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*Presented by Diana Voorhees,
Principal/CEO, DV & Associates, Inc.*

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Compliance Perspectives: How to Create a Legally Sound COVID-19 Medical Screening Policy

As essential workplaces, testing labs need to remain open and operating during the pandemic. At the same time, they need to ensure that employees practice social distancing and keep the infected and potentially infected away from the well. Like so many other companies facing the same challenge, you may be considering medically screening your employees each day before letting them into the workplace. While screening is highly problematic in normal times, regulators have grudgingly acknowledged that it may be a justified health and safety measure during the pandemic. The operative phrase is “may be,” which means that limits still apply. As lab director, you need to recognize and ensure keep your facility in compliance with those limits. Here’s how.

Three Ways COVID-19 Screening Can Get Your Lab into Legal Hot Water

Medically screening lab personnel can expose you to three kinds of liability.

Continued on page 2

Managing Lab Staff: Do Lab Employees Who Fear COVID-19 Infection Have the Right to Refuse Work?

In normal times, failure to show up for work or refusing to carry out work assignments is a form of insubordination subject to discipline. But in times of pandemic, work refusals by employees due to fears of COVID-19 infection may be deemed the exercise of a legitimate health and safety right. **Result:** Disciplining employees for engaging in such refusals may expose your lab to risk of liability under OSHA laws. Here’s a look at the COVID-19 work refusal conundrum and how to maneuver around it.

OSHA Work Refusal & Discrimination Laws

Section 11 of the *Occupational Safety and Health Act* makes it illegal for an employer to “discharge or in any manner discriminate

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1. Privacy Violations

Body temperature and information about an individual's symptoms (or lack thereof) collected during the screening process is personal health information (PHI) protected by HIPAA and other privacy laws. Under the unique circumstances of the pandemic, the employer's need to maintain social distancing and keep sick people out of the workplace temporarily trumps personal privacy rights. But the employer's leeway goes only so far. Rule: You can only collect the minimum PHI necessary to maintain social distancing in the workplace. Example:

- ▶ **OK:** Asking employees if they have COVID-19 symptoms;
- ▶ **Not OK:** Asking employees about other medical conditions or what medications they use.

2. Discrimination

Medical exams raise a red flag under the *Americans with Disabilities Act* (ADA) and other discrimination laws because they may reveal an employee's disabilities. Having—or merely being perceived as having—COVID-19 is considered a disability. So, using the positive results of COVID-19 screening to keep an employee from coming to work could make you liable for disability discrimination. People who test positive may also belong to groups protected by other discrimination laws like the *Age Discrimination in Employment Act* (ADEA). The good news is that EEOC has recognized that screening is a valid health and safety measure during the pandemic, as long as it's implemented fairly, consistently and without regard to age, race, religion, sex, etc.

3. OSHA Violations

The other legal pitfall of screening is temperature-taking, which involves the risk of infection to both test takers and persons being tested. Consequently, you need to ensure your screening methods and equipment meet OSHA requirements.

The 10 Things to Include in Your COVID-19 Screening Policy

The key to sidestepping these legal risks is to implement a policy that clearly explains your screening methods and includes safeguards to ensure it complies with privacy, discrimination and OSHA requirements. Like our Model on [page 5](#), your COVID-19 screening policy should include 10 provisions.

1. Policy Statement

Explain that screening is essential to prevent spread of COVID-19 and that nobody will be allowed to enter the work site or facility unless they undergo and pass screening (Policy, Sec. 1).

2. Policy Purpose

State that the purpose of the Policy is to ensure that screening is done fairly, effectively, safely, consistently and in a manner that complies with current CDC and other public health guidelines (Policy, Sec. 2).

3. Who Must Undergo Screening

Under current guidelines, where screening is used, it must apply to all would-be entrants and not just employees. To avoid potential discrimination claims, make it clear that there are no exemptions and that all persons must undergo screening each time they seek entry to the lab. This will provide employees advance notice and encourage them to self-monitor before coming to work (Policy, Sec. 3).

4. Temperature Check Criteria

Next, explain the actual screening procedures, starting with temperature checks. To ensure consistency and eliminate discretion that can lead to discrimination claims, set a specific fever threshold, i.e., precise body temperature (or temperature range) that entrants must be below to get in. Our Policy uses the CDC recommended 100.4°F but you may want to ask a medical professional for help in deciding where to set your own fever threshold (Policy, Sec. 4.1).

