionnaires, employee self-certification) and on-site temperature screening to provide safety insight on return to the workplace. To provide the required safety surveillance measures to enable safe return to work, educational and recreational facilities, employers will need to move toward objective and reliable measures of risk-based diagnostic testing.

As businesses return to work and students return to schools, colleges and universities, testing is becoming an increasingly central part of effective reopening. COVID-19 testing, now available in a variety of modalities, is the most effective and objective tool for identifying whether a person has the disease and poses a risk to others in the work or school environment. When in place, routine testing can provide aggressive case identification, establishing the need for isolation to limit disease spread.

02 | Diagnostic testing An enabler of successful physical return to work

Studies have indicated that the combination of presymptomatic and asymptomatic infections could be responsible for more than 50% of the overall attack rate in COVID-19 outbreaks, and that individuals might be most infectious during the presymptomatic phase.¹³ Therefore, the importance of diagnostic testing to curtail both the symptomatic spread and the silent transmission of COVID-19 that is apt to occur in the workplace should be understood and not underestimated.

Organizations should embrace a scientifically driven testing strategy as a fundamental competency to safely return employees to the workplace and students to school. Diagnostic testing alone is not a silver bullet but rather should be part of an overall strategy for managing the health and safety of employees/students that involves identifying those at risk, tracing the spread of infection and responding effectively to mitigate further infections.

¹"Timeline of WHO's response to COVID-19," *WHO* (June 29, 2020).

²*Ibid.*

³"WHO Director-General's opening remarks at the media briefing on COVID-19," *WHO* (March 11, 2020).

⁴"These countries are doing the best and worst jobs fighting coronavirus," *USA Today* (March 30, 2020).

⁵"COVID-19 Dashboard," *Center for Systems Science and Engineering at Johns Hopkins University* (2020).

⁶"Antarctica is the only continent free of COVID-19. How long can it stay that way?," *Euronews* (September 12, 2020).

⁷"COVID-19 Projections," *Institute for Health Metrics and Evaluation website*, (accessed September 7, 2020).

⁸"The Global Economic Impacts of Covid-19," *Center for Strategic & International Studies* (March 10, 2020).

⁹"The political implications of COVID-19," *Standard Chartered* (April 20, 2020).

¹⁰"Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States," *Center for Health Security at Johns Hopkins University* (August 2020).

¹¹"COVID-19 Critical Infrastructure Sector Response Planning," *Centers for Disease Control and Prevention* (May 6, 2020).

¹²"This is the impact of the Coronavirus on business," *World Economic Forum* (February 21, 2020).

¹³"The implications of silent transmission for the control of COVID-19 outbreaks," *Proceedings of the National Academy of Sciences* (July 28, 2020).

03 | EY testing strategy

Safe return to work

The purpose of a diagnostic testing plan should be to minimize employee and organizational risk. Its guiding principles should optimize the employee experience through ease of access to testing, a convenient testing approach, a clear process, rapid and accurate results, and cost-efficient testing. When deployed effectively, the testing plan will provide the workforce with confidence that health, safety and wellness are prioritized. It positions employers to minimize business continuity risk due to infection transmission and to avoid extended employee absences or site closures.

An effective testing strategy should incorporate options for **initial** testing of all employees, students and stakeholders, and/or **periodic random sampling** of relevant stakeholders in general on re-entry. This strategy would most likely involve sequential testing with statistically derived models to provide broad testing exposure and accuracy within acceptable levels of statistical confidence.

EY professionals provide clients with a foundational data-driven diagnostic testing strategy that develops a customized approach to diagnostic testing recommendations as needed based on a COVID-19 return to work risk assessment of each company. Testing plans are then provided within a holistic set of integrated recommendations aligned to specific business needs. These diagnostic testing recommendations will incorporate the competencies of symptom screening, contact tracing, workplace reconfiguration, worksite safety programs, workforce redesign and organizational change management as needed.

