COVID with Alliant

Webinar Series

The Road to Recovery

Clinical, Occupational, and Compliance Issues with Return to Work

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Return to Work
Health, Safety, and Occupational Issues

Returning to Work

Make a Plan

- ❑ Create a Pandemic Task Force
- ❑ Determine Employee Return Plan
- ❑ Assess Facility and Workspace Needs
- ❑ Procure Cleaning and PPE Supplies
- ❑ Establish a Screening and Testing Philosophy
- ❑ Craft a Communication Plan
- ❑ Long term Contingency Plan

Establish Protocols & Procedures

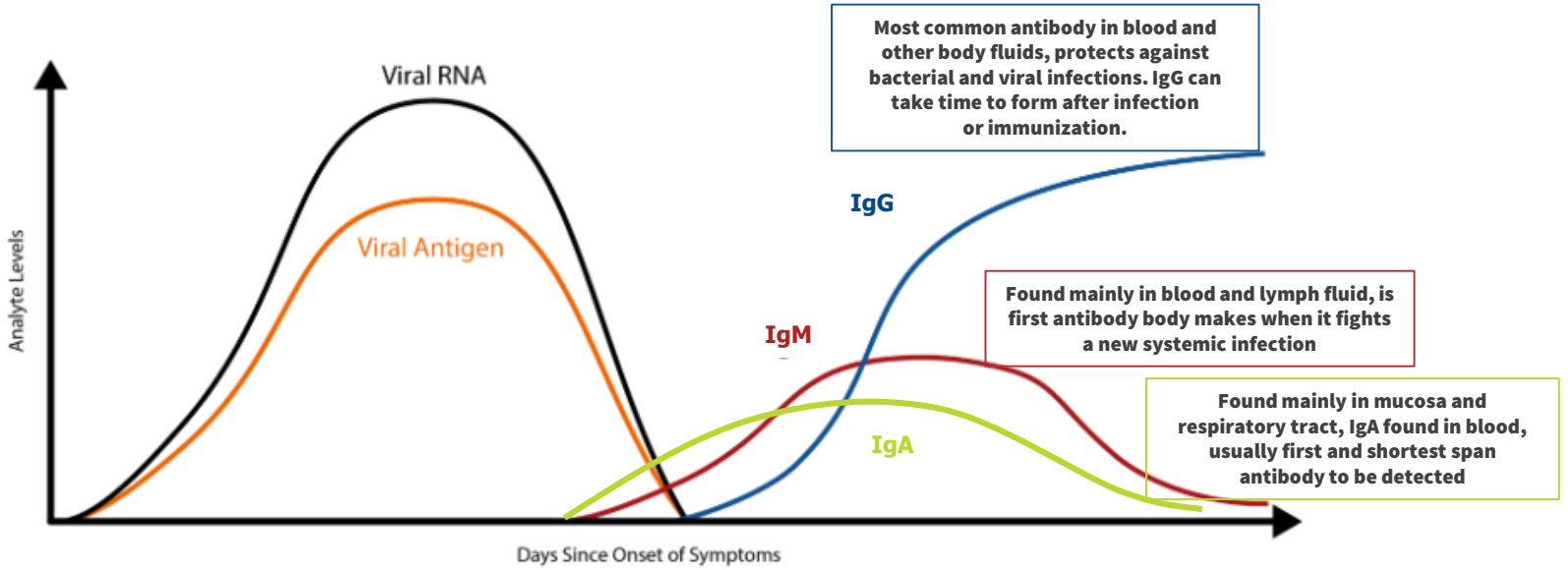
- ❑ Cleaning & Disinfecting
- ❑ PPE
- ❑ Daily Self Screening
- ❑ Onsite/Offsite Screening
- ❑ Temperature Testing
- ❑ Antibody Testing
- ❑ Isolation/Quarantine
- ❑ Social Distancing
- ❑ Reporting

