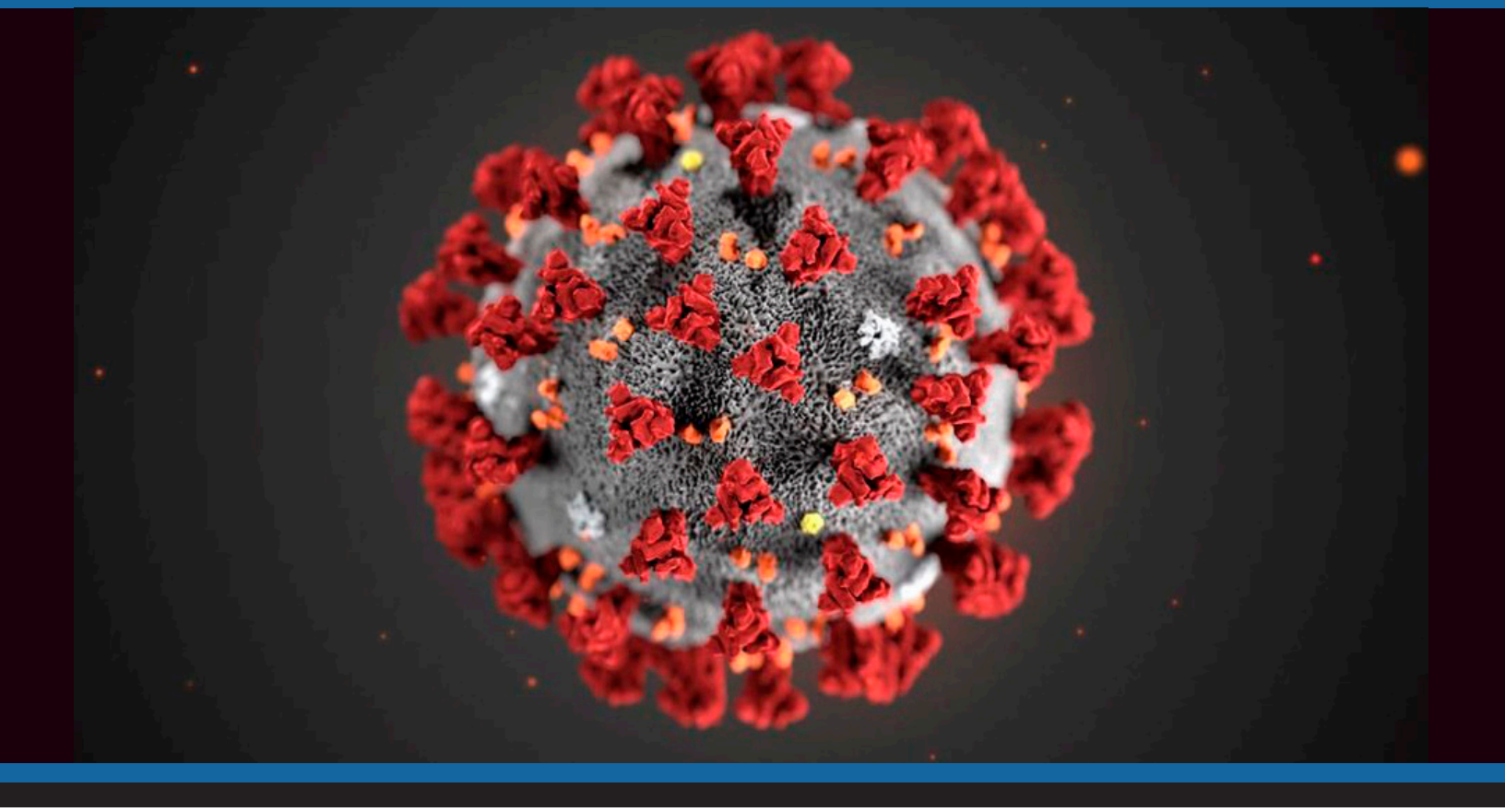
SPECIAL REPORT

COVID-19 PANDEMIC

The Lab Industry Response & How to Protect Your Employees

March 18, 2020 Update



From the Editors at G2 Intelligence

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COVID-19 PANDEMIC
The Lab Industry Response & How to Protect Your Employees

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Table of Contents

Introduction

The global coronavirus outbreak came without warning and is having a seismic impact on laboratories and the diagnostics business. The imperative for the industry right now is to develop a safe and rapid method of reliably detecting the virus, preferably at the point of care.

The first imperative for individual laboratories is to protect the workplace. Taking measures to protect laboratory employees from infection is a legal imperative; and implementing emergency response measures to minimize potential disruptions due to a coronavirus outbreak is a business imperative.

In meeting these challenges, laboratories and test companies will have to handle sensitive medical information about patients and cases. And while the usual HIPAA and other privacy restrictions apply, special information sharing rules pertain during public health emergencies such as the coronavirus outbreak.

The purpose of this Special Report is to break down each of these challenges. Specifically:

Part I looks at the government response to coronavirus and the efforts to ensure that reliable tests capable of detecting the virus become available as soon as possible;

Part II looks at the private sector response and the efforts of test companies around the world to develop new tests for coronavirus;

Part III looks at the impact of coronavirus on individual laboratories from a risk management perspective and lays out a practical strategy for preventing infection and the liability in which it may result; and

Part IV looks at the challenge of complying with privacy laws in the course of implementing coronavirus response measures, focusing on the privacy rights of both laboratory employees and patients.

At the end of this Special Report is a series of **TOOLS** you can use to implement the strategies.

Part I

THE U.S. RESPONSE: DEVELOPMENT OF A CORONAVIRUS DETECTION TEST

Because the 2019 novel coronavirus (COVID-19) outbreak was so unanticipated, there were no FDA-approved commercial products for it available in the U.S. during its early days. On Jan. 28, the FDA unveiled its **strategy** for promoting the rapid development and availability of safe and effective investigational medical products "to address this urgent public health situation." As with previous infectious disease outbreaks like Zika, the centerpiece of the FDA strategy is expedited clearance of new coronavirus tests and treatment products via the Emergency Use Authorization (EUA) pathway.

The FDA is following a two-prong strategy to promote and expedite development and validation of a test capable of safe, rapid and reliable detection of novel coronavirus (COVID-19), the disease caused by the SARS-CoV-2 virus. Here is an overview of the progress being made—and not made—on both fronts.

The Traditional EUA Pathway

The FDA is calling on test makers to seek rapid approval via the emergency use authorization (EUA) pathway the way it did with SARS, H1N1 and other previous outbreaks. The problem is that novel coronavirus isn't a known pathogen the way the previous outbreak viruses were. As a result, the diagnostics have to be created from scratch.

The other issue is time. Historically, it takes months to secure EUA clearance. The good news is that the FDA has streamlined its application process by implementing a rolling process using an electronic template. The agency reports that it has already contacted more than 70 test makers interested in seeking EUA for coronavirus detection tests.

In fact, the agency has already broken its own speed record by issuing its first EUA on Feb. 4, less than a week after mobilizing the pathway, for a reverse transcriptase real-time PCR (rRT-PCR) assay (aka, the 2019 Real Time RT-PCR Diagnostic Test Panel) developed by the U.S. Centers for Disease Control and Prevention (CDC). The test was approved for use only by CDC-designated laboratories certified to perform high-complexity testing in accordance with agency protocol.

