



COVID-19 ANTIBODY TESTING: WADING THROUGH THE CONFUSION

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A BRIEF REGULATORY HISTORY

- When COVID-19 hit, the FDA felt it was more important to get available antibody testing on the market and they waived the normal processes.
- Led to hundreds of tests on the U.S. market, many of which were shown to be wildly unreliable and made inappropriate claims. There was also outright fraud and criminal activity.
- On May 4, and then updated on Monday, the FDA released new guidance to address the problems.
- <https://www.fda.gov/media/135659/download>

A BRIEF REGULATORY HISTORY (CONTINUED)

- Overview of new guidance:
 - Commercial manufacturers will submit EUA requests, with their validation data, within 10 business days from the date they notified the FDA of their validation testing OR from the date of this policy, whichever is later.
 - The FDA has provided specific performance threshold recommendations for specificity and sensitivity for all serology test developers.
 - Two voluntary EUA templates for antibody tests have been made available by the FDA: one for commercial manufacturers, and one for CLIA certified high-complexity labs who decide to seek FDA authorization.



WHICH TESTS ARE AUTHORIZED BY THE FDA?

- At present, 12 antibody tests authorized by the FDA, and more than 200 going through the FDA process.
- You can visit the FDA web page below to review the FDA-authorized antibody tests. This will be updated as more tests are authorized.
- <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance>

WHAT ARE THE LIMITATIONS?

- Still a measure of unreliability—false negatives and false positives.
- While one may have the antibodies, as shown in a test, the amount of antibodies varies and the tests generally don't measure the amount of antibodies, just whether they are present or not.
 - One may not have a high enough level of antibodies to offer protection.
- Even if you do have sufficient antibodies, it is unknown whether the antibodies will offer sufficient protection, for how long, or against all mutations of COVID-19.

BOTTOM LINE: THERE IS STILL A LOT WE DON'T KNOW

- PROCEED WITH EXTREME CAUTION.
- Because of the room for error in these tests, and because we still don't know what protections will be provided, we cannot rely on current antibody testing with a significant measure of confidence.
- Do not make any representations or warranties to others, including your employees, regarding these tests and their meaning.
- However, one can cautiously use these test results as ONE DATA POINT of many, to make informed decisions.

EMPLOYER CONSIDERATIONS: KNOW THE LAW

- Americans with Disabilities Act (ADA)
 - Testing
 - Use of Testing
 - Disclosure of Testing
- Family and Medical Leave Act (FMLA)
 - Permissible inquiries
 - Leave
 - Reasonable accommodation
- Genetic Information Nondiscrimination Act (GINA)
 - How we use COVID-19 information
 - How we store COVID-19 information
 - Effective and legal use of COVID-19 information
- Occupational Safety and Health Act (OSHA)
 - Providing a safe workplace
 - Navigating employee complaints
- State law developments
 - Civil immunity from suit



NAVIGATING EMPLOYEE RIGHTS UNDER THE AMERICANS WITH DISABILITIES ACT (ADA)

ADA (42 U.S.C. § 12101 et seq.)

- [Considerations for Employers During the “Re-Opening” Phase – Holland & Hart Client Alert](#)
- Screening
 - Body temperature
 - Screening questions
 - testing
- Reasonable Accommodations
- Confidentiality

NAVIGATING CERTAIN EMPLOYEE RIGHTS UNDER THE FAMILY AND MEDICAL LEAVE ACT (FMLA)

FMLA in the “Old Normal” era

- The FMLA entitles eligible employees of covered employers to take unpaid, job-protected leave for up to 12 weeks for specified family and medical reasons.
 - Employers are entitled to require the following to establish eligibility under the FMLA:
 - Certification in support of the leave from a health care provider
 - Second or third medical opinions (at the employer’s expense)
 - Periodic recertification of a “serious health condition
 - FMLA in the “Old Normal” era
- This version of the law still applies, but...

