

Return-to-Work Town Hall Series: Webinar 4

Testing Considerations & Other Legal Concerns



Mid-America
Coalition
on Health Care

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Mid-America
Coalition
on Health Care

2020 COVID-19 Webinar Series 4

Return-to-Work Town Hall

Testing Considerations & Other Legal Concerns

Troy Ross

President & CEO

Mid-America Coalition on Health Care



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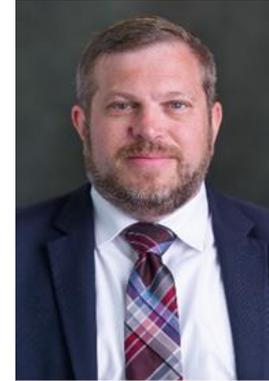


Collaborating for Value





Joseph Bogan, Ph.D.
**Director, Global Health
Surveillance & Diagnostics**



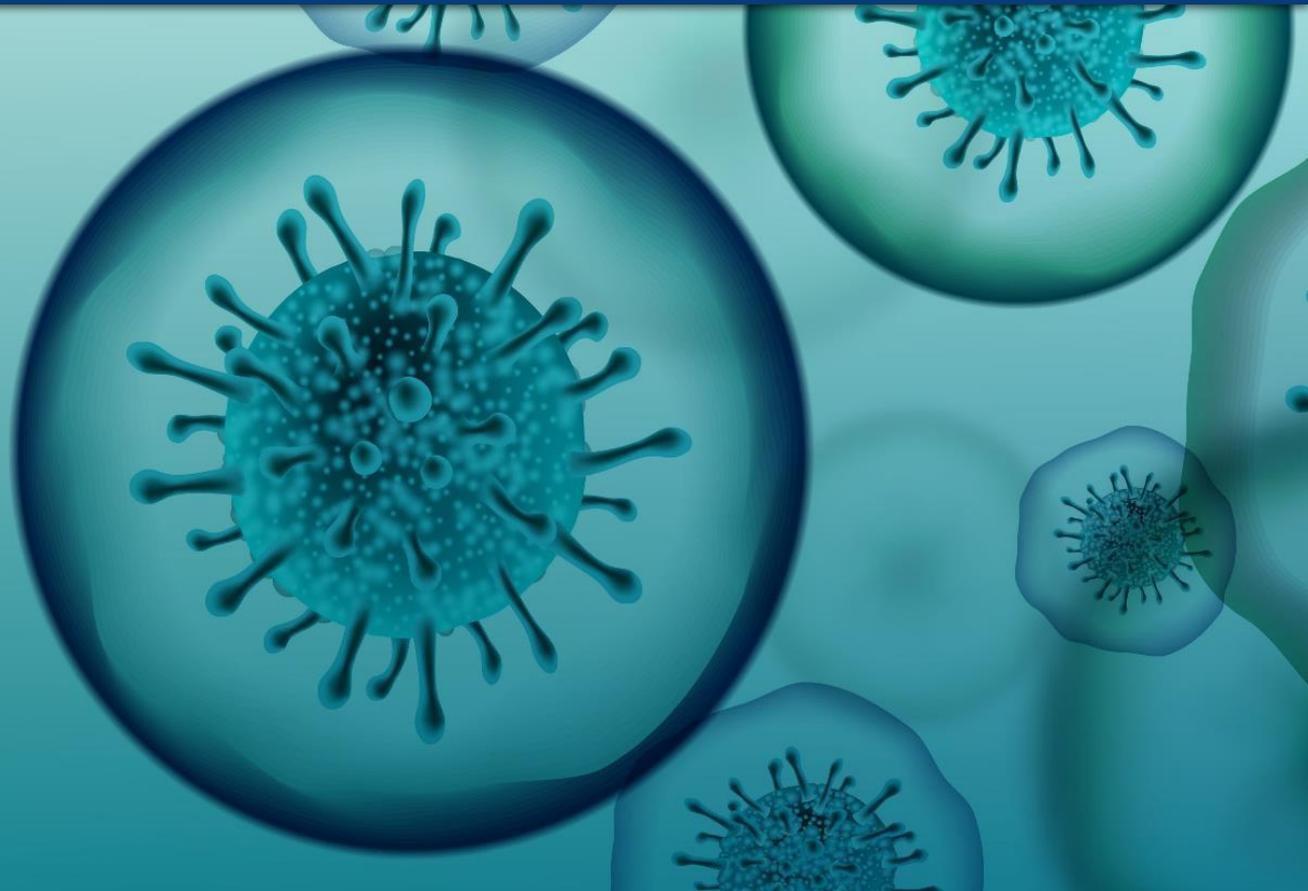
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Diagnostics***