To provide enterprise workplace surveillance related to the COVID-19 pandemic, EY professionals have developed a virtual command center competency for clients. This enables collation and integration of relevant workforce and stakeholder data, geographic and demographic data, technology considerations and other externally sourced data to provide a near-real-time holistic view of trending of the disease trajectory, and the impact of risk mitigation processes within the business. This technology harnesses the EY team's data fabric, which collates all relevant information into a usable format for C-level executives and people managers to make the right choices for the workforce as they continue to adapt to the challenges presented by the pandemic. Importantly, longer-term business benefits will be realized by those organizations that use this experience to embed proactive workforce health and wellness surveillance strategies and processes, developing business resiliency in event of future employee health risks that threaten business continuity.

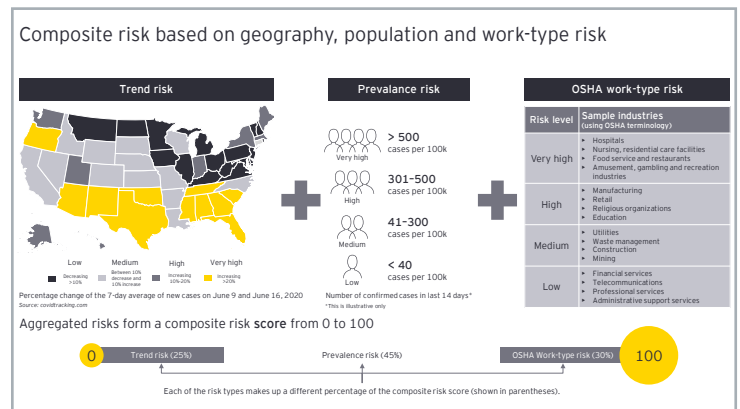
04 | EY solution methodology

Bespoke and data driven

1. Testing strategies should be customized to specific industries and businesses.

The differentiated EY methodology is data driven. It uses the principles of population risk quantification and statistical modeling to assist organizations in determining the depth, breadth and frequency of employee testing. This data-driven approach seeks the highest possible accuracy opportunity within acceptable statistical confidence levels, for identification of individuals who are presymptomatic and asymptomatic with COVID-19.

EY's point of view incorporates a risk management framework for employers to use in determining the composite risk level for returning their employees to the workplace. The composite risk is based on a blend of geographical disease trending, population disease prevalence within the business footprint and work-type risk based on specific client industry/ business. Most importantly, recommendations for diagnostic testing prior to and after reopening businesses are based on experts' current understanding of the evolving testing landscape and supply chain.

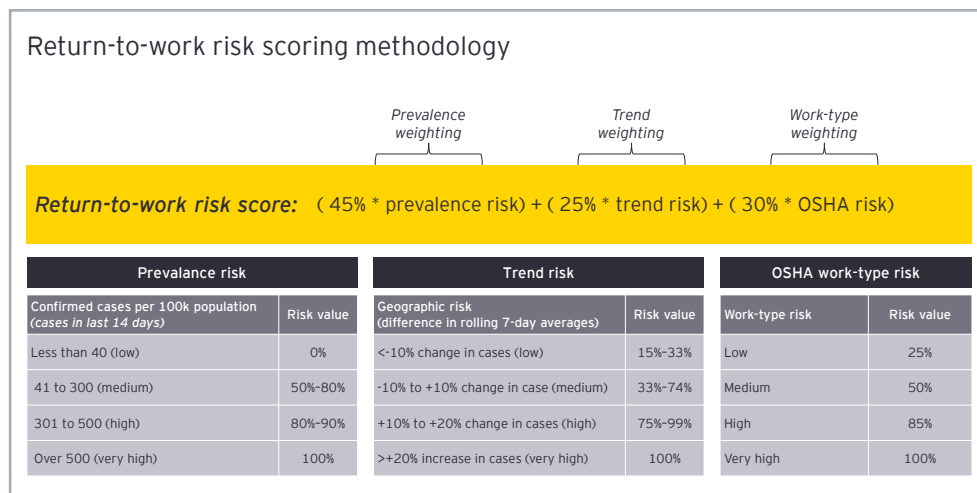


Source: EY Business Resiliency Data Fabric

EY has developed a proprietary interactive composite risk dashboard that incorporates these independent and composite risk variables to inform testing strategies for businesses from all industries and within all global geographies.