5. Other COVID-19 Risk Factors

Body temperature alone isn't enough to determine if a person should be admitted. That's because a person can have COVID-19 without having a fever. Accordingly, public health guidelines recommend asking about the other COVID-19 risk factors, specifically the following YES/NO questions:

- ▶ Are you experiencing any of the following symptoms: cough, fever, difficulty breathing or sudden loss of smell?
- ▶ Have you been outside the US within the past two weeks?
- ▶ Have you had close contact, i.e., within six feet of a person confirmed as having COVID-19 within the past two weeks?

(Policy, Sec. 4.2)

6. Criteria for Entry

There must be black-and-white criteria for using screening results to determine who does and doesn't get in. Under current guidelines, nobody should be admitted if they're at or above the fever threshold. Persons with normal body temperature should also be denied entry if they answer YES to any of the above risk factor questions. **Exception:** Current CDC guidelines allow for granting entry to lab (and other health care or critical infrastructure) workers that are potentially exposed, i.e., those who answer YES to questions 2 or 3 above, as long as they don't have any COVID-19 symptoms and agree to:

- ▶ Wear a face mask at all times while in the lab;
- ▶ Follow the lab's social distancing protocols and requirements; and
- ▶ Self-monitor while in the workplace in accordance with the lab's medical policies, procedures and protocols.

(Policy, Sec. 4.3)

7. Documentation of Screening Results

Require screening personnel to complete a form or otherwise document the results of each check. Attach a copy of a blank form to your Policy (Policy, Sec. 4.4).

Continued on page 4

■ Compliance Perspectives: A 5-Step Game Plan for Protecting Lab Employees from COVID-19 Infection, *from page 3*

8. HIPAA Privacy Protections

Include the following privacy protections:

- ▶ A promise not to request any PHI beyond body temperature and questions about symptoms;
- ▶ Assurance that screening records of employees who don't pass screening will be kept private and secure in a separate file; and
- ▶ Assurance that you won't retain the screening records of non-employees and individuals who pass screening at all.

(Policy, Sec. 5)

9. Health & Safety Measures

Include safeguards to ensure the health and safety of participants in the screening process, especially temperature taking, starting with a hazard assessment, followed by the implementation of measures to eliminate or minimize the hazards identified, including:

- ▶ Reasonably practicable engineering controls, e.g., use of infrared non-contact thermometers rather than contact thermometers;
- ▶ Safe work procedures, safety training for screening personnel and other work controls; and
- ▶ Use of appropriate personal protection equipment, including at a minimum, N95 respirator masks and protective gloves, and where necessary, aprons, gowns and/or eye/face protection protecting against splashes of bodily fluids.

(Policy, Sec. 6)

10. Policy Duration

Last but not least, indicate that the Policy is only a temporary measure for the pandemic that will end as soon as the threat subsides and public health officials send the all-clear on social distancing. Also be clear that you have the right to amend the Policy to keep up with changes and ensure compliance with the latest version of the public health guidelines (Policy, Sec. 7). 

WEBINAR ANNOUNCEMENT

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Diana Voorhees
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TOOL MODEL COVID-19 MEDICAL SCREENING POLICY

Regulators have made it clear that given the unique circumstances of the COVID-19 pandemic, employers may implement pre-screening measures to ensure that people who have or may have the virus don't get into work and spread it to others. But

limits still apply and you can get into a lot of trouble if you don't follow them. Here's a Model Policy your lab can adapt that provides for the necessary privacy, health and safety, non-discrimination and other protections.

COVID-19 PRE-SCREENING & TEMPERATURE CHECKS POLICY

1. POLICY STATEMENT

COVID-19 coronavirus is highly contagious and implementing social distancing practices is essential to prevent its spread. Accordingly:

During the current COVID-19 pandemic, no persons will be permitted to enter or remain at an XYZ Laboratory work site or facility unless and until they submit to and receive clearance under the pre-screening process set forth in this Policy.

2. PURPOSE

In recognition of the invasive nature of medical pre-screening and the potential hazards it poses, XYZ Laboratory has adopted this Policy to clearly explain how the process will work and ensure that it is done fairly, effectively, safely, consistently and in a manner that complies with current US Centers for Disease Control (CDC) and other public health guidelines (collectively, "Guidelines").