COVID-19 Diagnostics Explained

Joseph Bogan Jr., Ph.D.
Gene Olinger, Jr., Ph.D

May 28, 2020

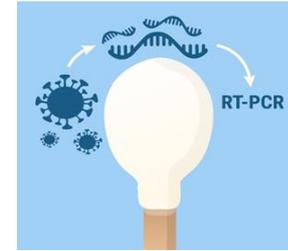


COVID-19 Diagnostics

Three Primary Types of COVID-19 Tests

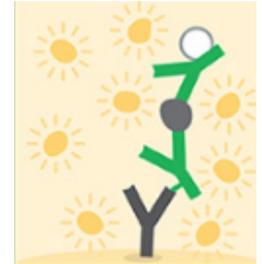
Molecular Tests

- Directly detect the COVID-19 causing virus SARS-Cov-2
- Detection is through the presence/absence of SARS-CoV-2 RNA
- Viral RNA is detected through RNA amplification (primarily RT-PCR)



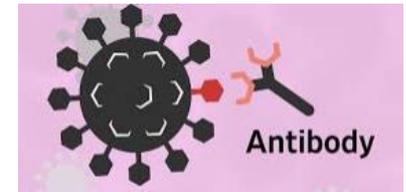
Serology/Antibody Tests

- Detect viral exposure and immunity
- Detection is through presence/absence of human IgM, IgA (exposure) and IgG (immunity)
- Human antibodies are detected with Rapid Diagnostic Tests (RDTs) or ELISAs



Antigen Tests

- Directly detect the COVID-19 causing virus SARS-Cov-2
- Detection is through the presence/absence of SARS-CoV-2 nucleocapsid protein
- Viral protein is detected with lateral flow immunofluorescent assays



COVID-19 Diagnostics

Types of COVID-19 Tests, Potential Uses and Benefits

Type of Test	Measure	Value	Beneficiary
 Nucleic acid amplification test for viral RNA <i>(nasopharyngeal swab, oropharyngeal swab, sputum, bronchoalveolar lavage fluid, others)</i>	Current infection with SARS-CoV-2	<ul style="list-style-type: none">• Inform individual of infection status so they can anticipate course of illness and take action to prevent transmission• Inform patient management and actions needed to prevent transmission• Inform actions needed to prevent transmission	<ul style="list-style-type: none">• Individual• Healthcare or long-term care facility• Public health
 Antibody detection	Past exposure to SARS-CoV-2	<ul style="list-style-type: none">• Detect susceptible individuals (antibody negative) and those previously infected• Identify individuals with neutralizing antibodies• Facilitate contact tracing and surveillance	<ul style="list-style-type: none">• Identify those potentially immune to SARS-CoV-2 (if tests can detect protective immunity, individuals could be returned to work)• Healthcare facilities: Experimental therapy• Public health

COVID-19 Diagnostics

Challenges

Identification of the most appropriate sample type

- What is the best sample type for the respective disease;
- Whole blood, serum, urine, stool, saliva, swabs, etc.

Determining the most appropriate time to collect samples

- What is the earliest time post-exposure that the biomarker is expressed and detectable?
- When is the earliest time post-exposure that the agent is present at detectable levels

Are the biomarkers or agent targets specific to a single disease agent?

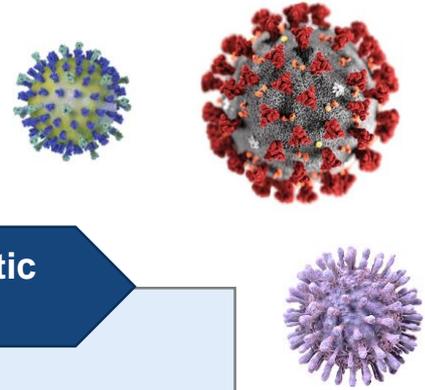
How many biomarkers or agent targets are required to make a definitive diagnosis?

Does the biomarker or agent targets only persists while the condition persists.



COVID-19 Diagnostics

Diagnostic Approaches



Pre-Symptomatic Diagnostics

Diagnostic Target:

Host Biomarkers (Antibodies, RNA, cytokines, etc.)
Agent Antigen (Protein, DNA, RNA)

Provide promise for early detection of exposure, before signs and symptoms of disease

Employed for surveillance of at-risk/high risk populations

Diseases that have asymptomatic incubation periods during which the disease is transmissible.