The CDC has distributed test kits to state health departments and public health laboratories around the country. But reagent, instrumentation and laboratory staff shortages, coupled with questions about the test's

reliability in ruling out infection, has made the pace of test validation and deployment frustratingly slow. As of March 10, the CDC reports that that 78 public health laboratories are now running the test. Those laboratories have the current capacity to test 75,000 people, which is not nearly enough.

To address the reagent bottlenecks, the FDA extended the CDC's EUA to cover kit lots from reagent two manufacturers validated at CDC laboratories, including two kit lots from Integrated DNA Technologies (IDT), which is owned by Danaher, and one kit lot from LGC Biosearch Technologies. But the shortages continue.

The other obstacle to deployment is the limitations of the CDC assay. Thus, while a positive result is a fairly reliable indicator of coronavirus infection, the early feedback suggests that a negative result cannot be counted on to rule it out. Accordingly, the FDA has warned against relying on negative tests as the lone basis for treatment and patient management decisions. Negative results must also be evaluated along with clinical observations, patient history and epidemiological information, the agency stresses. Meanwhile, the CDC acknowledged that it will probably need to remanufacture one of the kit reagents to address the test quality results issues.

In addition to the CDC assay, the FDA has recently issued EUA for two commercial tests:

- On March 12, EUA was granted to the Cobas SARS-CoV-2 rRT-PCR assay from Roche for qualitative detection used with the Cobas 6800 and 8800 systems; and
- On March 13, the FDA provided EUA clearance to ThermoFisher Scientific's TaqPath COVID-19 Combo Kit, is for the qualitative detection of SARS-CoV-2 nucleic acid in nasopharyngeal swab, nasopharyngeal aspirate, and bronchoalveolar lavage specimens from individuals suspected of having COVID-19 by their healthcare provider.

As of March 16, Thermo Fisher had 1.5 million tests available to ship under the EUA label and expects to increase production to reach 2 million tests per week. Based on available raw materials and the installed instrument base, the firm expects to ramp up production to up to five million tests per week in April. Thermo Fisher plans to initially ship those tests to approximately 200 laboratories in the U.S. and "will continue to work in partnership with government agencies and private partners to expand access," according to a company statement.

In addition to the two commercial assays, the FDA gave EUA to the Wadsworth Center, New York State Department of Public Health's New York SARS-CoV-2 RT-PCR Diagnostic Panel authorized for emergency use by a pair of public laboratories in the state. The flow of EUA tests is expected to accelerate with Qiagen and GenMark Diagnostics among the manufacturers with assays in the pipeline.

Non-EUA Pathway

In addition to EUA pathway development, the FDA is pursuing a second strategy of allowing high-complexity CLIA labs (of which there are a reported 300 to 400 across the country) to develop and start using validated coronavirus tests before the agency even completes review of their EUA applications. High-complexity labs are required to strictly follow CDC testing protocols, notify the FDA of test validation and submit a complete EUA request within 15 days after validation.

Among the first labs to follow this unprecedented pathway is LabCorp, which launched its LabCorp 2019 Novel Coronavirus (COVID-19) NAA test on March 6. Like the EUA tests, the LabCorp assay uses PCR technology to qualitatively detect the SARS-CoV-2 virus from respiratory samples collected at the point of care. Other major labs planning to launch their own SARS-CoV-2 tests prior to completion of EUA review include Quest Diagnostics, BioReference Laboratories (part of Opko Health) and Enzo Biochem.

CMS Issues Guidelines for Laboratories Performing Tests

On Feb. 6, two days after the FDA granted the EUA clearance for the CDC coronavirus detection test, the Centers for Medicare and Medicaid Services (CMS) issued **guidelines** laying out the standards laboratories must follow in performing the assay.

Technically, the CMS guidelines are addressed not directly to the testing laboratories but to the state regulators in charge of enforcing the Clinical Laboratory Improvement Amendment (CLIA),since they will police the performance of coronavirus testing within their jurisdiction. The guidelines instruct regulators to notify their CMS Location if they discover that a laboratory is using an assay without an EUA that is testing for the same agent for which the emergency has been declared, or a modified EUA assay. The CMS Location will then relay the notification to CMS headquarters in Baltimore which will determine what action to take against the offending laboratory.

The guidelines make four key points with regard to actual testing standards.

1. **Eligibility Criteria for Testing Laboratories**

   Panel tests may be performed only by laboratories that are CDC qualified, and, CLIA certified for high complexity tests.

2. **Testing Must Meet CLIA Standards**

   As with other assays that have received EUA from the FDA, use of the CDC test and corresponding protocols remains subject to CLIA regulations. In other words, being CDC qualified, which a laboratory

must be to perform the test, does not exempt the laboratory from the need to comply with CLIA requirements.

3. **Laboratories Must Follow Manufacturer's Instructions**

   CDC qualified laboratories must also follow any and all applicable Manufacturer's Instructions (MI) in performing the assay.

4. **Laboratories Must Verify Performance Specifications**

   Upon receipt of the assay, CDC qualified laboratories must verify assay performance specifications in their own laboratory as per the MI. Test laboratories are required to use the CDC kits and reagents but are permitted to use their own RT-PCR equipment and extraction kits.

Takeaway

If your laboratory is qualified to perform the new CDC Panel, be sure that you are aware of and strictly adhere to CLIA and the other requirements specified in the CMS guidelines. Also keep in mind that while similar eligibility and performance standards are likely to apply to other coronavirus detection tests if and when they receive EUA from the FDA, each test will come with its own MI.

Billing, Coding & Reimbursement Issues

Good news for laboratories that are or will be testing Medicare patients for COVID-19 using the newly approved assays: In billing for the tests, you don't have to list an unspecified code. Instead, you can use the new Healthcare Common Procedure Coding System (HCPCS) codes that CMS created for laboratories and other providers to use in billing CDC tests for the SARS-CoV-2 virus:

- HCPCS code U0001 for the CDC test, which CMS announced will be reimbursed at between $35.91 or $35.92 per test; and
- HCPCS code U0002 for other SARS-CoV-2 virus assays that have received EUA from the FDA, which will be reimbursed at between $51.31 and $51.33 per test.

The CMS claims processing system will be capable of accepting the new HCPCS codes on April 1 for dates of service on or after Feb. 4, 2020, the date the FDA issued EUA authorization for the CDC coronavirus test. Reimbursement rates vary slightly by region subject to the determination of the local Medicare Administrative Contractor. Commercial insurers haven't yet announced their reimbursement rates, but are expected to align their own prices with Medicare's.

The Private Sector

The next Section describes what's happening in the private sector, not only in the U.S. but globally.

Part II

PRIVATE SECTOR EFFORTS TO DEVELOP A CORONAVIRUS DETECTION TEST

As coronavirus continues to spread and claim more lives, the development of a quick, safe and effective diagnostic test for detecting the COVID-19 virus has become an urgent global priority. Here is a quick overview of some of the more promising initiatives that have emerged in Asia, Europe and the U.S.

The Central Role of RT-PCR Test Technology

Although much remains to be learned about COVID-19, researchers have noted its similarity to coronaviruses found in bats, including the severe acute respiratory syndrome (SARS) virus. Accordingly, test developers have based tests to detect and confirm the virus on rapid real-time reverse transcription polymerase chain reaction (RT-PCR) technology. Not coincidentally, this is the technology used by the CDC test which has received emergency authorization in the U.S.