2. These strategies use data-driven insights and statistical models to build initial and sequential testing methodology.

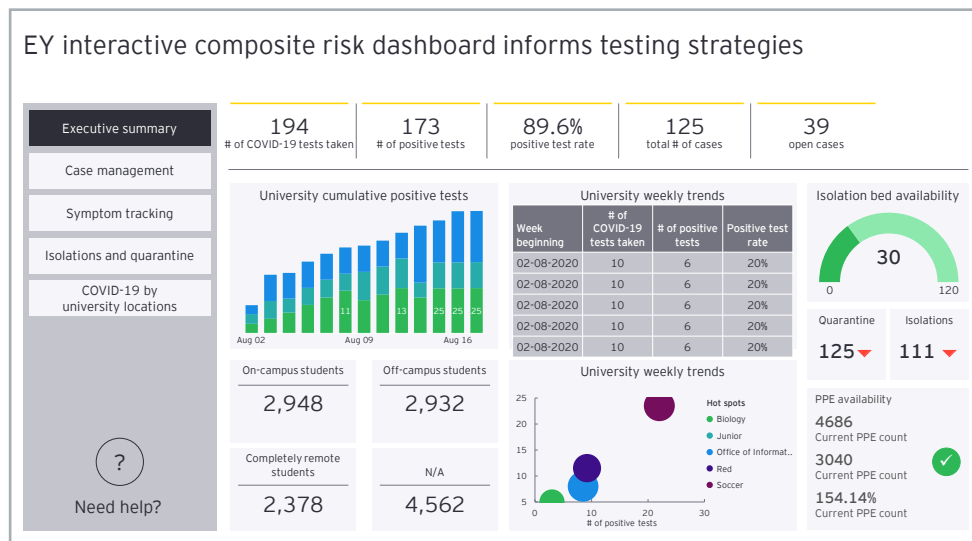
Initial diagnostic testing is informed by the derived composite risk of the business.



Source: EY Business Resiliency Data Fabric

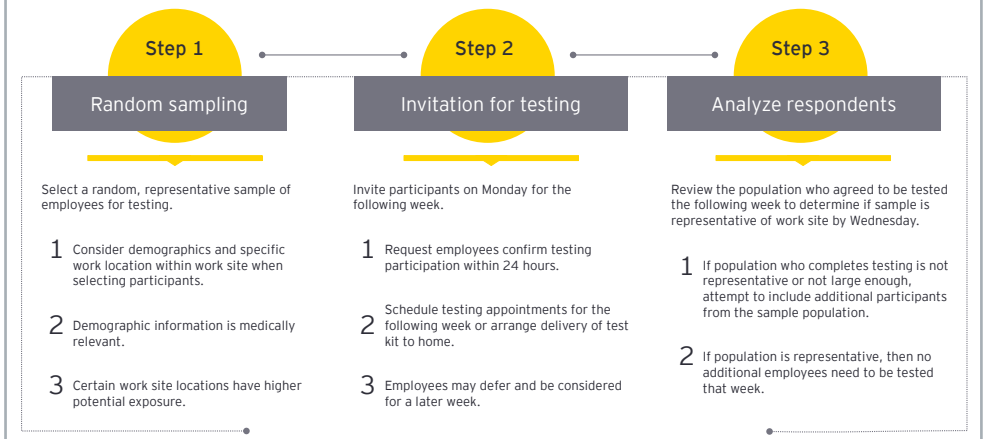
3. This insight will position the business for accurate disease identification and isolation of presymptomatic and asymptomatic employees within the business.

The testing strategy is customized for the specific business within regional, national or global footprints.



Sequential testing is driven by statistical modeling to derive an acceptable rate of low prevalence metrics within the tested population.