3. SCOPE

The requirement to undergo pre-screening under this Policy applies not just to laboratory employees but to all persons seeking entrance to XYZ Laboratory facilities, including but not limited to contract workers, courriers, clients, customers and visitors. **No person will be exempt from pre-screening and pre-screening will be required prior to any and all entry and not waived for any occasion.** Those wishing to avoid undergoing pre-screening may do so by staying away and not seeking to enter the facility.

4. PRE-SCREENING PROCEDURES

XYZ Laboratory will create a pre-screening checkpoint in the front entrance of the building that all persons will be required to pass through before entering the facility. A nurse or other qualified health professional stationed at the checkpoint will administer the pre-screening exam in accordance with the following procedures and criteria.

4.1 Body Temperature Check

Screening personnel will take each entrant's body temperature to ensure they do not have a fever. No person whose body temperature meets or exceeds the fever threshold of 100.4°F (38°C) shall be allowed entry into the facility.

Continued on page 6

■ Tool: Model COVID-19 Medical Screening Policy, from page 5

4.2 Other Symptoms & Risk Factors Check

In recognition of the possibility that a person can have COVID-19 without having a fever, the nurse or screener will ask all entrants the following YES/NO questions:

- ▶ Are you experiencing any of the following symptoms: cough, fever, difficulty breathing or sudden loss of smell?
- ▶ Have you been outside the US within the past two weeks?
- ▶ Have you had close contact, i.e., within six feet (two meters) of a person confirmed as having COVID-19 within the past two weeks?

4.3 Admittance Criteria

No person who answers YES to any of the above questions will be allowed to enter the facility. **Exception:** Individuals who provide critical health care or support services at the lab may be admitted if they are asymptomatic and agree to do ALL of the following:

- ▶ Wear a face mask at all times while in the facility;
- ▶ Adhere to all XYZ Laboratory social distancing protocols and requirements; and
- ▶ Self-monitor while in the workplace in accordance with XYZ Laboratory medical procedures, policies and protocols.

4.4 Pre-Screening Form

Screening personnel will record the results of each check on the XYZ Laboratory COVID-19 Pre-Screening Form, a copy of which is attached to this Policy as Exhibit A.

5. PRIVACY PROTECTIONS

XYZ Company will implement the following safeguards to minimize privacy intrusions during and after the screening process.

5.1 No Additional Information to Be Collection

In recognition of entrants' privacy rights and that the protected health information (PHI) collected under Sections 4.1 and 4.2 above is the minimum necessary to accomplish the social distancing and health and safety purpose of pre-screening, screening personnel will neither request nor seek to collect any further medical information of any kind during the pre-screening process.

5.2 Pre-Screening Records Retention

In recognition that the information contained in pre-screening records is PHI, XYZ Laboratory will retain the records of entrants who are employees that fail to pass the pre-screening criteria in a confidential personnel file that will not be used or disclosed except in accordance with the XYZ Laboratory Employee Privacy Policy, and that will be treated as confidential data that must be kept secure in accordance with the XYZ Laboratory Data Security Policy. XYZ Laboratory will not retain the pre-screening records of:

- ▶ Entrants who pass pre-screening; or
- ▶ Entrants who do not pass pre-screening and are denied entry but who are not employees of XYZ Laboratory.

6. HEALTH & SAFETY OF TEMPERATURE TAKING PROCESS

A competent person will perform a hazard assessment to identify potential infection, health and safety hazards to both screening personnel and entrants during the temperature-taking process and XYZ Laboratory will implement the following measures to eliminate or control identified hazards:

- ▶ Where reasonably practicable, the use of engineering control, e.g., substitution of contact thermometers with infrared non-contact thermometers to eliminate the need for contact between screening personnel and entrants;
- ▶ Administrative and work controls, including ensuring that screening personnel are properly trained and follow safe work procedures; and
- ▶ Use of appropriate personal protection equipment, including at a minimum, N95 respirator masks and protective gloves, and where necessary, aprons, gowns and/or eye/face protection to protect screening personnel from being splashed with bodily fluids.

7. DURATION OF POLICY

This Policy is a temporary measure that will last only as long as the COVID-19 pandemic and will end once the Guidelines' social distancing mandate becomes no longer necessary. In addition, XYZ Laboratory reserves the right to modify any and all of the Policy terms and procedures, including the elimination or addition of requirements, as Guidelines change over the course of the pandemic. 