Diseases that result in increased mortality rate after onset of symptoms.



Post-Symptomatic Diagnostics

Diagnostic Target:

Host Biomarkers (Antibodies, RNA, cytokines, etc.)
Agent Antigen (Protein, DNA, RNA)

Provide promise for early detection of disease, after signs and symptoms of disease.

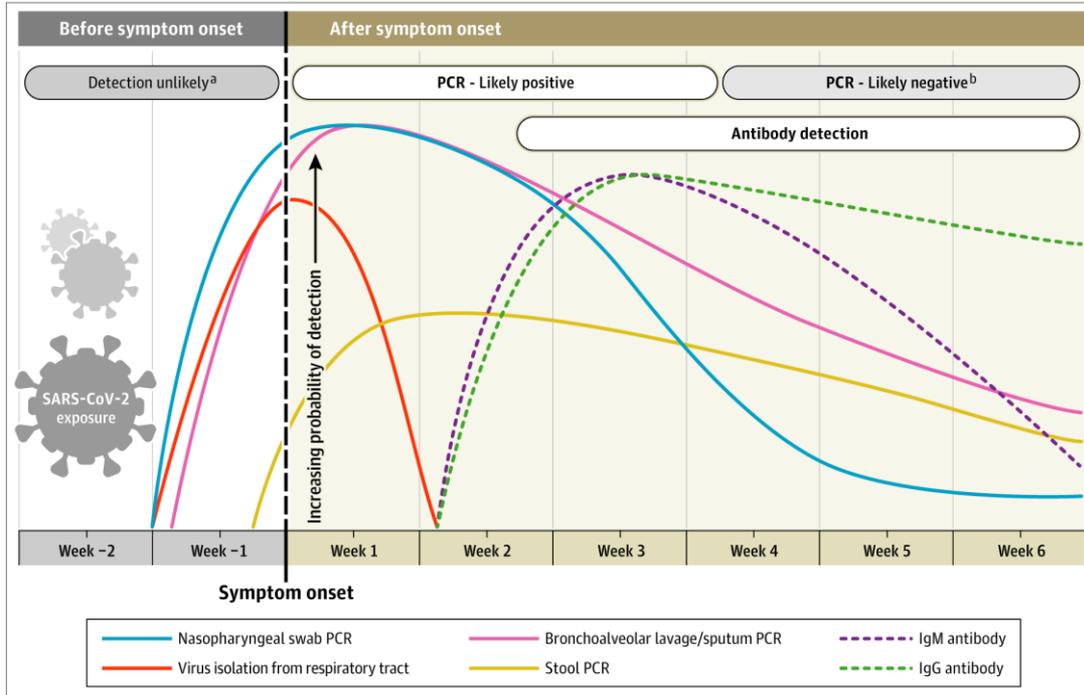
Employed for screening of symptomatic populations.

Differential diagnosis of diseases with “flu-like” symptoms that can be attributed to a number of infectious diseases.

Molecular based tests that target the infectious disease agent can be developed rapidly.

COVID-19 Diagnostics

Diagnostic Stages



The Critical Role of Laboratory Medicine in COVID-19
(Modified from: Lippi et al, PMID: 32191623)

COVID-19 Diagnostics

Emergency Use Authorized Tests



Search

Menu

← Home / Medical Devices / Medical Device Safety / Emergency Situations (Medical Devices) / Emergency Use Authorizations

In Vitro Diagnostics EUAs

On the basis of the February 4, 2020 HHS EUA determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus (2019-nCoV) subject to the terms of any authorization issued under section 564(a) of the Act.

On February 29, 2020, the FDA issued [an immediately in effect guidance](#) with policy specific to this public health emergency. This guidance was updated on March 16, 2020, May 4, 2020, and May 11, 2020.