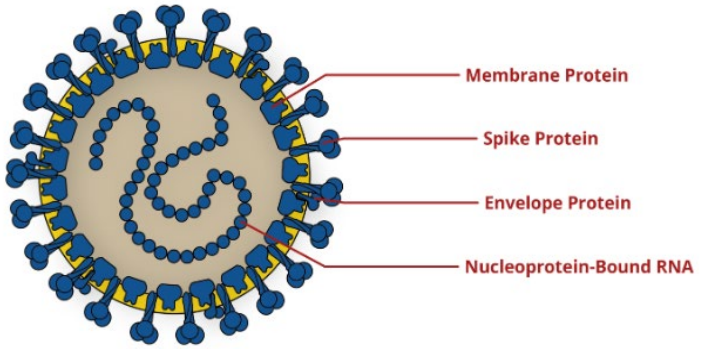
Prepare Employees

- ❑ Communication Plan
- ❑ Signage
- ❑ Leave Policies
- ❑ New Hire Onboarding

- Monitor updates and changes in guidelines and restrictions (CDC, OSHA, WHO, UNESCO)
- Collaborate with local health agencies, landlords and other key partners
- Understand legal and compliance landscape

COVID-19 Diagnostic + Antibody Testing Overview





Current testing/screening focus

- Diagnostic testing (Viral RNA/Antigen detection RT-PCR/RDT)
  - Active virus detection
- Antibody testing (IgM, IgG, IgA)
  - Detection of immune response to infection
    - IgM: Fight and recover antibody
    - IgG: Prevent and protect antibody
    - IgA: Fight and recover antibody (largely respiratory), shortest immunity span

Future focus

Vaccine development focused on Spike proteins; these proteins induce strongest immune response with ability elicit high antibody levels to support sustained immunity (in absence of viral mutation)

Source: The Native Antigen Company. Retrieved from https://thenativeantigencompany.com/why-we-need-antigen-and-antibody-tests-for-covid-19/

COVID-19 Antibody Testing

Testing for COVID-19 Antibodies

Rapid Diagnostic Test (RDT) [Lateral Flow Assay]
Culture (cotton or fingerstick with capillary tube)
Provide positive or negative result
Cannot quantify amount of antibodies present or if they are able to protect against future infection

Serum Enzyme-Linked Immunosorbent Assay (ELISA)
Venipuncture
Detects the presence or absence of IgA, IgG and IgM antibodies
Can't tell if antibodies are able to protect against future infection

Molecular Virus Neutralization Assay (VNT)
Venipuncture
Detects presence or absence of IgG and IgM antibodies
May miss other antibodies to viral proteins not involved in replication

Centers for Disease Control and Prevention. 2020. Real-Time RT-PCR Primer And Probe Information. [online] Available at: https://www.cdc.gov/coronavirus/2019-ncov/lab/rt-pcr-panel-primer-probes.html

Johns' Hopkins University COVID-19 Serology-Based Testing. **Johns Hopkins Center for Health Security. Available at:** https://www.centerforhealthsecurity.org/resources/COVID-19/serology/Serology-based-tests-for-COVID-19.html

Pros and Cons of Various Tests

Rapid diagnostic test (RDT): Quick and relatively inexpensive way to administer antibody test similar to pregnancy tests in that test shows user colored lines to indicate positive or negative results (antibody presence). *Concerns with inconsistent/accuracy of results have been raised.*