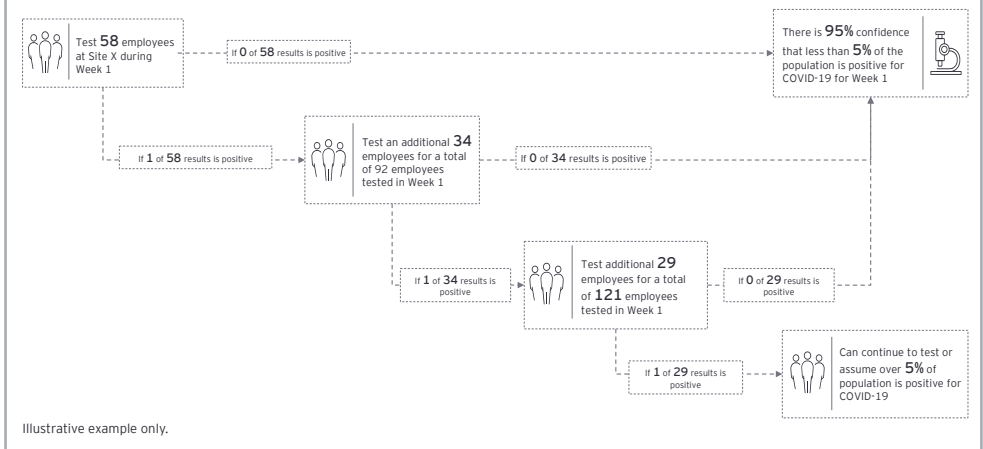
Employees selected for diagnostic testing reflect site demographics



Source: EY analysis, COVID-19 testing strategy playbook

Testing frequency is informed by the level of disease detection within the tested employee population.

Illustrative example | Weekly random sample testing approach



Stratified sampling and sequential testing can be used to estimate the share of a workforce that is COVID-19 positive without having to test everyone. The EY team used this approach to help a company in the aerospace industry develop a testing approach for its 100,000+ employees across 500 sites. By testing a representative sample of employees at each site in specific sequence, the company gained insights into the prevalence of COVID-19 as compared to the broader community.

05 | Case reports

Opportunities for customized solutions

Colleges, universities and the cruise industry curiously share the commonality of significant complex ecosystem health risk assessment, understanding that bringing together large groups of people from diverse geographies almost always means some of them will be carrying the novel coronavirus at any point in time. Variable prevalence rates in the US and in other parts of the world must be considered as stakeholders converge on campuses and cruise ships. When we factor in the diverse national and global geographies involved, these risks can be exponential.

Several US universities opened campuses for in-person instructions during the fall 2020 semester, only to see clusters of COVID-19 outbreaks. Many of those decided to revert to remote learning, and some delayed or canceled plans to reopen for in-person instruction altogether. Despite months of strategic modeling, planning and safety guideline drafting, these universities saw their reopening strategies fail.

This experience was evidenced by a leading university in the Midwest that reported a spike in COVID-19 cases within a week of reopening for the fall semester in August 2020.¹⁴ Factors such as off-campus gatherings, noncompliance with safety protocols and a lack of widespread testing reportedly converged to result in 147 confirmed cases and a positivity rate of nearly 16% after a week.¹⁵ News reports indicate that students had to wait for days to get tested, quarantine areas and facilities were not appropriately prepared, and in certain instances the faculty were not notified that their students had tested positive. Since then, the university has adapted its strategy, which now includes an expansion of testing on campus and even randomized testing of its student body to help identify asymptomatic or presymptomatic cases.

Similarly, the global cruise industry is battling a rough restart as the few international cruise lines that resumed operations later reported COVID-19 cases onboard. **A leading Norwegian cruise line reportedly** halted all its trips after an outbreak on one of its ships infected at least 5 passengers and 36 crew members in August 2020, resulting a review of COVID-19-related screening processes.¹⁶

Meatpacking plants in the **food processing industry** serve as another example of continued struggle with COVID-19 outbreaks. The Kansas Department of Health and Environment recently made public a list of active COVID-19 clusters, with thousands of cases attributed to a few meatpacking plants.¹⁷ Elsewhere in the US and in other countries such as Germany, France and Spain, such outbreaks in meatpacking plants were also reported. Several factors seem to contribute to this phenomenon, including working conditions where social distancing is difficult, lack of sunlight in such facilities and noisy machinery that requires workers to talk louder. Moreover, many of these factories or plants have on-site or nearby accommodations where people live in crowded spaces.

EY teams meet clients where you are in your journey. In the education industry, universal testing of all faculty, students and workers on re-entry to facilities and classrooms may not capture all infections due to the presence of false negatives. The same is true for the cruise industry, where false negatives among passengers and crew before boarding are likely to be present, as well as for the meatpacking industry. Stratified, sequential sampling driven by statistical modeling to test random samples of the campus, shipboard or meatpacking plant population every day, designed within high levels of statistical confidence intervals, can help detect outbreaks for rapid containment.