Test Kit Manufacturers and Commercial Laboratories Table:

Search: Show entries

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s) ¹	Authorization Documents ²	Other Documents/
05/22/2020	dba SpectronRx	Hymen SARS-CoV-2 Test Kit	Molecular	H	HCP, Patients, IFU	None
05/21/2020	BioCore Co., Ltd.	BioCore 2019-nCoV Real Time PCR Kit	Molecular	H	HCP, Patients, IFU	None
05/21/2020	SolGent Co., Ltd.	DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit	Molecular	H	HCP, Patients, IFU	None
05/21/2020	Seasun Biomaterials, Inc.	AQ-TOP COVID-19 Rapid Detection Kit	Molecular	H	HCP, Patients, IFU	None

Current EUA Approved COVID-19 Tests include:

- 67 Molecular Tests (64 are CLIA Highly or Moderately Complex Tests; 3 CLIA Waived Tests)
- 1 Antigen Test (CLIA Waived Test)
- 12 Serology Tests (All CLIA High or Moderately Complex Tests)

COVID-19 Diagnostics

Emergency Use Authorized Tests

Appendix A Table¹:

Search: Show 100 entries

Date EUA Issued	Laboratory	Letter Granting Inclusion under EUA	EUA Summary	Other Documents
05/22/2020	Exact Sciences Laboratories	Exact Sciences SARS-CoV-2 (N gene detection) Test	EUA Summary	None
05/22/2020	Express Gene LLC (dba Molecular Diagnostics Laboratory)	Express Gene 2019-nCoV RT-PCR Diagnostic Panel	EUA Summary	None
05/22/2020	Avera Institute for Human Genetics	Avera Institute for Human Genetics SARS-CoV-2 Assay	EUA Summary	None
05/18/2020	Color Genomics, Inc.	Color SARS CoV-2 Diagnostic Assay	EUA Summary	None
05/13/2020	One Health Laboratories, LLC	SARS-CoV-2 Real-Time RT-PCR-Test	EUA Summary	None

High Complexity Molecular-Based Laboratory Developed Tests:

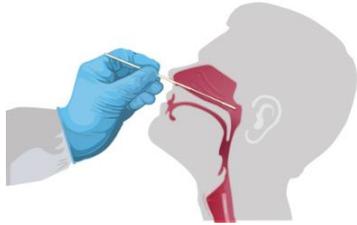
On March 31, 2020, the FDA concluded based on the totality of scientific evidence available that molecular-based laboratory developed tests (LDTs) that are authorized for use by the singular developing laboratory are appropriate to protect the public health or safety (as described under the Scope of Authorization (Section II)) under section 564 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360bbb-3). Under this EUA, authorized tests are authorized for use in the single laboratory that developed the authorized test and that is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a to perform high complexity tests.

Current LDT Approved COVID-19 Tests include:

- 32 Molecular Tests/Laboratories (All High Complexity Tests performed in approved CLIA Labs)

COVID-19 Diagnostics

Diagnostic Test Components and Options



Specimen Collection

- Nasopharyngeal (NP) swab
- Oropharyngeal (OP) swab
- Nasal mid-turbinate swab
- Anterior nares swab
- Nasopharyngeal wash
- Nasal wash/aspirate



Specimen Transport

- Sterile transport tube containing 2-3 mL of either:
- Viral transport medium (VTM),
 - Amies transport medium
 - Sterile saline



Specimen Analysis

- RT-PCR (Viral RNA)
- Serology (Human IgA, IgM and IgG)
- Antigen (Viral Protein)

- *The objectives of the COVID-19 testing drive the selection of testing option(s)*
- *Selection of testing options ultimately involves a series of potential trade-offs*
- *Trade-offs decisions are based on available resources, population, funding, etc.*

Is a COVID-19 Diagnostic Test Required?

Does it matter which sample types or sample transport media is used?

Do all Molecular Tests perform equally well?

What are the challenges and limitations of Molecular Tests?

Questions?

What is the risk of a false positive or false negative result?

What are the challenges and limitations of Antigen Tests?

What are the challenges and limitations of Serology Tests?

Do all Serology Tests perform equally well?

Which tests should be used; Molecular, Antigen, Serology?

How frequently should testing be conducted?





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Return to Work Implications of Coronavirus