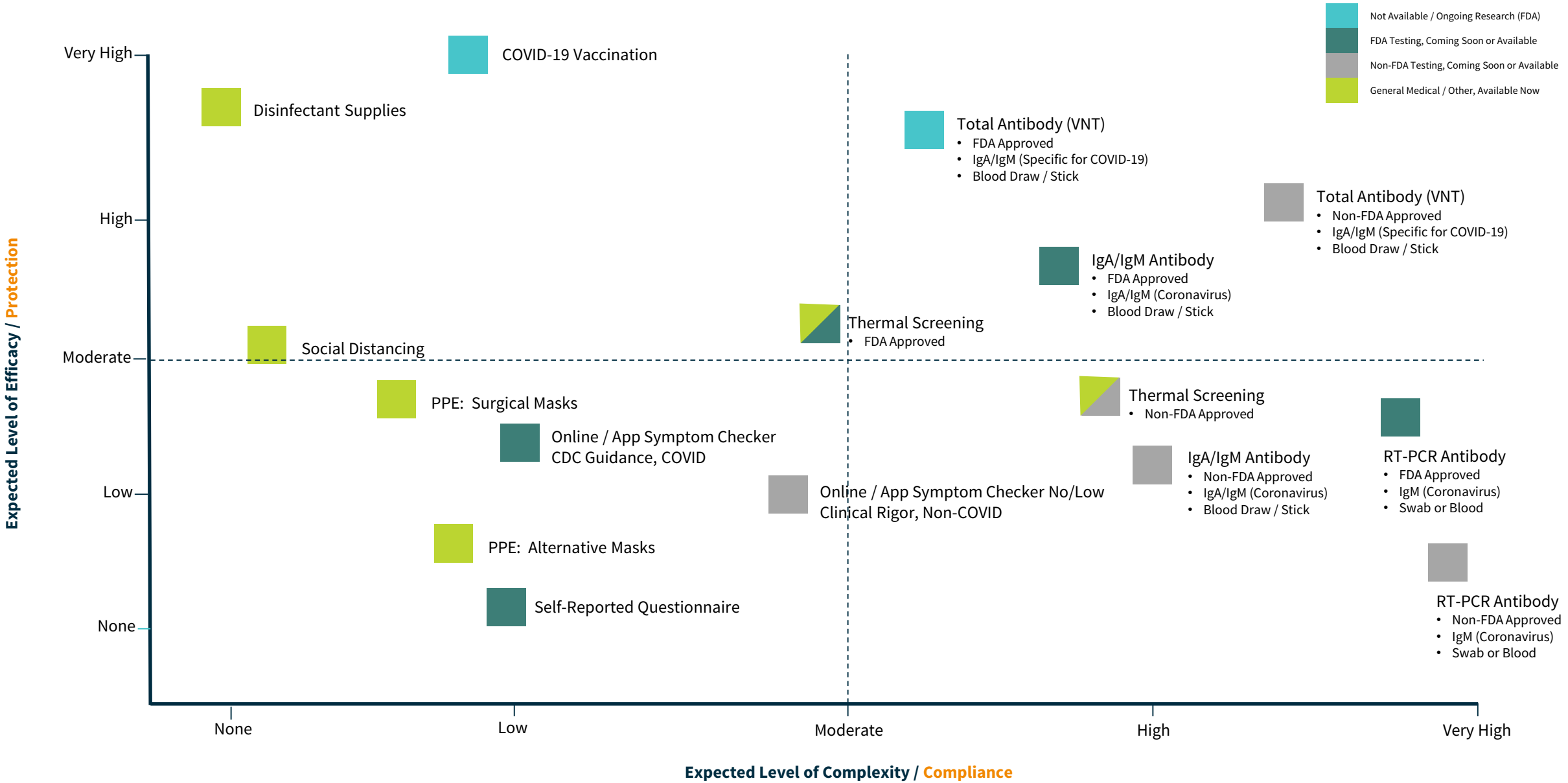
Serum ELISA: Venipuncture test performed in laboratory setting can detect the leading viral antibodies that help determine if an individual is actively infected, had been infected or had been infected and still carries the virus. *Serum assays still target coronavirus family, not only COVID-19.*

Molecular VNT: Venipuncture test requiring whole blood plasma can detect if an individual has antibodies that are active and effective against the virus, even if they have already cleared the infection. *Longevity of any presumed immunity is still unknown due to nature of COVID-19's mode of replication.*

Under Review:

- Mayo Clinic/University of Minnesota release ELISA test for COVID-19; however, types of antibodies are not stated, nor is sensitivity or specificity
- ScanWell Health/INNOVITA's kit is for detection of IgG and IgM for COVID-19 expected between 5/1 – 5/15
- Several RDT and ELISA tests in research in-vitro diagnostic testing phases (IVDs) only
- Lateral flow assay testing (molecular testing) in research in-vitro diagnostic testing phases (IVDs) only