A clear majority of traditionally in-person roles are expected to remain virtual for the foreseeable future. Industries that traditionally require in-person interaction, such as travel and leisure, hospitality, higher education, life sciences, the cruise industry, airlines, food and beverage, theme parks, manufacturing and others that present similarly high occupational risk, are the most significantly impacted. Remote-work simply does not meet the needs of their customers or their workforce, and industries must continue to determine a path forward. The EY approach helps clients as they develop data-driven, risk-adjudicated diagnostic testing strategies.

¹⁴“University of Notre Dame changes ‘battle plan’ after rise in COVID-19 cases,” ABC News (August 27, 2020).

¹⁵*Ibid.*

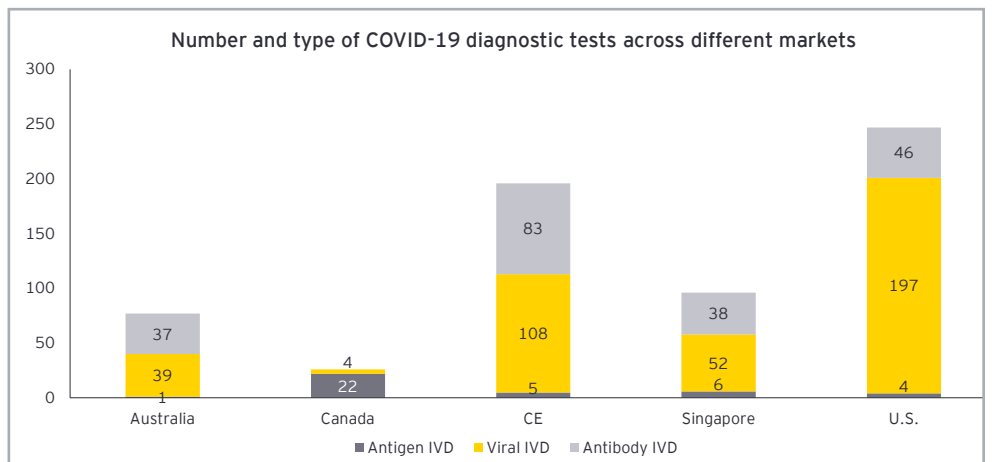
¹⁶“Coronavirus outbreak hits Norway cruise ship that stopped at dozens of ports,” CBS News (August 3, 2020).

¹⁷“New Kansas coronavirus data shows meatpacking plants still struggling with outbreaks,” Kansas City Star (September 9, 2020).