Mid-America Coalition on Health Care

Brian M. Johnston

May 28, 2020

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Disclaimer

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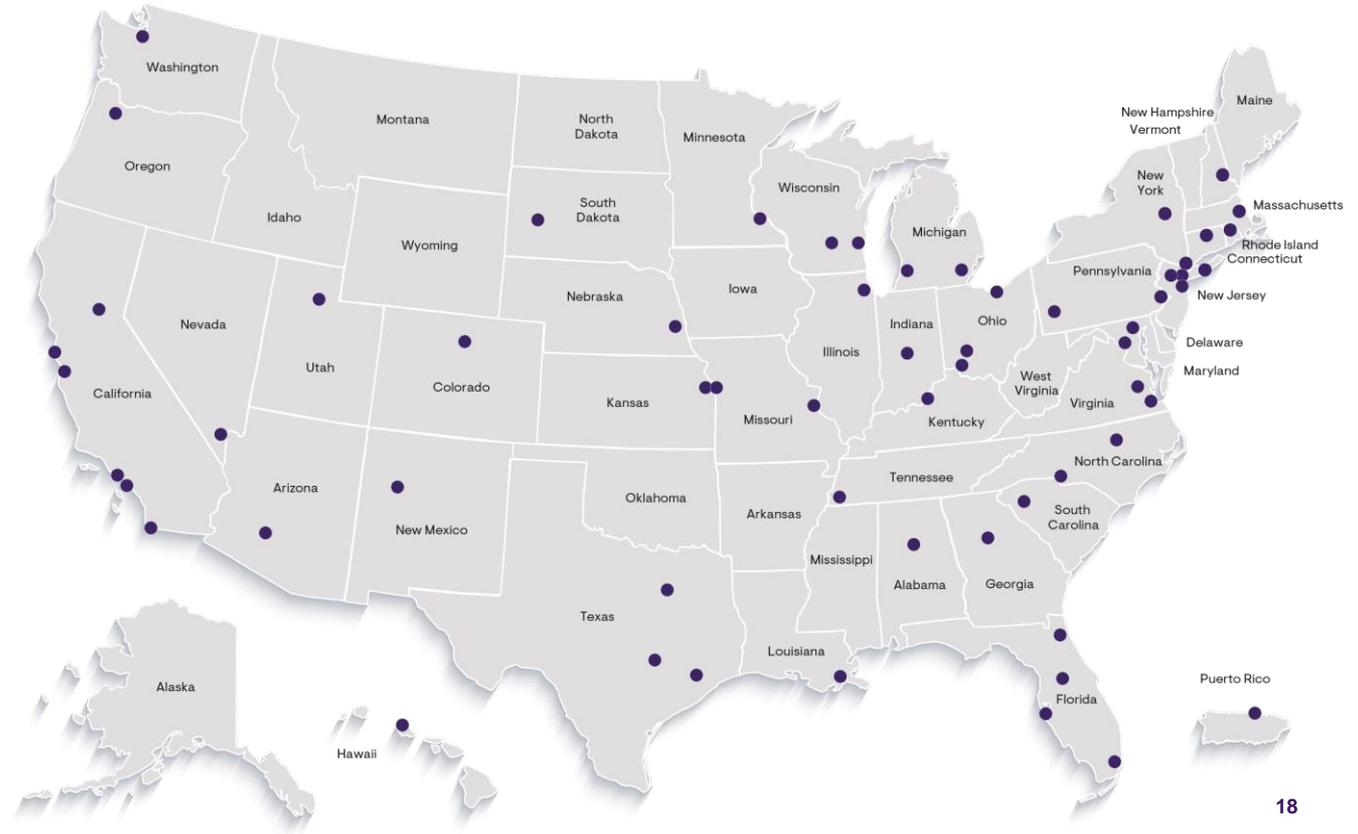
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Agenda

- 1. Agency Updates**
- 2. Litigation Trajectory**
- 3. Developing a Plan**
- 4. Anticipating your Return-to-Work Questions**
- 5. Preparing for a Second Wave**

Agency Updates

Agency Updates

EEOC Publications To Review

- Pandemic Preparedness In The Workplace And The Americans With Disabilities Act
 - Originally issued in 2009 during the spread of H1N1
 - Updated to address COVID-19
 - https://www.eeoc.gov/facts/pandemic_flu.html
- What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws
 - Technical assistance questions and answers
 - https://www.eeoc.gov/eeoc/newsroom/wysk/wysk_ada_rehabilitaion_act_coronavirus.cfm

Agency Updates

Notable EEOC Guidance

- COVID-19 meets the ADA “direct threat” standard
- Disability-related inquires and medical exams
 - May require employees to wear masks in the workplace
 - May ask employees calling in sick if they are experiencing COVID-19 symptoms
 - Can measure body temperature and administer COVID-19 testing
 - Can follow CDC/public health advice when permitting employee’s return to work
- Accommodations
 - The interactive process can be more fluid to suit changing circumstances
 - Sudden loss of an employer’s income stream is relevant consideration in whether a requested accommodation poses a significant expense

Agency Updates

Department of Labor: Families First Coronavirus Response Act

- Applies to employers with 500 or fewer employees
- Leaves taken April 1, 2020 through December 31, 2020
- Two Types Of Leave:
 - Emergency Paid Sick Leave (2 weeks)
 - Expanded Family and Medical Leave (12 weeks)