Infection Control Measures – Efficacy vs. Complexity



COVID-19 Rapid Antibody Testing Confusion & Concerns

- As of mid-April, the FDA had not blocked production of rapid antibody testing from manufacturers, but have referenced taking action against companies; as of mid-April, more than 90 companies (many based in China) were able to sell tests within the US that have not received FDA approval/authorization. These companies were only required to validate their results on their own and notify the agency that they have done so.
  - *On April 20th, NIH announced taking lead for review of antibody & diagnostic testing*
- Concerns about quality of tests being sold:
  - Variation in antibody type (which will be confusing to employers as they look to procure tests)
  - False positive and false negative results will occur
  - Rapid tests, while easy to administer are considered unreliable by some organizations (WHO recommends against use)
- Unclear guidelines for use; some healthcare providers are using antibody testing to diagnose disease, though antibody testing is not accurate in early stages of disease.
- FDA has conflicting messages: agency initially released guidance that antibody tests could be performed at Point of Care settings (e.g., in provider office); however, FDA also acknowledges that under federal law, if a test does not have FDA approval/emergency use authorization, it must be conducted in high-complexity laboratories (e.g., commercial and/or public health labs).
- FDA has received requests for emergency-use authorization from over 120 antibody-test developers. **As of May 4th , there are only 11 that have been granted approval; all for use within laboratory settings (not point of care).**

On May 3rd, the FDA authorized an antibody test by Roche with results of 100% sensitivity + 99.8% specificity. This is in comparison to the first test given authorization on April 1st that had results of 93.8% sensitivity + 95.6% specificity.

Sources

https://www.who.int/news-room/commentaries/detail/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19#.Xo_1jdsCuUE.twitter
https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations
https://www.nytimes.com/2020/04/19/us/coronavirus-antibody-tests.html
https://jamanetwork.com/journals/jama/fullarticle/2764954
https://www.fiercebiotech.com/medtech/fda-cdc-nih-to-begin-validating-covid-19-antibody-tests-as-more-enter-market

COVID-19 Testing & Detection: Employer Considerations

Where is Testing Performed?*

- Triage Tents / Makeshift Intake Locations
- Hospitals and Emergency Departments
- Urgent Care Centers
- Drive through testing sites
- Community / Medical Centers (incl. doctor's office)
- Convenience Clinics (i.e., Minute Clinic, etc.)
- At-home kits (1st FDA authorization 4/21/2020; diagnostic test)

Funding for testing has included State & Federal resources; many triage and drive through testing sites have been supported through this funding vs. filing claims, as such, client-specific testing data may be limited.
Note: Federal funding for national and international organizations may influence availability of future resources, including testing, supplies and other healthcare resources.

What questions are Employers asking specific to testing options?

- Should we bring onsite diagnostic COVID testing to our site?
  - There are still access limitations for diagnostic test kits and providers continue to screen for risk/symptoms before collecting specimens. Individuals who would qualify for testing would be symptomatic or have known exposure, and therefore concerns remain about those individuals coming to the workplace. It is also important to remember that there is still a risk of false negative results with diagnostic tests. While the desire for organizations to support asymptomatic screenings is understood, it is not something that is currently available in a fashion that would protect workplaces and align with existing infection protocols. *Compliance Consideration: if diagnostic testing is part of RTW strategy, will need to address compensable time.*
- Are at-home diagnostic test kits available?
  - The FDA authorized LabCorp's Pixel at-home RT-PCR (swab) test collection kit on April 21, 2020; initial roll-out will be to healthcare personnel, with direct to consumer availability in the weeks to follow.
- Should we be considering serology antibody testing as part of a broader return to business strategy?
  - Antibody testing will be strongly considered as part of return to business/work strategies. There are limitations to antibody testing (e.g., some are not specific to COVID-19, false positive/negative results still of concern) and there is no evidence to confirm the length of immunity one has to COVID-19 based on antibody presence. Cost is a concern given likely need to repeat screenings over time. Extensive research is being done across the world to further support recommendations.
- When will broad-based serology screening be available?
  - A Morgan Stanley[+] biotech research report is showing that by mid-June supply will meet demands for more widespread testing; it is important to note that that there are concerns with credibility of test kits that are flooding the market due to limitations in FDA regulations.