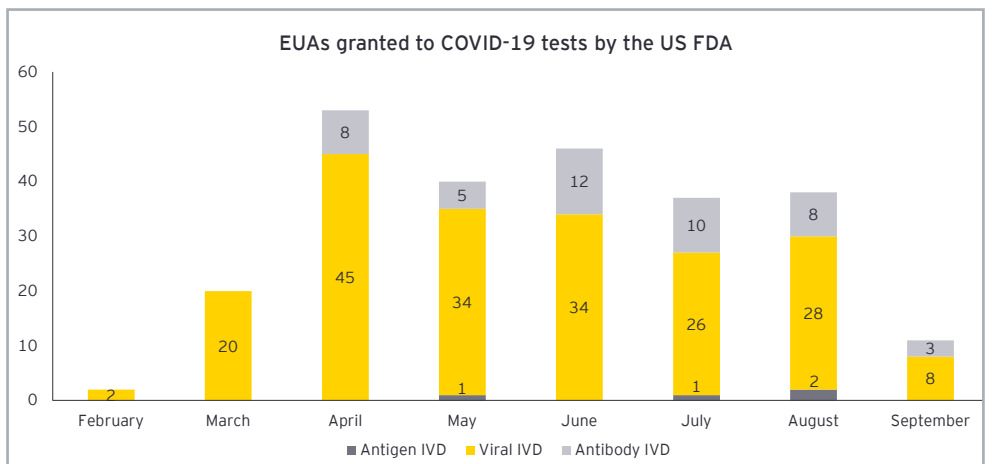
06 | COVID-19 diagnostic testing

A landscape overview

While deployment of SARS-CoV-2 testing has varied widely across the world, aggressive and widespread use of COVID-19 diagnostics has enabled many countries, including South Korea and Singapore, to effectively slow down the disease's spread. Rapid and collaborative scientific data sharing, a prompt response from the medical diagnostics industry and supportive regulatory guidelines have resulted in the development and commercialization of COVID-19 diagnostic technologies at an unprecedented pace. As of September 17, 2020, the U.S. Food and Drug Administration (FDA) has provided emergency use authorization (EUA) to 247 COVID-19 diagnostic tests, spanning different modalities.¹⁸ More than 700 tests are commercialized globally, and more than 90 are under development.¹⁹



Source: BioCentury



Source: U.S. FDA

¹⁸"In Vitro Diagnostics EUAs," U.S. Food and Drug Administration website, (accessed September 7, 2020).

¹⁹"SARS-CoV-2 Diagnostic Pipeline," Foundation for Innovative New Diagnostics (accessed September 7, 2020).

COVID-19 diagnostic testing capabilities continue to rapidly evolve. The landscape is complex, with evolving regulatory guidance, different test types and methods provided through multiple vendors with varying processes and technological developments. Real-time reverse transcriptase polymerase chain reaction (RT-PCR) based assays are the gold standard for diagnosing current infections. Several of these assays must be carried out by highly skilled technicians at centralized facilities and usually have long test turnaround times of more than 48 hours. Also, most PCR-based diagnostic tests for COVID-19 use nasopharyngeal (nose) or oropharyngeal (throat) swab specimens. To enable point-of-care testing, low-complexity and rapid molecular diagnostic tests have been commercialized by Abbott Laboratories (Abbott), bioMérieux, Roche Diagnostics and Cepheid, among others. Companies are exploring novel technologies, such as clustered regularly interspersed short palindromic repeats-based diagnostics, next-generation sequencing and loop-mediated isothermal amplification to develop rapid, simple and low-cost diagnostic tests.

Recently, the FDA granted an EUA for PCR testing of saliva.²⁰ Pooled saliva testing and low-cost, self-administered at-home saliva tests show significant promise in providing broader access to testing. In addition, newer antigen tests have been approved that require less infrastructure, can return results very quickly and are less expensive than currently approved PCR-based tests.²¹ The recent EUA for Abbott's *BinaxNOW Covid-19 Ag Card* rapid test could be a game changer for mass testing as it gives results in 15 minutes and doesn't require any instrumentation.²² While the current authorization is for symptomatic individuals, the company will be initiating trials in asymptomatic patients, and off-label use may be seen if inventory capacity is robust and regulatory approval is relaxed.

Serology tests, on the other hand, identify antibodies to SARS-CoV-2 and can confirm prior infection with the virus, even if the individual was asymptomatic. Although they have limited utility in diagnosing active infection, these tests are essential for epidemiologic studies, ongoing surveillance and vaccine studies, and potentially for risk assessment of health care workers. However, antibody testing is not yet approved to determine the immune status of previously infected individuals, and as such the CDC and the U.S. Equal Employment Opportunity Commission (EEOC) prohibit employers from using mandatory antibody testing to determine whether employees are allowed to return to the workplace.²³

07 | Current challenges Diagnostic testing

As availability of both COVID-19 diagnostic tests and serology tests expands, and societies move closer to availability for mass testing, the limitations and challenges with the different testing approaches must be considered. False positive and false negative results from COVID-19 tests impede the ability to accurately diagnose patients. These could arise due to individual variation in the actual level of the virus, the technique used by the tester, or lower sensitivity and specificity of the tests.

The current serology testing pipeline reveals several commercial antibody tests in play at present – however, many of them are not validated, making their reliability questionable due to existing gaps in the understanding of immunity to COVID-19.

The temporal dynamics of antibodies to SARS-CoV-2 in patients have not been clearly defined as antibody titers change rapidly during and after the course of infection. As of September 2020, none have received regulatory approval for establishing immunity from repeat infection.