As we noted in our analysis of the CDC test, the tendency to generate false negatives is the principle weakness in this technology.

Private Sector Initiatives in Asia

Not surprisingly, the most progress has been made in China, Hong Kong, and Southeast Asia where the outbreak began and continues to pose the greatest threat.

The BGI Group Assay

Few private diagnostic companies have played a more direct and active role in COIVD-19 response on the ground in Asia than Chinese genome sequencing company, the BGI Group. BGI and its MGI Tech subsidiary were the first to sequence the 2019-nCoV genome and subsequently developed a real-time fluorescence PCR kit for detecting coronavirus in a few hours. The kit received emergency clearance from China's National Medical Products Administration (NMPA). In addition to scaling up production of the assay, BGI donated 230,000 kits and opened a medical test laboratory to support COVID-19 response efforts in Wuhan and Hubei Province.

Other private firms that are seeking or have received regulatory approval for COVID-19 detection assays in Asia include:

- Luminex, which is seeking NMPA approval in China for its NxTag Respiratory Pathogen Panel, but only for ruling out COVID-19 infection;
- Kogene Biotech, which received emergency clearance for its 2019 Novel Coronavirus Real-time PCR Kit in Korea; and
- Seegene, which also received emergency clearance in Korea for its Allplex 2019-nCoV Assay.

The Hong Kong Assays

On Jan. 31, the journal Clinical Chemistry published the results of a study by investigators from China and Hong Kong claiming to have developed a pair of assays for rapid identification and confirmation of 2019-nCoV. Using publicly available sequencing information about the virus, the researchers focused on viruses in the sarbecovirus subgroup of betacoronaviruses and developed one-step RT-PCR tests targeting two regions of the viral genome—ORF1b and N. They then evaluated the tests in a panel of negative and positive control samples, including respiratory specimens from patients suspected of having COVID-19 during different stages after the onset of the illness. Each RT-PCR took about an hour and 15 minutes to run.

The researchers found that the assays were sensitive only to sarbecoviruses, with both suspected patients testing positive. They also determined that the N gene assay was 10 times more sensitive than the ORF1b assay in detecting positive samples. Based on these findings, the researchers recommended:

- Using the N gene assay for initial COVID-19 testing;
- Using the ORF1b assay if the patient tests positive to confirm the result; and
- Follow up testing by a World Health Organization (WHO) reference laboratory if the first test is positive and the second test is negative.

The PolyU Multiplex Respiratory Screening Panel

Less than a week after publication of the Clinical Chemistry RT-PCR tests study, scientists from The Hong Kong Polytechnic University (PolyU) announced that they have developed a comprehensive panel capable of detecting 30 to 40 respiratory infectious disease pathogens, including COVID-19, in less than an hour via a single test. Incorporating polymerase chain reaction technology into the diagnostic system allows the device to be fully automated from sample nucleic acid extraction and amplification to signal detection and analysis to achieve point-of-care capability. The system does not require manual interaction across the testing process.

Chips and Apps

Response has also extended to mobile point-of-care test lab-on-chip solutions that can diagnose pathogens via an end user's cell phone. One of the first applications of this technology to COVID-19 came on Jan. 24 when Singapore biotech firm Veredus Laboratories announced plans for a Feb. 1 commercial launch of a kit capable of detecting the coronavirus with "high specificity and sensitivity." The VereCoV kit is based on lab-on-chip technology which integrates two molecular biological applications, polymerase chain reaction and microarray. This is the same application that Veredus, which is currently owned by Japanese plastics giant Sekisui Chemicals, has used to create kits for detecting the Mers, Zika, Dengue and H1N1 viruses. The company claims the new kit can detect, differentiate and identify all three coronaviruses in a single test in about two hours.

The Private Sector Response in Europe

Although East and Southeast Asia have been the center of activity, scientists, public health laboratories and commercial test makers in the U.S., Europe and other regions affected by the outbreak are also working furiously to develop and secure expedited emergency regulatory approval for new experimental COVID-19 detection tests.

The first private sector company to gain approval for a COVID-19 to gain test in Europe is Primerdesign, the molecular division of Novacyt. On Feb. 17, just two weeks after launching a research-use-only coronavirus test, Novacyt announced that it had received CE marking for a commercial molecular COVID-19 test. The Paris-based firm is also seeking FDA EUA authorization in the U.S.

On Feb. 24, U.S. firm Co-Diagnostics announced that it has received CE-IVD marking for its Logix Smart Coronavirus COVID-19 test. The reverse-transcriptase quantitative PCR assay uses proprietary Co-Primer technology that the company claims can improve test specificity, reducing the likelihood of a false positive. "We look forward to scaling up production to meet global demand with this regulatory clearance in place, and to obtaining approvals from other bodies that will allow us to further increase the reach of this invaluable diagnostic tool," noted Dwight Egan, CEO of the Utah-based company, whose stock shout up nearly 30% to $3.93 on the day CE-IVD approval was announced.

Meanwhile, the pioneering BGI Group has teamed with Curetis Group company Ares Genetics to make its COVID-19 molecular tests available in Europe. Under the deal, Ares will launch a next-generation sequencing testing service for the virus using BGI reagents and collaborate in the distribution of NGS and PCR testing kits.

The Private Sector Response in the U.S.

In the U.S., the FDA is following the same playbook it used in responding to previous virus outbreaks like SARS and Zika, by calling on diagnostic test sponsors interested in potential EUA for coronavirus detection tests to contact the agency's Center for Devices and Radiological Health (CDRH) (**CDRH-EUA-Templates@fda.hhs.gov**) for information and templates. Several firms have announced plans to seek EUA for new coronavirus tests but, as of Feb. 26, the CDC assay remains the only product approved for COVID-19 detection in the U.S.

Private sector companies developing tests for EUA from the FDA include:

- Cepheid is developing an automated molecular test for use on its GeneXpert Systems to detect the 2019-nCoV strain in around 30 minutes;
- Qiagen is developing an expanded version of its QiaStat-Dx Respiratory Panel to include molecular assays for detecting COVID-19 from nasal swabs of symptomatic patients, which it hopes to submit for FDA approval before the end of February;
- Finnish company Mobidiag also initiated development of a Novodiag molecular diagnostic test to identify novel coronavirus and other influenza viruses in 30 minutes via its joint venture with Chinese company Autobio Diagnostics; and
- Hibergene, a Dublin-based medtech company specializing in developing tests for infectious diseases has fast-tracked a new, rapid test for coronavirus that it hopes will be on the market "in months".

Part III

CORONAVIRUS & YOUR LABORATORY: INFECTION CONTROL & RESPONSE

Let's move from the global response to how coronavirus and the threat of pandemic impacts your own laboratory personnel and operations.

Your Coronavirus Legal Obligations & Liability Risks

The best reason to prepare your laboratory for coronavirus is to protect the health of your employees and viability and continuity of business operations. The next best reason is to protect your laboratory from liability risks. There are five ways coronavirus can get you into legal hot water:

1. OSHA Violations

The OHSA laws are the principle source of the obligation to protect employees against work-related hazards. Neither the U.S. Occupational Safety and Health Act (Act) nor its implementing regulations mention anything about viruses or the risk of infectious illnesses. For purposes of this analysis, the key provision is Section 5(a)(1) of the Act, which requires employers to provide its employees a workplace that's "free from recognized hazards that are causing or likely to cause death or serious physical harm." This provision is called the "general duty clause." And we know from the SARS, West Nile and avian influenza outbreaks that OHSA considers an infectious illness like coronavirus to be a "recognized hazard" that the general duty clause covers.