*Subject to availability. Testing sites and permission may change based on evolving circumstances, including updated/modified legislative guidelines, supply, outbreak and/or need for redistribution/repurposing of health care resources.
[+]https://www.dcba-pa.org/UserFile/files/events/Biotechnology_%20COVID-19_%20A%20Prescription%20To%20Get%20The%20US%20Back%20To%20Work.pdf
https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-test-patient-home-sample-collection

Alternative vs. Surgical Masks

- Non-FDA regulated
- Homemade or disposable
- May reduce outward viral transmission
- May build up moisture and collect bacteria
- Not healthcare grade or quality for hospital staff
- Not suitable for persons will illness signs/symptoms

- FDA regulated or approved by FDA for use
- Manufacture-grade material to create solid barrier
- Protects against inward/outward viral transmission
- Requires proper donning and care when in use
- Used in healthcare setting for hospital staff
- Suited for all individuals including asymptomatic or the ill

Protection

Availability

Return to Work
Compliance

Our Focus

Three Major Issues

1. Employee testing (everything from temperature checks to COVID-19 testing)
2. Data from testing and data privacy (HIPAA vs. ADA)
3. Employees unwilling to return to work (why and what to do next)

Employee Testing

The EEOC
Background

EEOC enforces workplace anti-discrimination laws, including:

- **The Americans with Disabilities Act** (includes rules on reasonable accommodation and non-discrimination based on disability and rules about employer medical examinations and inquiries)
- **Title VII of the Civil Rights Act** (prohibits discrimination based on race, color, national origin, religion, and sex, including pregnancy)
- **The Age Discrimination in Employment Act** (prohibits discrimination based on age, 40 or older)
- **The Genetic Information Nondiscrimination Act** (prohibits discrimination based on genetic information by group health plans and health insurance issuers (enforced by HHS) and prohibits discrimination based on genetic information by employers)

Employee Testing

The EEOC
Background

- Historically, permissible medical exams and inquiries limited to:
  - A post-offer, pre-employment medical exam
  - A medical exam or inquiry that is job related and consistent with business necessity
  - A direct threat analysis has historically been a litigation defense (an exception for employers who fire or refuse to hire an employee who poses a direct threat)

- Medical Exams include:
  - Temperature Checks
  - COVID-19 Testing
    - Diagnostic Testing
    - Antibody Testing

Employee Testing

The EEOC
A New Landscape in Response to COVID-19

- Temperature Checks
  - Because the CDC and state/local health authorities have acknowledged community spread of COVID-19 and issued attendant precautions, employers may measure employees' body temperature. **Employers should be aware that some people with COVID-19 do not have a fever.**

- COVID-19 Testing
  - Employers may take steps to determine if employees entering workplace have COVID-19 because an individual with the virus will pose a direct threat to the health of others. An employer may choose to administer COVID-19 testing to employees before they enter the workplace to determine **if they have the virus.**
    - **Diagnostic Testing** – Guidance covers diagnostic testing
    - **Antibody Testing** – Logic should extend to less invasive antibody testing.
      - A-symptomatic individuals can pass the virus on.
      - Knowing who has already had it is key, they are less likely to be a-symptomatic carriers
      - With know antibodies, there is limited to no need for diagnostic testing. Employers cannot do a diagnostic test every time/each day employees enter the work place.

Employee Testing

The EEOC
A New Landscape in Response to COVID-19

- Medical inquiries are now more broadly permissible
  - Employers may ask employees if they are experiencing symptoms of COVID-19 on entering the workplace or when calling in sick. Symptoms include fever, chills, cough, shortness of breath, or sore throat. Public health authorities may expand the list of symptoms. Employers should rely on the CDC, other public health authorities, and reputable medical sources for guidance on symptoms.