²⁰"Coronavirus (COVID-19) Update: FDA Authorizes First Diagnostic Test Using At-Home Collection of Saliva Specimens," *U.S. Food and Drug Administration* (May 8, 2020).

²¹"Coronavirus (COVID-19) Update: FDA Authorizes First Antigen Test to Help in the Rapid Detection of the Virus that Causes COVID-19 in Patients," *U.S. Food and Drug Administration* (May 9, 2020).

²²"Abbott's Fast, \$5, 15-Minute, Easy-to-Use COVID-19 Antigen Test Receives FDA Emergency Use Authorization," Abbott (accessed September 7, 2020).

²³"What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws," (September 8, 2020).

08 | Conclusion

Navigating current and future workforce risk and positioning the business for resiliency

It seems that each day, there are new developments that complicate organizations' efforts to write a playbook to mitigate the health, safety and financial implications of this crisis. As the pandemic continues to unfold, there is an ever-growing web of interrelated challenges and obstacles for organizations to navigate in developing return-to-work strategies for their workforce.

In addition, individual employees and students face unprecedented amounts of financial uncertainty, health and wellness insecurity and financial stability concerns that employers and employees alike need to react to during these uncertain times. Concurrent natural disasters and social unrest, arising from a divisive political climate and questions about racial injustice, are only exacerbating these challenges.

The primary focus for all organizations has been and continues to be preserving the health and safety of employees, followed immediately by assessing short-term business continuity considerations, all while preparing for the longer-term business resiliency challenges employers face because of the current crisis. Some key questions include the following:

- ▶ When should employees return to the workplace?
- ▶ Who should return?
- ▶ How will they return?
- ▶ What should the role and scope of testing be, and how should contact tracing be integrated?
- ▶ Is there a need for workplace reconfiguration?
- ▶ What are the human resources, organizational culture and change management implications?
- ▶ Are there legal risks to the business associated with the physical return to the workplace, and how are these risks identified and mitigated?
- ▶ What social distancing, testing protocol and other risk mitigation strategies will need to be put in place?
- ▶ What legal and regulatory considerations exist for reopening?

There may never be a return to business as usual as we knew it before this crisis for many industries. Yet, some will succeed and thrive through a process of reinvention of business models and reimagining of the workforce, while others will find themselves in the unfortunate position of obsolescence. A testing strategy with a focus on diagnostic testing in conjunction with an adaptable response effort is critical to organizations' successful navigation of this event and future risk events.

Appendix

Appendix 01

Risk variables explained

Risk of employee exposure to COVID-19 in the workplace can depend in part on the industry type, the presence of asymptomatic yet infected workers and whether required social distancing can be responsibly maintained during routine work, among other challenges. As such, the U.S. Occupational Safety and Health Agency (OSHA) has provided several categories of risk that must be monitored to prevent the spread of COVID-19 in the workplace.²⁴

These categories are:

- ▶ Occupational exposure risk
- ▶ Population risk (prevalence)
- ▶ Geographical risk (infection trending)

Appendix 02

Occupational risk for COVID-19 as defined by OSHA

The focus of work-type risk is targeted where physical interaction of individuals is required as a function of completed job-related tasks. OSHA has divided job tasks into four risk exposure levels: **very high, high, medium and lower risk**.²⁵

The four risk exposure levels represent the probable distribution of risk across the employed population. A thorough analysis of where individuals fall in these risk categories is critical to determining the overall risk profile that will influence testing recommendations for a given organization.

EY teams see challenges with regard to social distancing in industries where direct coworker, customer or general public interaction is most frequent.

Even for those industries that fall outside of the highest-risk categories, this has been a real challenge to navigate successfully and sustainably. Unfortunately, there is no easy solution to defend against the spread. Adhering to guidance from health agency and state and federal regulations is key to maintaining a safe workplace, as we all have come to fully appreciate. Testing, however, in conjunction with safety guidance has been shown to better define areas of risk, spikes or changes the number of infections, preventative mitigation and other benefits.

²⁴"Worker Exposure Risk to COVID-19," U.S. Occupational Safety and Health Agency (2020).