<https://www.dol.gov/agencies/whd/pandemic/ffcra-questions>

	Reason for Leave	How to Pay	Length
Expanded FMLA	<p>Caring for child and unable to work or telecommute (#5)</p> <p>(Must be employed 30 days)</p>	<p>Weeks 1-2: Unpaid. Can use PTO, other leave, or emergency sick time</p> <p>Weeks 3-12: 66.67% of pay*</p> <p>Daily Max: \$200 Total Cap: \$10,000</p>	12 weeks at 40 hrs/wk (FT), or hours normally scheduled (PT)
Emergency Paid Sick Leave (Employee)	<ul style="list-style-type: none"> In quarantine (#1-2) Experiencing symptoms & seeking diagnosis (#3) 	<p>100% of pay*</p> <p>Daily Max: \$511 Total Cap: \$5,110</p>	80 hours/2 Weeks
Emergency Paid Sick Leave (Family Member)	<ul style="list-style-type: none"> Caring for someone in quarantine (#4) Caring for own child (#5) Other similar condition (#6) 	<p>66.67% of pay*</p> <p>Daily Max: \$200 Total Cap: \$2,000</p>	PT based on avg. hours in 2 week period; if varies, use 6 month avg.

*Or minimum wage, if greater

Litigation Trajectory

Whistleblower Retaliation

- *Bryant v. Gray Construction*, 20-18587 (Multnomah Cnty, OR, May 20): Employee was temperature-taker at construction site, terminated after she reported employer was manipulating temperature readings to allow employees with fevers to return to work
- *Reggio v. Tekin & Assoc.*, 20-986-B (Dallas Cnty, TX, April 23): GC fired after refusing to violate shelter-in-place orders
- *Milanes v. Alaris Health*, 1582-20 (Hudson Cnty, NJ, April 22): Employee fired after complaining about failure to test
- *Manning v. Little Rock*, 20-2727 (Pulaski Cnty, AR, April 22): Employee fired for reporting co-worker's violation of city's travel policy

Discrimination & Retaliation

- *Kanyuk v. Shearman & Sterling*, 20-3567 (S.D.N.Y. May 7): 62 year old was first employee selected for layoff
- *Gasper v. Mack Industries*, 20-359 (Medina Cnty, OH, May 20): Older employees terminated under pretext of COVID-19, later replaced by younger, less-qualified employees
- *Racioppi v. Bosov*, 20-3797 (C.D. Ca. April 24): Purported reason for terminations was economic impact of COVID-19 when it really was a sordid tale of corporate mismanagement, subterfuge, and fraud

Refusing To Work/Unsafe Conditions

- *Lange v. PBS*, 2005-CT-95 (Elkhart Cnty, IN, May 1): Employee terminated after stating she intended to work from home due to COVID-19 concerns
- *Korloff v. Barclay Water*, 1399-20 (Monmouth Cnty, NJ, May 4): Employee terminated after choosing to self-isolate because of COVID-19 symptoms
- *Doe v. Hillstone Rest. Group*, 20-6494 (Dallas Cnty, TX, May 7): Restaurant employer threatened to terminate employee if she wore a face mask

Other Disability/ADA

- *Link v. Disciplined Growth Investors*, 20-6781 (Hennepin Cnty, MN, May 7): After returning from medical leave, employee demoted and mocked due to hesitancy to meet in person due to pandemic
- *Frunzi v. MEI Group*, 141-316580-20 (Tarrant Cnty, TX, April 22): Employee with lung issues fired after seeking accommodations
- *Wells v. Enterprising Leasing*, 200004595 (Norfolk Cnty, VA, May 11): Wrongful termination and HIPAA violation by demanding employee provide medical testing for himself and family members, then fired for non-compliance

FMLA/FFCRA

- *Robtoy v. Kroger Co.*, 20-173 (N.D. Ind. April 28): Employee terminated after taking FMLA
- *Lewin v. San Francisco Travel Ass'n*, 20-584296 (San Francisco Cnty, CA, April 27): VP laid off after asking for three-month leave to care for her sick mother
- *Benavides v. Univ. of Mich.*, 20-392 (Washtenaw Cnty, MI, April 21): Employee fired when she missed time due to illness and waited for test results