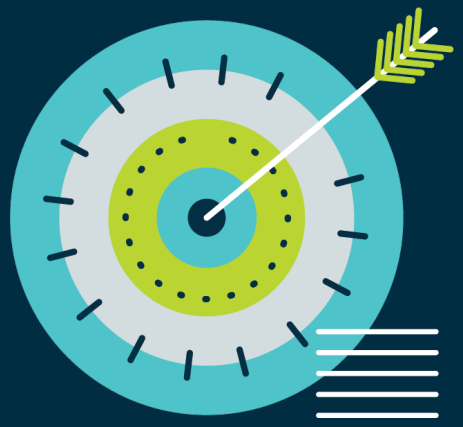
- Fitness for Duty certifications
  - Employers can require a doctor's note certifying fitness for duty on return after illness. Such inquiries are permitted under the ADA either because they would not be disability-related or as justified under the ADA standards for disability-related inquiries.
  - Doctors and healthcare professionals may be too busy during and immediately after the COVID-19 crisis to provide fitness-for-duty documentation.

What's Next in Testing?

The EEOC
A New Landscape in Response to COVID-19

- Flu Shots?
  - This year's Flu season could coincide with increased COVID-19 cases. Similarities between COVID-19 and Flu symptoms potentially create confusion and increase testing demand.
    - Mandating Flu shots unless employees have a medical exception (allergic to the vaccine) would alleviate some COVID-19 testing demand that will increase in the fall.
    - There may not be enough COVID-19 tests to rule out COVID-19 when COVID-19 and Flu coexist in coming months.
  - EEOC would need to act to allow mandatory Flu shots
  - This may encourage employees to get Flu Shots

Data Privacy



HIPAA vs. ADA Data Protection

- HIPAA only applies to Individually Identifiable Health Information created, received or maintained by a group health plan **(Protected Health Information)**.
  - HIPAA DOES NOT APPLY to employment records, including any records maintained by an employer to carry out its obligations under FMLA, ADA, and similar laws, as well as records related to occupational health or injury, disability policy eligibility, sick-leave requests, drug screenings, workplace medical surveillance, and fitness-for-duty tests of employees.
  - HIPAA does not apply to temperature test data or COVID testing data obtained as part of a workplace safety protocol.
- HIPAA DOES apply to any COVID-19 testing results where the test was administered as party of the group health plan and results are created, received or maintained by the plan – regardless of whether or not the test is done at the employer's request.
  - An employer cannot access PHI COVID-19 testing results under HIPAA.