²⁵*Ibid.*

Jobs that fall in the **lower exposure risk (caution)** classification typically do not require contact with people known to be, or suspected of being, infected with SARS-CoV-2. Workers in this category have minimal occupational contact with the public and other coworkers. Examples include remote-work/virtual collaboration, some office situations, manufacturing and industrial facility workers, telemedicine, and long-distance shipping and delivery.

Roles with **medium exposure risk** require frequent or close contact with individuals who are potentially infected but not known to have or suspected of having COVID-19. Examples in this category include some in the retail, hospitality, travel, aviation, transportation and education sectors, and roles in high-population density areas or work environments.

High exposure risk is focused on jobs with a high potential for exposure to known or suspected sources of SARS-CoV-2. Examples in this category typically include health care delivery and support, fire and rescue, and mortuary workers.

Last, OSHA has classified jobs that fall in the **very high exposure risk** category as those that inherently involve an extremely high potential for exposure to known or suspected sources of SARS-CoV-2 during specific medical, postmortem or laboratory procedures. Typical roles include health care workers on the front lines of the response to the pandemic, laboratory personnel and morgue employees.

Appendix 03

Population risk (prevalence and incidence)

Population risk can be determined using two measures. The first, prevalence, is how much active disease exists across the population. This can be reported as point prevalence (active infections at a specific point in time) or overall prevalence (the cumulative number of diagnosed individuals alive within a population). The second, incidence, is the number or rate of new infections in a population. Both are useful measures to understand the underlying risk to individuals of getting infected and have implications on testing strategies.

When the prevalence is high, it means that the disease (in this case, COVID-19) is widespread and that overall risk is elevated. The prevalence at a point in time doesn't tell you about the trajectory of infections – in other words, whether they are increasing, decreasing or staying the same. Incidence rates are better indicators of that metric, identifying new infections instead of total existing infections. Some testing methods are more effective when overall disease prevalence is high, while others are better when it is low. With COVID-19, we have seen significant changes in the prevalence of active infections across the US. For example, New York state had an early and intense

outbreak where prevalence was very high for much of April, but by May the area began to recover, and incidence rates went down significantly.²⁶ Today, prevalence is very low in New York State compared to currently higher prevalence areas such as Texas or California. Both prevalence and incidence can be understood in absolute numbers of cases, or more frequently as rates of disease per 100,000 people. Rates are better for understanding the comparative impact in areas of different size or density. Both prevalence and incidence are determined by positive COVID-19 test results, and in some cases supplemented by cases deemed positive due to compelling clinical presentation in the absence of a positive RT-PCR test.

Appendix 04

Geographical risk (infection trending)

Geographic risk describes the environmental risk associated with a given geographic area. The prevalence and incidence of a town, city, state or country determine that area's geographic risk. However, increasing or decreasing numbers of new infections (infection incidence trending) play a large part in identifying specific geographical risk even in the presence of stable, low or high disease prevalence.

As such, geographic risk can and does vary significantly around the globe. In some areas, there is widespread, active community infection currently occurring without significant containment. In other areas, rates are very low, with test positivity rates under 2%. Geographic risk can also be impacted by behavior-based community risk factors such as compliance with behavior modification requirements, including mask wearing and social distancing. Over time, the US has seen shifting risk trajectories of the pandemic, with the areas of highest risk moving from the West Coast to the Northeast, South and Midwest. Urban hubs most impacted by the first waves are bracing for possible second waves.

The COVID-19 pandemic has resulted in unprecedented challenges to people, communities and businesses across the world. Absent deliberate approaches to containing the risk of ongoing disease transmission, these challenges will limit the safe return of employees to workplaces until a vaccine is approved, available and effectively deployed across the world. Until then, laser focus on effective risk-driven employee diagnostic testing strategies must be used to identify infection and limit disease spread both locally and globally.

²⁶"Lockdown Led to 70% Drop in NYC COVID Spread, Masks Also Effective," Columbia University Mailman School of Public Health (September 14, 2020).

About EY

EY is a global leader in assurance, tax, strategy, transaction and consulting services. The insights and quality services we deliver help build trust and confidence in the capital markets and in economies the world over. We develop outstanding leaders who team to deliver on our promises to all of our stakeholders. In so doing, we play a critical role in building a better working world for our people, for our clients and for our communities.

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