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Quiz: Spot the HIPAA Violation

SITUATION

Lab technician Khan Tajus reports to his manager that he's just tested positive for COVID-19 coronavirus. The manager orders him to go home, talk to a doctor and stay in self-isolation for at least 14 days. He also asks Khan for the names of any lab employees with whom he's had close contact, i.e., within six feet, in the past two days. He then calls every co-worker listed, lets them know that Khan has COVID-19 and orders them to also go into self-isolation for 14 days.

QUESTION

What, if anything, did the lab manager do wrong?

- A. Order Khan to go home and self-isolate
- B. Order Khan to reveal the names of co-workers with whom he had close contact
- C. Tell the co-workers that Khan has COVID-19
- D. Order the potentially exposed co-workers to go home
- E. Nothing

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■ Quiz: Spot the HIPAA Violation, from page 7

ANSWER

C. The only thing the lab manager did wrong was disclose Khan's illness to his co-workers.

EXPLANATION

The fact that Khan tested positive for COVID-19 is protected health information (PHI) that can't be disclosed without Khan's consent. However, consent isn't required if the disclosure serves a legitimate employment purpose and the PHI disclosed is limited to the minimum necessary to accomplish that purpose.

The manager disclosed Khan's diagnosis to his co-workers to protect their health and safety. And that's a legitimate purpose, especially in time of pandemic. The problem is that the manager could have achieved that objective simply by notifying Khan's colleagues that one of their co-workers tested positive. In mentioning Khan by name, the manager disclosed more PHI than necessary to accomplish his health and safety objective. So, C is the right answer.

WHY WRONG ANSWERS ARE WRONG

- A. is wrong** because ordering employees and others who are confirmed to have (or even just exhibit symptoms of) COVID-19 is something employers are required to do under current public health guidelines.
- B. is wrong** because the guidelines also call on employers to identify the people in the workplace with whom the person with COVID-19 has had close contact within the past 48 hours of testing positive.
- D. is wrong** because, once more, the guidelines mandate that employers bar entry to individuals that have had close contact with somebody who has COVID-19 within 48 hours. Exception: Under revised CDC guidelines, health care workers that are "potentially exposed" the way Khan's colleagues were, can keep working as long as they're symptomatic, wear a respiratory mask at all times, follow social distancing protocols and self-monitor. But when and if they exhibit COVID-19 symptoms, they have to go home and self-isolate. 🚫

Trap to Avoid: Keeping Lab Employees On Call during Breaks without Paying Them for the Time

Does this sound familiar? A hospital lab needs around the clock staffing so that tests for acutely ill patients in the ER can be performed at any time without delay. But staffing is tight and often lab technician Ms. W is the only employee on duty. During her 12-hour shifts, hospital personnel rely on her as the "go-to" person for lab testing, including during her 30-minute meal breaks. The hospital's policy is that meal breaks don't count as compensable work. Ms. W believes this is unfair and sues for unpaid wages during breaks. The state labor standards tribunal rules in her favor and the hospital appeals.

Ruling

The Colorado court finds the tribunal's decision reasonable and refuses to set it aside.

Reasoning

Under the Colorado Minimum Wage Order (MWO), employees who work more than five consecutive hours are entitled to a "duty free" meal break of at least 30 minutes. The break can be treated as uncompensated non-work time, provided that the employee is "completely relieved of all duties and permitted to pursue personal activities."

According to the court, the tribunal was justified in finding that Ms. W's meal breaks weren't "duty free." On the contrary, she was basically "on call" during her break periods and required to:

- ▶ Carry the lab phone and respond to all lab calls;
- ▶ Leave a sign at the lab instructing nurses to call her back to work when dropping off specimens;
- ▶ Answer questions from hospital doctors, nurses and paramedics about lab tests, equipment and instruments.

Ms. W also had to stay on hospital grounds at all times during her break, which precluded her from pursuing "personal interests" during that time. As a result, the hospital had to pay her several years' worth of break time (except for a brief period after which it changed its work break compensation policy) and penalties [*HCA-HealthONE LLC v. Colo. Dep't of Labor & Empl.*, 2020 COA 52, 2020 Colo. App. LEXIS 658].