Contract Breaches & Non-Competes

- *Kraemer v. Golding Radiology*, 20-794 (Washoe Cnty, NV, May 20): Employer improperly characterized termination as “for cause” to avoid paying severance although termination coincides with drop in work during pandemic
- *Turnage et al v. Coastal Anesthesiology*, 2020-511 (St. Johns Cnty, FL, May 6): Doctors were not paid 2019 bonuses and told their PTO would be cut by 20% due to crisis
- *Haz Mat Special Servs v. Cleaning Guys*, 20-25532 (Harris Cnty, TX, April 23): Declaratory judgment to invalidate non-compete so plaintiff can hire more specialized workers

Wage & Hour, Pay Issues

- Failure to pay wages or benefits upon termination
 - *Mabry v. Tex. S. Op. Co.*, 2020-25552 (Harris Cnty, TX, April 23): Contract claim for failure to pay wages after layoff
 - *Ferrante v. Ratner Cos.*, 20007011 (Broward Cnty, FL, April 24): Hairdressers did not receive wages accrued during a pay period cut short when employer closed operations
- Pay rate/Misclassification during job changes
 - *Bates v. Reg'l Med. Group*, 20-2052 (N.D. Ga. May 13): Employer violated minimum wage provisions by failing to provide 2 weeks paid leave when employee needed to care for son whose school was closed
- Off-the-clock work performed at home
- Failure to comply with wage notification requirements

Torts & More

- Defamation
 - *Knapp v. Wei*, 200400373 (Philadelphia Cnty, PA, Apr. 9, 2020): Defendant falsely claimed plaintiff coughed in his face in violation of social distancing and with discriminatory intent
- Negligence/Failure to Provide a Safe Workplace
 - *Smith v. Corecivic*, 20-808 (S.D. Ca. Apr. 29, 2020): Employer failed to provide safe environment, including lack of PPE, sanitizer dispensers, and directions on how to practice social distancing in the facility
- Workers' Compensation
 - *Long v. Baptist Healthcare*, 20-206 (Whitley Cnty, KY, May 4): Pregnant employee terminated after pursuing workers' compensation claim after she felt she was exposed to COVID-19 and decided to self-quarantine

Labor

- Over 100 walk outs or strikes
- Unions are helping non-union workers stage actions and educating them on their right to protest unsafe conditions and demand protections under NLRA
 - Teamsters launch Solidary is Essential, “a comprehensive online resource guide for non-union workers to take action and fight for safer working conditions”
 - Communications Workers of America released resources for nonunion workers, including a template for demanding protections and in-depth guide to their NLRA right to take action

Develop a Plan

Develop a Plan

- 1. If you haven't already, establish a COVID-19 Task Force.**
- 2. Review OSHA's Guidance on Preparing the Workplace.**
<https://www.osha.gov/Publications/OSHA3990.pdf>
- 3. Review EEOC's Guidance on Testing in the Workplace.**
 - Who will be tested?
 - Who will conduct the testing?
 - What protocols are needed to protect the disclosure of health information?
 - How will employees be compensated for their time?
 - How will the Company respond to employees who refuse testing?

Develop a Plan

4. Identify Locations and Employees Who Will Be Returned.

- Expect high variability and uncertainty with respect to each jurisdiction's approach to “re-opening” (federal, state, and local).
- Establish a proper date for return.
- Consider giving written notice even if not legally required.
- Be aware of the potential risks associated with employee selection.

Develop a Plan

SAMPLE WRITTEN NOTICE

As we hoped in sending you a notice of furlough back on____, (the Company) is thrilled to be able to invite you to resume working with us.

Your return is scheduled to begin on [DATE] working in the _____ department with your prior regular schedule/at a reduced work schedule of _____ to _____ on the following days. Your rate of pay shall be ____ and if your return as scheduled, you will receive your first paycheck on _____.

According to our records, you will resume work with _____ hours of PTO in your bank and will begin to accrue additional hours consistent with our policies upon your return. (modify if reduced schedule).

Letting us know of your return: Please reach out to us immediately to confirm your return to work. You should call _____ at _____ or via email at _____. If we do not hear from you by _____, we will assume you are not interested in remaining with the Company and we will convert your furlough status to one of voluntary separation.