Bottom Line: Protecting laboratory employees from coronavirus infection is an OSHA duty.

2. Negligence

Workers' compensation laws bar employees who suffer work-related injuries and illnesses from suing their employers for negligence. However, the bar is subject to restrictions, e.g., injuries and illnesses due to gross negligence; and it doesn't apply to third parties that become infected in your workplace or as a result of work-related contact with one of your infected employees.

Bottom Line: You could be sued for negligence if a laboratory employee suffers or causes a coronavirus infection.

3. Wage & Hours Violations

Absenteeism from coronavirus infection might force you to use employees for longer hours; it may also test the limits of policies providing for medical, family caregiving and other leaves of absence.

Bottom Line: A coronavirus pandemic could open you to complaints under the federal Fair Labor Standards Act and equivalent state laws.

4. Workers' Compensation Claims

Contracting coronavirus infection at work may be deemed a work-related illness, particularly for laboratory employees.

Bottom Line: Coronavirus infections by your employees may lead to a spike in workers' compensation claims.

5. Disability Discrimination & Failure to Accommodate

An employee who becomes infected or shows symptoms of infection may be considered "disabled" under the Americans with Disabilities Act and other employment discrimination laws.

Bottom Line: You must be prepared to make accommodations for employees who suffer (or are unusually vulnerable to) coronavirus infection to the point of undue hardship.

The Four Things You Must Do to Avoid Liability

So, what exactly are employers required to do to comply with their legal duties, including the general duty to protect laboratory employees against the recognized hazard of coronavirus infection?

The best way to answer that question is by looking to government guidelines issued during previous infectious illness outbreaks. While not technically binding law, these guidelines are crucial because they lay out the actual criteria that government inspectors who enforce the law use to evaluate whether an employer has taken the reasonable measures the general duty clause requires. Even though they address West Nile, SARS, avian influenza and other previous illnesses, these guidelines are based on fundamental principles and best practices promulgated by the WHO, CDC and other internationally recognized health agencies. Let's look at the 4 sets of measures they require employers to take:

1. Educate Employees

Ensuring that employees know about the hazards to which they're exposed is a fundamental duty under the OSHA laws. In the context of infectious illness, the right to know requires:

General Education: First, you must familiarize employees with the nature of the risk posed by coronavirus—what it is, how it can infect them and how to protect themselves. (Go to TOOL 3 at the end of this Report to find an Employee Briefing Fact Sheet based on the CDC model that you can

distribute to your own laboratory employees.)

Prevention Measures: You must acquaint your employees with personal hygiene and other measures they can take to guard against the risk of infection, including:

- Hand washing;
- "Cough etiquette";
- Social distancing;
- Proper use of personal protective equipment (PPE);
- Vaccination (although there is currently no vaccine for COVID-19); and
- Precautions for employees planning to travel to affected areas.

Notification & Communication: Education also involves keeping your employees apprised of recent developments, both public and within your workplace. Laboratory employers must provide clear, timely and proactive communication to staff, including how their organization is handling the situation. This includes posting information on your laboratory's web site and/or starting an internal phone service that employees can call for information. Also post the location of hospitals, clinics, public health authorities and other health resources in your community. In addition, you need to establish and maintain communication with any of your employees who are absent due to infection.

2. Control Workplace Infection

The heart of the employer's duty is to implement infection countermeasures to safeguard employees from infection risks. These measures include:

- Basic hygiene measures such as furnishing soap, anti-bacterial products and paper towels;
- Keeping sinks and surfaces that people touch, e.g., doorknobs, clean;
- Posting signs, posters and notices reminding employees to wash their hands properly, use cough etiquette, keep social distances, etc.;
- Implementing work practices to promote social distance, e.g., use of conference calls instead of face-to-face meetings;
- Physical design measures, such as keeping workstations as far apart as possible;
- Screening employees and visitors entering the laboratory for risks of having and spreading coronavirus; (Go to TOOL 2 at the end of this Report to find a Model Screening Form that you can use at your own laboratory)
- Disciplining employees who don't practice proper hygiene, come to work infected or otherwise endanger co-workers; and

- Managing cases of infection at work, including telling those suspected of having coronavirus to go home immediately and monitoring which employees get infected, where they work, etc.

3. Ensure Use of Appropriate PPE

While we still don't know much about how coronavirus is transmitted, PPE has been an essential element in preventing previous infectious illness outbreaks. Such PPE typically includes:

- Protective gloves that are disinfected and disposable;
- Disposable particulate or other respirators, e.g., N95, N99 or N100;
- Protective gowns for medical workers; and
- Eye protection for medical workers within three feet of infected patients.

4. Create Preparedness Plan

Last but not least, you must incorporate the above countermeasures into a broader policy or plan on responding to coronavirus and other infectious illnesses at your workplace. The policy should include:

- Hazard assessment gauging your laboratory's vulnerability in case of outbreak or pandemic;
- Identification of key personnel and operations that are a priority to protect and/or replace;
- Revision of integral OSHA and HR policies, e.g., regarding absences, cancellation of vacations, overtime or temporary workers to ensure availability of labor during an outbreak;
- Provisions to ensure business continuity;
- Preparation for labor, service and supply disruptions; and
- Creation of secure lines of communications with employees, physicians, customers, suppliers, government agencies and other key parties during an outbreak.

(Go to **TOOL 1** at the end of this Report to find a **Model Coronavirus (COVID-19) Policy** that you can adapt for use at your own laboratory.)

Part IV

CORONAVIRUS & COMPLIANCE WITH PRIVACY LAWS

Another set of legal challenge posed by coronavirus outbreak is ensuring compliance with the Health Insurance Portability and Accountability Act and other laws protecting the privacy of personal medical information. Admittedly, complying with these laws is a year-round concern. But while coronavirus outbreak doesn't create the laws, it creates new operational challenges requiring you to test their limits. In addition, the usual restrictions on unauthorized collection, use and disclosure of personal health information (PHI) loosen up during a public health emergency. As a laboratory manager, it's crucial that you understand and ensure your laboratory complies with the privacy rules. There are actually two different aspects of this challenge:

Reconciling your infection control and emergency response measures with the privacy rights of your employees; and

Sharing test results and other coronavirus-related patient PHI with other providers, public health agencies and others.

This Section of the Report explains how to meet both of these challenges.

Coronavirus Response & Employee Privacy

As with any other infectious illness, COVID-19 risk management may require you to collect, use and disclose (which we'll refer to collectively as "use") private medical information about your employees, e.g., determine if they're infected to assess the need to implement quarantine measures. So, you need to be aware of your employees' privacy rights and adjust your emergency response measures accordingly. Here's how:

What the Privacy Laws Require

While HIPAA is about patient rather than workplace privacy, it comes into play when laboratories use their employees' PHI. Employees may also have privacy rights vis-à-vis their employers under:

- State personal privacy laws, both statutory and common law, i.e., case law;
- The collective bargaining agreements and individual employment contracts covering the employee involved;

- Your laboratory's internal HR policies and Code of Conduct; and
- Any other things you do to foster reasonable expectations of privacy in your employees.