Takeaway

The HCA case is of obvious relevance to the current COVID-19 pandemic where demands for testing is at record levels, staffing is short and just about all lab personnel are overworked. And while the case took place in Colorado, the same basic fair wage rules and principles apply in all parts of the country. Moreover, those laws remain very much in play, even during the pandemic. Specifically, there are points lab managers need to keep in mind when managing staff during the emergency:

- ▶ *Employees who work long shifts, typically five hours or more, are entitled to meal breaks, the length of which varies by state;*
- ▶ *The ideal situation is letting employees have their break time all to themselves;*
- ▶ *Where the nature of the business or other circumstances make that impractical, you're allowed to interrupt employees and keep them on call during breaks; and*
- ▶ *What you **can't** do is expect employees to be available during their breaks and then treat break time as non-work time.*

Bottom Line: *If you expect employees to be available for lab duties during breaks, you must compensate them for the time, regardless of whether you actually do call on them during a particular break.* 

Labs IN COURT

A roundup of recent cases and enforcement actions involving the diagnostics industry

Florida Lab, Execs Settle False Billing of Urine Drug Test Charges for \$41 Million

Case: Prosecutors accused a Tampa reference lab, pain clinic and two former executives of billing Medicare, Medicaid and TRICARE for medically unnecessary presumptive and definitive Urine Drug Testing (UDT). The defendants denied the charges but decided to pay \$41 million to settle rather than risk a trial.

Significance: Presumptive UDT screens for the presence of drugs, while definitive UDT identifies how much of the drug is in a patient's system. The latter are medically necessary only when presumptive screening produces a positive result. But the feds claim the lab and clinic routinely and automatically ordering both kinds of testing for all patients at every visit, without having a physician make an individualized determination of whether either test was medically necessary for that particular patient.

Commercial Labs Trade Accusations of False Advertising of TSI Assays

Case: The nasty litigation between Quidel and Siemens continued with both sides accusing the other of false and deceptive advertising. The touchstone of the suit are ads run by Siemens referring to Quidel's TSI and TBI detection assay IMMULITE as a "TSI only" product. The latest installment raises the question of whether Quidel has "unclean hands," a legal doctrine that means a plaintiff can't sue a defendant for the same wrongs the plaintiff is committing itself. Specifically, Siemens charged Quidel of making two false claims about its own Thyretain TSI assay:

- ▶ Thyretain, which is a qualitative assay, can be billed under the higher-reimbursing CPT code 84445 reserved for quantitative assays; and
- ▶ Thyretain can deliver test results in three to four hours which belies the fact that tested cells must be cultured overnight.

Quidel defended both claims and asked the federal district court to toss Siemens' unclean hands defense. The court refused.

Significance: All that's at stake with the unclean hands defense at this point is whether there's enough evidence to warrant a trial. Siemens will still have to prove the claim at trial. In fact, all of the other rulings in the case have also revolved around summary judgment. Thus after protracted litigation and lord knows how many hundreds of thousands of dollars in legal fees, the companies have yet to reach the merits and, barring a settlement, are now looking at a huge and very risky trial [*Quidel Corp. v. Siemens Med. Sols. USA, Inc.*, 2020 U.S. Dist. LEXIS 63405]. For more about the case and labs' general liability risks for deceptive advertising, see [Lab Compliance Advisor \(LCA\), Nov. 28, 2019](#).

Colorado MDs Pay \$55K for Taking Specimen Processing Fee Kickbacks from HDL and Singulex

Case: Two physicians and their family medical practice have agreed to fork over \$54,982 to the OIG to settle claims of soliciting and accepting illegal

remuneration from lab companies Health Diagnostic Laboratory, Inc. (HDL) and Singulex, Inc., in the form of processing and handling fees for blood samples. Collecting patient blood samples for testing is generally something physicians are expected to do and thus built into the test payment rate; so, charging extra crosses the line into illegal remuneration.

Significance: HDL and Singulex, Inc. were accused by a whistleblower of paying physicians processing fees of \$10 to \$17 per test exchange for orders of medically unnecessary blood tests, which were subsequently billed to Medicare and TRICARE. In April 2015, the case settled with HDL agreeing to pay \$47 million and Singulex \$1.5 million. The Colorado settlement is the most recent settlement involving downstream physicians who accepted processing fees from HDL and Singulex. 



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■ Managing Lab Staff: Do Lab Employees Who Fear COVID-19 Infection Have the Right to Refuse Work?, From Page 1

against any employee” for raising a health and safety complaint or exercising any right under the Act. Potential penalties for “discrimination” include reinstatement, back pay and fines.