Data Privacy

ADA Data Protection

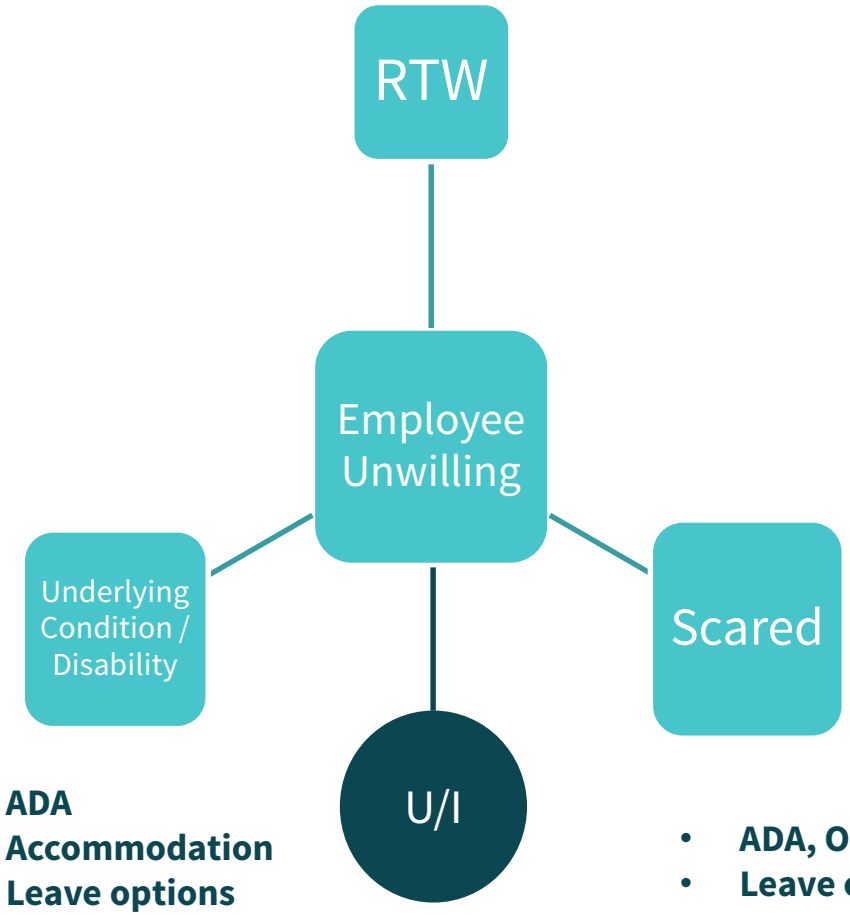
- The ADA requires all medical information about an employee be stored separately from the employee's personnel file, limiting access to this confidential information.
- Confidential Information includes:
  - A record or log of an employee’s daily temperature
  - COVID-19 testing records or results
    - Employers may notify public health officials of positive results but this is generally not required
- Record location must be secure and access must be limited (generally ADA responsible HR representative and supervisors only on a need-to-know basis).
- ADA requires 1 year record retention.

Data Privacy

Other Privacy Laws may Apply

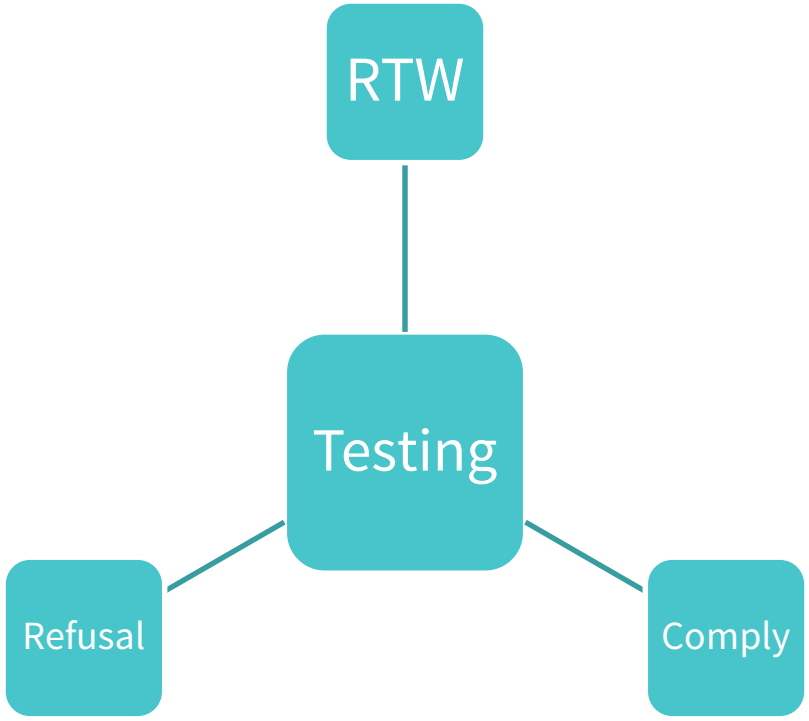
- California Consumer Privacy Act (CCPA)
- European Union General Data Protection Regulation (GDPR)

Employees Unwilling to Return



- **ADA**
- **Accommodation**
- **Leave options**

- **ADA, OSHA, NLRA**
- **Leave options**



- **Objections**
- **Accommodation**
- **Leave options**

- **COVID + procedures**
- **Privacy**
- **Leave options**

Employees Unwilling to Return

Increased Unemployment Compensation

- CARES Act provides for expanded unemployment benefits in terms of weekly amounts and duration of benefits.
- Individuals otherwise eligible for unemployment will receive an additional $600 a week through July 31, 2020.
- Depending on state, which determines unemployment benefit levels, some employees may receive more pay on unemployment than they would if employed, at least in short-term.
- An individual is unlikely to be eligible to receive unemployment after a return to work request because, generally, an employee cannot refuse work without good cause (this analysis may vary by state).