> The most significant privacy restriction for laboratories, is the need to get employees' consent to use their PHI. The consent form must be clearly written so employees know how you propose to use their PHI; and the decision to sign must be totally voluntary. Any signs of trickery or coercion nullify the consent. However, as a practical restriction, there are situations where you're allowed to use PHI without consent.

Rule 1: You Probably Need Consent to Use PHI for COVID-19 Planning

Despite the experience of previous pandemics, it remains unclear whether use of PHI for COVID-19 preparation and response would be exempt from consent requirements. Equally unclear, then, is whether employees must provide the PHI your laboratory needs to carry out preparation and response measures.

Bottom Line: Unless clear guidance states the contrary, you should plan to get consent for COVID-19-related uses of employee PHI.

Rule 2: You Must Keep PHI to Minimum Necessary

Use of PHI must also be kept to the minimum necessary to accomplish whatever COVID-19 planning or response function you need the PHI to carry out. Thus, for example, it would be inappropriate to ask employees to undergo a physical exam or submit a complete medical record to assess their vulnerability to infection. Note that the minimum necessary restriction applies regardless of whether the use is consented to.

Rule 3: You Must Notify Employees of PHI Use

You must also notify employees of the PHI you use and why you need it for COVID-19 planning and response purposes.

Rule 4: You Must Keep PHI Secure

You must maintain the security of any PHI you collect from employees, including via use of:

- Physical barriers such as keeping files locked;
- Electronic measures such as password protection and encryption; and
- Administrative controls such as keeping the number of staffers with access to employee PHI limited to the minimum necessary.

Rule 5: You Must Properly Destroy PHI Information After Use

Finally, you must ensure that the PHI you collect from employees for COVID-19 planning and response is properly destroyed after it's no longer needed.

How to Handle 5 Key Situations

Here are some practical pointers based on government guidelines, expert opinions and privacy best practices from previous outbreaks, addressing the privacy boundaries to follow when carrying out operations related to coronavirus prevention and response.

1. Identifying Employees Needing Alternative Work Arrangements

Challenge: Although you can't generally ask employees whom they live with, this may become crucial information for COVID-19 planning to the extent it enables you to identify which employees may need alternative work arrangements.

Wrong: Asking: "Do you have young children or elderly parents that you might have to stay home and care for in the event of a COVID-19 pandemic?"

Right: Distributing a survey asking employees if they may have to make alternative work arrangements to care for kids or elderly parents. This way, you will be able to estimate how many employees may be absent without collecting detailed personal information.

2. Identifying Employees Who Might Be Susceptible to Infection

Challenge: You may want to identify employees with asthma, immunity deficiencies or other vulnerabilities to viruses so you can warn them to take special precautions against COVID-19.

Wrong : Asking employees for detailed information about their medical condition, e.g., asking if they have asthma.

Right: Letting all employees know that individuals with certain conditions are at risk and need to consider additional precautions.

3. Asking Employees for Personal Contact Information

Challenge: You need contact information so you can provide employees updates about a pandemic situation.

Wrong: Requiring or asking employees to give you their personal email or phone number.

Right: Asking employees how they prefer to be contacted and giving them alternative ways to get information from you without having to disclose their private contact information, e.g., having them call in to the laboratory at agreed-upon intervals.

4. Asking Employees Who Call In Sick If They Have COVID-19

Challenge: In a pandemic situation, you'll need to keep track of how many employees are diagnosed with COVID-19.

Wrong: Asking employees who call in sick: "Do you have COVID-19?," or "What illness do you have?"

Right: Asking employees who call in sick how long they expect to be out and when they plan to return. In short, you can ask for a prognosis but not a diagnosis.

5. Notifying Other Employees that a Co-Worker Has COVID-19

Challenge: If you learn that an employee has COVID-19, you might want to notify others at the lab, including the employee's co-workers.

Wrong: Disclosing an employee's diagnosis to somebody else.

Right: Letting others know that the employee isn't available, and if necessary, when he/she's expected to return.

COVID-19, Privacy & Practical Limits

X What You CAN'T Do	√ What You CAN Do
Ask: "Do you have kids or older parents that you might have to stay home and care for?"	Hand out a survey asking employees if they might have to make alternative work arrangements without specifically asking who they live with.
Ask: "Do you have asthma or other medical condition that makes you at high risk of infection?"	Notify ALL employees that certain medical conditions heighten the risk of infection and advise any employee who has such conditions to take special measures to protect themselves.
Asking employees for personal emails or other contact information in case you need to notify them of developments.	Ask employees what contact arrangements they want to make and explore ways to maintain contact that don't involve getting private emails, e.g., letting employees call in themselves at agreed intervals.
Asking an employee who calls in sick: "Do you have COVID-19?"	Asking an employee who calls in sick: "How long do you expect to be out of work?"
Telling an employee's colleagues: "Joe has COVID-19."	Telling an employee's colleagues: "Joe has called in sick and isn't expected to return until Thursday."

Coronavirus Response & Patient Privacy

Let's now turn to the compliance challenges posed by patient privacy rights. The starting point is that coronavirus has officially been declared a public health emergency. That's significant because the usual HIPAA Privacy restrictions on collecting, using and disclosing *patients'* PHI (PHI) without consent are relaxed during public health emergencies.

The bottom line: There may be situations where labs can and, in some cases, must take liberties with PHI. Here's a look at what you can and can't do based on Feb. 3, 2020 guidance from the Office for Civil Rights (OCR), the HHS agency charged with enforcing the HIPAA rules.

The OCR Guidance

HIPAA doesn't go away during a public health emergency; but the restrictions on sharing PHI do loosen up, at least in certain situations. OCR issued the guidance to clarify the privacy rules that laboratories and other HIPAA covered entities (which, for simplicity's sake, we'll refer to collectively as "laboratories" unless the context requires otherwise) must follow during the COVID-19 outbreak.

Sharing Patient Information

The HIPAA Privacy Rule requirement that laboratories not disclose a patient's PHI without the patient's authorization is subject to exceptions, including disclosure necessary to treat the patient or another patient. This is true even when there's no public health emergency. Treatment, the guidance explains, includes coordination or management of health care and related services by one or more health care providers and others, consultation between providers, and the referral of patients for treatment.

Disclosure for Public Health Activities

The HIPAA Privacy Rule recognizes the legitimate need for public health authorities to have access to PHI that's necessary to carry out their public health mission. Accordingly, it allows laboratories to disclose such PHI without individual authorization

To federal, state or local health departments or other public health authorities for the purpose of preventing or controlling disease, e.g., reporting cases of patients exposed to, suspected of or confirmed as having COVID-19;

At the direction of a public health authority, to a foreign government agency acting in collaboration with the public health authority; and

To persons at risk of contracting or spreading a disease or condition where state or other law authorizes the laboratory to notify such persons as necessary to prevent or control the spread of the disease.

Disclosures to Individuals Involved in Patient's Care

Laboratories may share PHI with a patient's family members, relatives, friends or other persons: i. that patients identify as being involved in their care; or, ii. as necessary to identify, locate and notify family members, guardians, or anyone else responsible for the patient's care, of the patient's location, general condition or death, which may include via the police, press or public at large. But the guidance stresses that the laboratory should, if

possible, get verbal permission or otherwise be able to reasonably infer that the patient doesn't object. A laboratory may also share PHI with disaster relief organizations such as the American Red Cross that are legally authorized to assist in disaster relief efforts.