The regulations implementing Section 11 send conflicting messages. On the one hand, they say that employees aren’t allowed “to walk off the job because of potential unsafe conditions at the workplace.” But in the very next paragraph, they say that employees can’t be disciplined for not performing tasks or subjecting themselves “to serious injury or death arising from a hazardous condition at the workplace.” Specifically, a refusal is allowed under four conditions:

1. The employee, with no reasonable alternative, refuses in good faith to expose himself to the dangerous condition;
2. A reasonable person would conclude that there’s real danger of death or serious injury;
3. Due to the urgency of the situation, there isn’t enough time to eliminate the danger “through resort to regular statutory channels,” e.g., calling an OSHA inspector; and
4. The employee “seeks from the employer, and is unable to obtain, a correction of the dangerous condition.”

And in a 1980 case called *Whirlpool Corp. v. Marshall* involving two employees’ refusal to perform maintenance tasks that led to the death of their co-worker under the same conditions, the US Supreme Court upheld the regulation as reasonable and consistent with the purposes of the Act. The Court went on to find that the employer committed “discrimination” by placing reprimands in the workers’ employment files.

How to Handle a COVID-19 Work Refusal

Under what conditions would the fear of contracting COVID-19 at work satisfy the refusal criteria set out in the Regulation? Unfortunately, there’s never been a court case addressing the issue of whether an infectious illness can be grounds for a work refusal. But here’s what we can tell you based on the caselaw that does exist, as well as the OSHA refusal guidelines in the event any of your lab employees engage in a work refusal.

1. Employees Must Show Up to Work to Initiate a Refusal

It’s not just the basis of the refusal but also how the employee initiates it that determines its validity. During the pandemic, there have been reports of employees refusing to come to work due to fears of COVID-19 infection. Phoning in a refusal is beyond what OSHA guidelines list as the steps employees should take to initiate a work refusal:

- ▶ Ask their employer to correct the hazard or assign them to other work;
- ▶ Tell the employer they won’t perform the work unless and until the hazard is corrected; and
- ▶ Remain at the worksite until ordered to leave by their employer.

The clear understanding from the guidelines is that the employee must show up

for work and refuse in person. **Result:** Lab employees who won't report for duty due to infection fears don't have a valid work refusal and are subject to discipline.

2. Beware of Kneejerk Discipline

Lab managers also need to prepare for COVID-19 refusals. Specifically, supervisors need to understand that there is such a thing as a refusal right and that dispensing discipline on the spot without hearing out the employees' health and safety concerns may be illegal discrimination.

3. Investigate the Refusal

Instruct supervisors to investigate the situation and determine whether the danger prompting the employee's COVID-19 refusal is one that a reasonable person would see as constituting a real danger to health and safety. Fear of COVID-19 infection is likely to be found reasonable where:

- ▶ There's a known or confirmed case of COVID-19 in the workplace;
- ▶ The lab isn't following the required CDC and other public health guidelines with regard to social distancing, personal protective equipment, handwashing and hygiene and/or cleaning and disinfection; and/or
- ▶ The employee is over age 65 or has other medical conditions rendering him particularly susceptible to COVID-19.

By contrast, COVID-19 fear is likely not "reasonable" where an employee's infection risks are basically no different from those of any person that chooses to leave the home and go out into public during the pandemic. In other words, the mere fact that people who come to work are more likely to contract COVID-19 than people who stay home isn't enough.

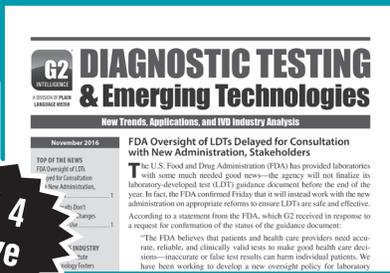
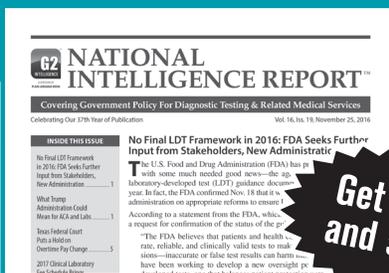
4. Take Corrective Actions

If supervisors conclude that there is a real danger, tell them to consider whether there are any immediate actions that can be taken to correct the problem and allay the employee's concerns, e.g., disinfecting a piece of equipment recently used by a worker who tested positive for COVID-19. 



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