Employees Unwilling to Return

Medical or Mental Health Issues Impede Return

- Under the ADA, an employer is required to engage in interactive process to identify a reasonable accommodation that will allow a disabled employee to perform essential job duties.
- An individual with a preexisting disability or a health condition that subjects them to a higher risk related to COVID-19 could be considered disabled. A reasonable accommodation could be:
  - Telework or unpaid leave, which has long been a reasonable accommodation under the ADA
  - Changes to the work environment such as one-way aisles, plexiglass, tables, or other barriers to ensure minimum distances between the employee and customers and coworkers
  - Temporary job restructuring, temporary transfers to a different position, or modifying a work schedule or shift assignment
- An employer is not required to provide a reasonable accommodation if it would cause undue hardship to the employer (significant difficulty or expense in providing a specific accommodation based on specific facts and circumstances).

Employees Unwilling to Return

Mental Health Issues with COVID-19

- Many people feel significant stress due to the COVID-19 pandemic. This stress could rise to the level of a disability or exacerbate existing mental health issues.
  - Anxiety disorder, obsessive-compulsive disorder, or post-traumatic stress disorder, may arise or increase as a result of the COVID-19 pandemic.
- As with any accommodation request, employers should ask questions to determine whether condition is a disability and discuss possible accommodations that would enable ability to keep working.
- See prior slide.

Employees Unwilling to Return

Simply Scared to Return

- First consider whether ADA could apply (see prior slide).
- If no evidence of disability, employers should try to allay employee fears by reviewing employers Return to Work Policy or Policies, including any use of personal protective equipment, cleaning regimens, and spacing or distancing practices.
- If an employee still will not return to the workplace, “fear” may be covered under Section 13(a) of OSHA if “a danger exists which could reasonably be expected to cause death or serious physical harm immediately[.]”
- Refusal to work may also qualify as protected-concerted activity under NLRA if an employee has a “reasonable, good-faith belief” that working under certain conditions is not safe, or if they are “honestly mistaken.”
- Consult employment counsel.

Employees Unwilling to Return

COVID-19 Testing Refusal Issues

- Assess reason for refusal (disability related or religious objection).
- Employers should individually assess each request for a faith-based accommodation.
- Title VII protects workers from employment discrimination based on a variety of protected characteristics, including religion.
- Title VII also requires reasonable accommodation of employees' sincerely held religious beliefs, observances, and practices when requested, unless accommodation would impose an undue hardship on the employer.
- A leave of absence can constitute a reasonable accommodation if no other arrangement can be reached.
- An accommodation is not required if it would pose an undue hardship on the company ("more than de minimis cost" on the operation).
- Consult employment counsel.

Employees Willing to Return

COVID-19 Testing Time Issues

- Time spent by an employee getting a required drug test or medical exam at direction of an employer is compensable time under Fair Labor Standards Act (FLSA).
  - If employer mandates an employee attend an appointment to be tested, then time spent obtaining a test and at an appointment is compensable.
  - Challenges in tracking testing time and assessing whether reported hours for testing are reasonable.
  - The results may be PHI if testing is done through the group health plan.
- Employers may want to facilitate testing through a vendor to streamline process.
  - A safe on-site location or at designated off-site facilities will depend on employer's specific needs and options available in marketplace.
- Employers are not required to compensate applicants for time spent on pre-employment testing.
- Store testing data consistent with ADA rules.

Questions

For more information:
Contact your Alliant representative

or

Visit www.alliantbenefits.com to access the latest COVID-19 and Return to Work Resources