**Implement Policies &
Practices to Address New
COVID-19 Operating
Realities.**

Implement Policies & Practices to Address New COVID-19 Operating Realities

- Off-Duty Activities.
- Off-Site Work Activities.
- Fitness for Duty.
- Modified Work Practices to Enhance Social Distancing.
- Personal Protective Equipment (PPE).
- Infection Control.
- Reasonable Accommodation.
- Statutory/Policy Leave Obligations



**Anticipate Responses to
COVID-19 Related
Scenarios Upon Employees'
Return to Work.**

Anticipate Responses to COVID-19 Related Scenarios Upon Employees' Return to Work

Consider Preparing A List of FAQs for HR and Lead Management Team to address a list of “What if?” scenarios including:

- What if an employee's health, contacts or behaviors raise safety concerns?
- What if an employee continues to request leave to care for dependent minors even after the school year is over?
- What if an employee requests leave because they live with an individual in a vulnerable population?
- What if an employee is capable but unwilling to work from home in compliance with the Company's social distancing policy?
- What if an employee is incapable of working from home but also unwilling to be physically present at work due to COVID-19 related concerns?

Anticipate Responses to COVID-19 Related Scenarios Upon Employees' Return to Work (continued)

- What if employees are asked to report to work but prefer to and are capable of working from home due to COVID-19 related concerns or other reasons?
- What if employees share rumors or concerns of employees or customers being sick?
- What if employees request information about another employee's health condition?
- What if employees engage in collective or other protected activity to raise concerns about the return to work or workplace?
- What if non-exempt employees are emailing and/or working outside normal business hours?
- What if an employee comments on social media that the workplace is unsafe?

Anticipate Responses to COVID-19 Related Scenarios Upon Employees' Return to Work (continued)

- What if an employee regularly violates social distancing requirements?
- What if an employee openly discusses travel to attend large group gatherings?
- How will we respond if an employee suspects COVID-19 and is showing symptoms?
- How will we respond if an employee is diagnosed with COVID-19?
- What if a vendor shows symptoms of COVID-19 (i.e. coughing, heavy breathing, reporting “doesn’t feel well)?)
- What vendors do we need to alert if there is an employee diagnosed with COVID-19?

**Begin Preparing NOW for a
Second Wave of
COVID-19 Infections
(Pandemic Planning).**

Begin Preparing NOW for a Second Wave of COVID-19 Infections (Pandemic Planning)

- Develop “lessons learned” from first COVID-19 closures. Consider surveying managers and/or front-line employees.
- Review technology to enhance and improve remote work capabilities, including privacy and security issues.
- Cross-train employees.
- Expand, develop or leverage geographically diverse work populations and suppliers.
- Expand products or service offerings that do not require customer on-site presence.
- Procure appropriate sources of PPE.

Begin Preparing NOW for a Second Wave of COVID-19 Infections (Pandemic Planning) (continued)

- Explore additional or different insurance to support business interruption and employee wage protections.
- Consider strategies for potential furloughs, closings, or reductions in force.
- Revise budgets including forecast for revenue and expenses.
- Revisit wellness and health offerings to respond to employee physical, mental and emotional health needs.
- Determine temporary practices to implement regarding travel restrictions, more aggressive social distancing practices, sanitation, other efforts to minimize exposure/spread.

**Special Focus:
Managing Continued
Requests to Work Remotely**

Remote Work Policy Checklist

- Determine under what circumstances remote work will be permitted or required.
- Identify which positions are/are not conducive to working from home.
- Identify the equipment necessary for employees to work from home.
- Develop and implement a remote work policy or agreement.
- Address timekeeping procedures for nonexempt employees if these will differ for teleworkers and address expectations for authorized overtime work.
- Develop an information security policy for remote workers.

Reimbursements

- **What does the Company have to reimburse if the Company implements a mandatory work from home arrangement?**
 - This is a state-specific inquiry.
 - For example, the general rule in California is that an employer is required to indemnify an employee for necessary expenditures incurred on the employer's behalf (Labor Code section 2802). For a remote worker this may include telephone and internet service.
- **What is “reasonable reimbursement” for phone/internet charges?**
 - Again, this depends on the state.
 - In California, no definitive answer. Recommend providing a flat rate (stipend), but also allow for employees to request more if actual costs exceed the flat rate amount.

Other Reasonable Accommodation Issues

- If job could be performed from home during COVID-19 crisis, will telecommuting be a *per se* reasonable accommodation moving forward?
- Claims arising from employer's failure to accommodate home worker (ergonomic desks, *etc.*), especially when employee has been adversely affected

Q&A

Stay Up To Date

- Jackson Lewis COVID-19 Webpage and Resource Page:
<https://www.jacksonlewis.com/practice/coronaviruscovid-19>
- [Agencies Publish Guidance for Employers on Responding to the COVID-19 Crisis](#)
- CDC, OSHA, EEOC, DOL, State and Local Government

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Thank **you.**



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