Disclosures to Prevent Serious & Imminent Threat

Laboratories may share patient information with anyone as necessary to prevent or reduce a serious and imminent threat to the health and safety of the patient, another person or the public, subject to state and other applicable law and ethical standards of conduct.

Disclosures to the Media or Others Not Involved in Care

With limited exceptions, laboratories may not disclose PHI about the treatment of an identifiable patient, e.g., coronavirus detection test results, without the patient's written authorization. But if a patient hasn't objected to or restricted the release of PHI, a covered hospital or other health care facility may, upon request, disclose information about a particular patient by name, may release limited facility directory information to acknowledge an individual is a patient at the facility, and may provide basic information about the patient's condition in general terms (e.g., critical or stable, deceased or treated and released).

Minimum Necessary

For most disclosures, a laboratory must make reasonable efforts to limit the information disclosed to the "minimum necessary" to accomplish the purpose. **Exception:** Minimum necessary requirements don't apply to disclosures to health care providers for treatment purposes.

The guidelines clarify that laboratories may rely on representations from a public health authority or other public official that the requested information is the minimum necessary for the purpose, as long as that reliance is reasonable under the circumstances. For example, a laboratory may rely on representations from the CDC that the PHI requested about all patients exposed to or suspected or confirmed to have coronavirus is the minimum necessary for the public health purpose.

Safeguarding Patient Information

In an emergency situation, laboratories must continue to implement reasonable safeguards to protect patient information against intentional or unintentional impermissible uses and disclosures. Laboratories (and their business associates) must also implement the administrative, physical and technical safeguards required by the HIPAA Security Rule for electronic PHI.

TOOLS & ATTACHMENTS

TOOL 1: Model Coronavirus (COVID-19) Policy

Although not officially a pandemic, the coronavirus (COVID-19) outbreak may rise to that level. And even if it doesn't, the risk of future outbreaks and pandemics will always remain. That's why your laboratory should have a response and prevention policy. The starting point is a policy like the one below. The Model Policy draws on actual examples used by government agencies and private companies in previous pandemics, but we've modified it for coronavirus. That should make your life a little simpler if coronavirus becomes a pandemic. Otherwise, you should treat the Model Policy as a generic template that you can adapt for other infectious illness that may reach pandemic levels in the future.

XYZ LABORATORIES
CORONAVIRUS (COVID-19) POLICY

1. PURPOSE

The purpose of this Policy, which is Part of XYZ Laboratory's emergency-preparedness and business continuity plan, is to set the broad parameters of our corporate-wide response to outbreaks of coronavirus (COVID-19) and other contagious or infectious illnesses (which we'll refer to as "outbreaks") and outline the specific steps XYZ Laboratory takes to safeguard employees' health and well-being during such outbreaks while ensuring the organization's ability to maintain essential operations and continue providing essential services to our clients, customers and patients.

2. IDENTIFICATION OF ESSENTIAL PERSONNEL

XYZ Laboratory has identified and designated as essential personnel certain employees whose jobs are vitally important to its continued operation during outbreaks. XYZ Laboratory expects only designated essential personnel to be available for work during an outbreak XYZ Company acknowledges, however, that even essential personnel might become ill and unavailable to work or not be able to reach our worksite because of conditions beyond their own or XYZ Laboratory's control. Consequently, XYZ Laboratory and its partners have made back-up arrangements under which designated personnel in locations outside our respective areas are trained and equipped to fulfill the duties of unavailable essential employees.

In addition, XYZ Laboratory has equipped most essential personnel with all the resources, including computers, cell phones, and back-up generators, that essential employees need to work remotely during outbreaks and other emergencies.

3. REMOTE WORK LOCATIONS

During an outbreak, local, state or federal authorities might prohibit or severely curtail individuals' access to and use of public services and public transportation; close or prevent access to buildings or public highways; isolate or quarantine buildings' occupants; and prevent inter- or intraprovince delivery of goods and services. XYZ Laboratory cannot predict and has no control over such authorities' actions and acknowledges its legal duty to comply with outside authorities' directives. XYZ Laboratory is, however, prepared to continue key "bare bones" operations from a number of remote work locations, including essential employees' home offices. XYZ Laboratory has installed at all remote work locations all the equipment necessary for off-site telecommuting operations. In addition, XYZ Laboratory has designated a secure web site through which essential personnel can communicate with each other and outside authorities.

4. INFECTION-CONTROL

XYZ Laboratory takes steps to minimize exposure to and spread of infection in the workplace and recommends measures that employees can take to protect themselves outside the workplace and encourages all workers to discuss their specific needs with a family physician or other appropriate health or wellness professional.

4.1. Ill Employees

XYZ Laboratory expects employees who contract or been exposed to the coronavirus or other infectious illness that is highly contagious to stay home and seek medical attention as necessary and appropriate. XYZ Laboratory expects such workers to notify their manager or supervisor as soon as possible of exposure or illness. At XYZ Laboratory's discretion or the direction of outside authorities, XYZ Laboratory can require the isolation and quarantine of any infected employees who come to work despite exposure or need for medical attention.

4.2. Vaccinations

There is currently no approved vaccination against the coronavirus. However, as a general matter, XYZ Laboratory requires all essential personnel to maintain up-to-date vaccinations and to obtain annual XYZ Laboratory-paid flu shots, if available and not medically contraindicated. XYZ Laboratory also requires essential personnel to certify that they have obtained the necessary inoculations and to maintain a copy of that certification, which must be provided at XYZ Laboratory's request.

XYZ Laboratory is also entitled under our state's pandemic and emergency health preparedness laws to receive from health care providers medical information created as a result of employment-related health care services, such as inoculations, provided to employees at XYZ Laboratory's specific request and expense when such information is needed to process insurance claims. XYZ Laboratory maintains the confidentiality of all such employee medical information in accordance with applicable personal and medical privacy laws.

5. MANDATORY EMPLOYEE TRAINING

All employees are at risk of exposure to coronavirus and other infectious illness and agents, both in and outside the workplace; therefore, all employees are required to attend initial or refresher training annually to become informed about what to do when an outbreak occurs covering such issues as:

- Availability of vaccinations, symptoms and health effects of infectious illnesses;
- Treatment and sources to contact for appropriate medical care, steps to take if exposure is suspected;
- XYZ Laboratory representatives to whom to report known or suspected exposures;
- Procedures for reporting exposure to co-workers, family members, friends or others who are ill;
- Proper use of XYZ Laboratory-provided personal-protection equipment (PPE);
- Proper hygiene in the workplace and at home; and
- Communications.

Training includes role-plays based on scenarios developed to test employees' understanding of our planned emergency response. Supervisors are responsible for recording and maintaining documentation on every employee's participation in required training.

6. PPE

XYZ Laboratory maintains on site adequate supplies of recommended PPE, such as face masks, eye protection, rubber gloves, and anti-bacterial hand gels and wipes, which workers may be required to use. XYZ Laboratory urges all employees to speak with their personal physician about types and proper use of PPE in the home.

7. FACILITIES MAINTENANCE

XYZ Laboratory's Facilities manager regularly inspects the workplace for signs of heating, air conditioning, or other equipment in need of replacement

or repair and coordinates closely with our cleaning and waste-removal contractors to maintain our physical plant in top condition. XYZ Laboratory approves the installation or use wherever possible of improved equipment or cleaning methods to guard against the spread of infection in the workplace.

8. EMPLOYEE LEAVE & PAY

In the event of coronavirus and other outbreaks, XYZ Laboratory will grant all nonessential personnel immediate administrative leave. XYZ Laboratory will pay workers on administrative leave a reduced salary, and continue such reduced salary for one-week periods up to a maximum of six weeks. XYZ Laboratory will monitor emergency conditions daily to determine how long administrative leave must continue and, following consultation with outside authorities, advise employees when to expect to return to work.

9. FAMILY & MEDICAL LEAVE

XYZ Laboratory will place on family and medical leave any workers who fall ill or must be absent from work to care for an infected family member in accordance with the applicable employment standards laws of the state. Such employees must notify XYZ Laboratory as soon as possible of need for family and medical leave. Employees may use accrued paid annual and sick leave in lieu of unpaid family and medical leave. XYZ Laboratory requires all employees to certify that they have received, read, and fully understand our family and medical leave policy and its use in an outbreak.

10. BUSINESS TRAVEL

Generally, in the event of an outbreak, travel on XYZ Laboratory's behalf will be immediately suspended and limited to a select group of essential personnel who have obtained required travel authorizations from XYZ Laboratory and, if necessary, outside authorities. Essential personnel or other employees traveling anywhere on XYZ Laboratory's behalf and exposed to the infectious illness may be eligible for workers' compensation benefits.

11. EMERGENCY CONTACT INFORMATION

Workers must notify their immediate supervisor and HR of any change in emergency-contact information within two weeks of such change. When providing such information, employees must identify individuals on whom they can depend in the event they become sick at work and must be isolated and quarantined. HR is directed to verify electronically employees' emergency contact information twice a year, in January and July. Supervisors are required to maintain in the workplace and at home an up-to-date emergency-contact list for their unit or department.

12. SPECIAL NEEDS AND ACCOMMODATIONS

XYZ Laboratory is required by law to notify first-responders about employees

with medical conditions that could be compromised because of an outbreak. XYZ Laboratory urges such employees to confidentially self-identify to HR so that we are aware of and can prepare for you to receive any special medical expertise you might require if you become severely ill on the job. HR will maintain the confidentiality of any information you provide and make it available solely on a need-to-know basis and only when needed by emergency responders.

13. COMMUNICATIONS

Outside Authorities: XYZ Laboratory and its Emergency Operations Team partner with local, state and federal emergency-response and health agencies to ensure legal compliance with emergency-response protocols to which XYZ Laboratory is subject and to coordinate efforts to maintain safety and security in and outside the workplace.

Call Center: Our remote emergency-response call center is activated in the earliest stages of an outbreak. Employees are instructed to call this center, using our secure hotline number, for pre-recorded messages and assistance from live operators.

Dedicated Web Site: XYZ Laboratory maintains a secure (password-protected) web site that is devoted to outbreak issues and XYZ Laboratory response.

Other Media Channels: In the event of an outbreak, XYZ Laboratory will consult with outside authorities to coordinate dissemination of instructions or other important information as quickly as possible to all employees. XYZ Laboratory will communicate with employees via its secure emergency-information hotline and dedicated web site, local radio and TV stations, and secure web sites of industry partners and affiliates.

TOOL 2: MODEL SCREENING FORM FOR CORONAVIRUS COVID-19

We don't yet know how contagious coronavirus (COVID-19) is but we do know that it can spread via human-to-human contact. We also know that the risk of contracting the diseases is significantly greater if the person has lived or traveled to the Chinese city of Wuhan where the virus originated. Similarly, individuals who've been to other countries where cases of COVID-19 has been reported may also pose a greater risk. Accordingly, should it become necessary to implement quarantine measures to prevent spread of the disease, you need to be able to determine who at your workplace has been to high risk countries. And that's what the Screening Form below enables you to do.

XYZ Laboratories
Coronavirus (COVID-19) Screening Form

Name: _____
Last First Middle

Date: _____

Please answer the following questions.

1. Have you traveled to any of the following countries within the past 14 days?

China	Yes ☐	No ☐
Cambodia	Yes ☐	No ☐
Thailand	Yes ☐	No ☐
Vietnam	Yes ☐	No ☐
Philippines	Yes ☐	No ☐
Japan	Yes ☐	No ☐
Korea	Yes ☐	No ☐
Hong Kong	Yes ☐	No ☐
Macao	Yes ☐	No ☐
Taiwan	Yes ☐	No ☐
Singapore	Yes ☐	No ☐
Malaysia	Yes ☐	No ☐

Australia	Yes ☐	No ☐
Nepal	Yes ☐	No ☐
Sri Lanka	Yes ☐	No ☐
India	Yes ☐	No ☐
UAE	Yes ☐	No ☐
Canada	Yes ☐	No ☐
UK	Yes ☐	No ☐
Spain	Yes ☐	No ☐
France	Yes ☐	No ☐
Belgium	Yes ☐	No ☐
Germany	Yes ☐	No ☐
Italy	Yes ☐	No ☐
Sweden	Yes ☐	No ☐
Finland	Yes ☐	No ☐
Russia	Yes ☐	No ☐

[This is a list of countries other than the US with confirmed reported COVID-19.]

2. If you answered Yes to any of the countries in the above question, were you in any farms, live animal markets or other areas where animals may have been slaughtered? Yes ☐ No ☐

If Yes:

Did you make contact with any animals, live or dead?
Yes ☐ No ☐

Did you make contact with surfaces that had animal droppings or secretions on them?
Yes ☐ No ☐

Did you eat any raw or undercooked animal products?
Yes ☐ No ☐

Did you spend time in large crowds or crowded areas?
Yes ☐ No ☐

Did you have contact with sick people, especially those with a fever, cough or difficulty breathing?
Yes ☐ No ☐

3. Have you been in close contact or staying in the same household as someone with a known or suspected case of coronavirus?
Yes ☐ No ☐

4. Do you have any of the following symptoms:

Fever	Yes ☐	No ☐
Cough	Yes ☐	No ☐
Difficulty breathing	Yes ☐	No ☐

5. Have you been in close contact or staying in the same household as someone with any of the above symptoms? Yes ☐ No ☐

Testing for coronavirus is considered on a case-by-case basis in consultation with local health departments. XYZ Laboratories reserves the right to restrict entry to its facility for any individuals it feels present a risk of infection. Entry will not be permissible without documentation indicating an absence of infection from an appropriate health care provider.

TOOL 3: MODEL CORONAVIRUS BRIEFING FOR EMPLOYEES

The coronavirus, which the World Health Organization (WHO) has declared as a global public health emergency, has now made its way to the U.S. And that means some of your employees may be exposed, especially if they work in health care or jobs that involve world travel or contact with people who've been in Wuhan China from where the coronavirus originated or other countries where cases have occurred. As with other hazards, you have an OSHA duty to ensure employees exposed or potentially exposed to coronavirus receive appropriate notification and education about the virus. The problem is that because coronavirus is so new, we don't know much about it at this point. Accordingly, the go-to source for information are governments and global health agencies like the WHO and the U.S. Centers for Disease Control and Prevention (CDC). Here's a CDC factsheet on coronavirus that you should distribute to your own employees.

XYZ Laboratories
EMPLOYEE BRIEFING: WHAT YOU NEED TO KNOW ABOUT 2019 NOVEL CORONAVIRUS (2019-nCoV)

What is 2019 novel coronavirus?

- The 2019 novel coronavirus (2019-nCoV) is a new virus that causes respiratory illness in people and can spread from person to person. This virus was first identified during an investigation into an outbreak in Wuhan, China.

Can people in the U.S. get 2019-nCoV?

- The 2019-nCoVis spreading from person to person in China and limited spread among close contacts has been detected in some countries outside China, including the United States. At this time, however, this virus is NOT currently spreading in communities in the United States. Right now, the greatest risk of infection is for people in China or people who have traveled to China. Risk of infection is dependent on exposure. Close contacts of people who are infected are at greater risk of exposure, for example health care workers and close contacts of people who are infected with 2019-nCoV. CDC continues to closely monitor the situation.

How does 2019-nCoV spread?

- This virus probably originally emerged from an animal source but now seems to be spreading from person to person. It's important to note that person-to-person spread can happen on a continuum. Some viruses are highly contagious (like measles), while other viruses are less so. At this time, it's unclear how easily or sustainably this virus is spreading between people. Learn what is known about the spread of newly emerged coronaviruses at https://www.cdc. gov/coronavirus/2019-ncov/about/transmission.html

What are the symptoms of 2019-nCoV?

- Patients with 2019-nCoV have reportedly had mild to severe respiratory illness with symptoms of:
  - fever
  - cough
  - shortness of breath

What are severe complications from this virus?

- Many patients have pneumonia in both lungs.

How can I help protect myself?

- The best way to prevent infection is to avoid being exposed to this virus.
- There are simple everyday preventive actions to help prevent the spread of respiratory viruses. These include:
  - Avoiding close contact with people who are sick.
  - Avoiding touching your eyes, nose, and mouth with unwashed hands.
  - Washing your hands often with soap and water for at least 20 seconds. Use an alcohol-based hand sanitizer that contains at least 60% alcohol if soap and water are not available.

If you are sick, to keep from spreading respiratory illness to others, you should:

- Stay home when you are sick.
- Cover your cough or sneeze with a tissue, then throw the tissue in the trash.
- Clean and disinfect frequently touched objects and surfaces.

What should I do if I recently traveled to China and got sick?

- If you were in China within the past 14 days and feel sick with fever, cough, or difficulty breathing, you should seek medical care. Call the office of your health care provider before you go and tell them about your travel and your symptoms. They will give you instructions on how to get care without exposing other people to your illness. While sick, avoid contact with people, don't go out and delay any travel to reduce the possibility of spreading illness to others.

Is there a vaccine?

- There is currently no vaccine to protect against 2019-nCoV. The best way to prevent infection is to avoid being exposed to this virus.

Is there a treatment?

- There is no specific antiviral treatment for 2019-nCoV. People with 2019-nCov can seek medical care to help relieve symptoms.

For more information: **www.cdc.gov/nCoV**

G2 INTELLIGENCE

About the Editor

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Barbara Manning Grimm is the managing editor of Plain Language Media, the parent company of G2 Intelligence, and is responsible for editorial production of print and online periodicals and related books and reports. She has more than 25 years of experience in business-to-business publishing. She has designed and developed targeted content and training programs for today's workplace, including safety, HR, management, customer service, and employee communication programs for a wide variety of industries, including healthcare. She has managed editorial content and operations for both print and online information sources. Prior to entering the business-to-business field, she was a newspaper editor.

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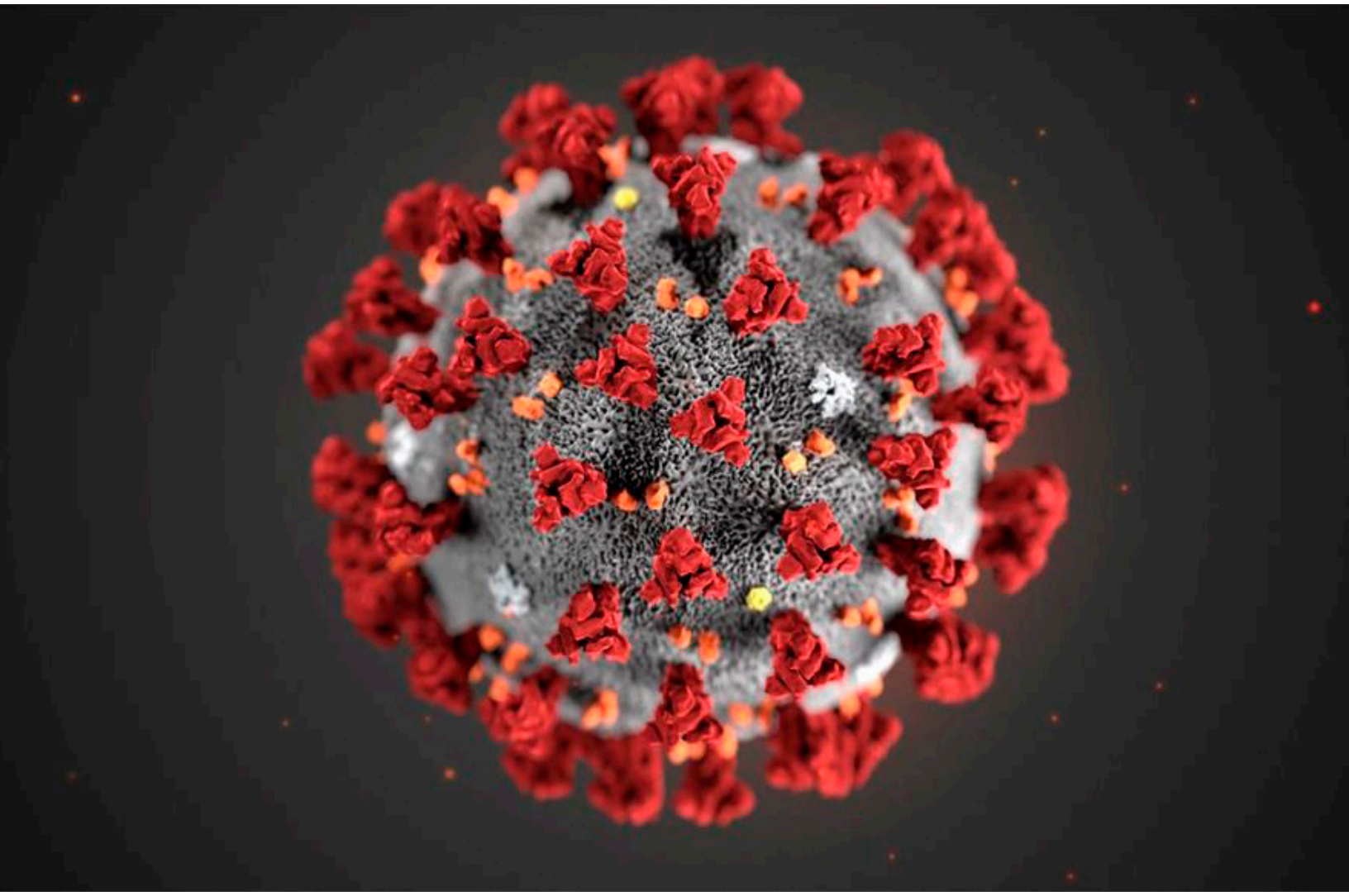

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