NAVIGATING EMPLOYEE RIGHTS UNDER THE FAMILIES FIRST CORONAVIRUS RESPONSE ACT (FFCRA) AND THE ADA

FMLA in the “New Normal” era

- The Families First Coronavirus Response Act (FFCRA) provides eligible employees of covered employers with paid leave for certain COVID-19 related occurrences under either the Emergency Paid Sick Leave Act or the Emergency Family and Medical Leave Expansion Act.
 - The FFCRA incorporates the employer ability to request information to establish eligibility for and extent of FFCRA leave, however:
 - The ADA relaxes the medical examination prohibitions and allows an employer to, consistent with the ADA and FMLA (to determine leave):
 - Take the body temperature of an employee for COVID-19 related screening
 - Ask screening questions for COVID-19 related symptoms and exposures
 - Require negative COVID-19 test results and certification of symptom free status before return to work

NAVIGATING EMPLOYEE RIGHTS UNDER THE GENETIC INFORMATION NONDISCRIMINATION ACT (GINA)

GINA (42 U.S.C. § 2000ff-1 et seq.)

- Is a COVID-19 test result genetic information? Yes! (including positive, negative, and antibody results)
- Applies to all terms and conditions of employment from hiring to fringe benefits
- Applies to the employee and family medical history
- May not be used to make any employment decision unless related to the individual's current ability to work (see ADA/FMLA/FFCRA)
- COVID-19 related:
 - You may require
 - Body temperature
 - Symptom screening
 - Negative test to return to work
 - Health care provider
 - Certification
 - information to evaluate FMLA, EPLA, and EFMLEA
 - Information to evaluate reasonable accommodation under the ADA
 - You may request a test if written informed consent is obtained

WHAT IS CONSENT FOR COVID-19 RELATED TESTING UNDER GINA?

- Acquisition of genetic information is prohibited except in narrow circumstances. Related to COVID-19 testing:
 - 202(b)(2)(B) – “the employee provides prior, knowing, voluntary, and written authorization[.]”
 - 202(b)(3) – “ where an employer requests or requires family medical history from the employee to comply with the certification provisions of [the Family and Medical Leave Act (FMLA)] or [equivalent] State family and medical leave laws[.]”



CONFIDENTIALITY OF GENETIC INFORMATION UNDER GINA

■ Records

- All forms and data **must** be maintained separate from personnel and other files (206(a))
- Store with other medical files
- Treat as a confidential medical record
- ADA compliance = GINA compliance (e.g. maintain in a separate medical file)

■ Disclosures allowed

- To the employee if the employee makes a written request (206(b)(1))
- To an occupational or other health researcher if the research is conducted in compliance with the regulations and protections provided for under the Code of Federal Regulations
- Pursuant to Court order – but only as narrowly tailored in the Court order (206(b)(3))
- Government investigators (206(b)(4))
- Consistent with the FMLA or State equivalents (206(b)(5))
- to a Federal, State, or local public health agency only with regard to information that is described in section 201(4)(A)(iii) and that concerns a contagious disease that presents an imminent hazard of death or life-threatening illness, and that the employee whose family member or family members is or are the subject of a disclosure under this paragraph is notified of such disclosure. (206(b)(6))

EMPLOYEE REMEDIES AND EEOC ENFORCEMENT UNDER GINA

- EEOC Enforcement
 - Charge of discrimination
 - Hostile work environment claims
 - Retaliation
- Remedies/Damages
 - Back pay
 - Compensatory damages (capped based on number of employees)
 - Emotional distress and pain and suffering
 - Costs and attorney fees

NAVIGATING EMPLOYEE RIGHTS UNDER FEDERAL OCCUPATIONAL SAFETY AND HEALTH ACT (OSHA)

OSHA (29 USC §651 et seq.)

- General duties clause – Section 5(a)
- “[A]s a general matter, there is no right afforded by [OSHA] which would entitle employees to walk off the job because of potential unsafe conditions at the workplace.” (See 29 CFR §1977.12(b)(1)).
- Employer right to correct. Employee right of inspection – section 8(f) of OSHA.
- Be aware of discrimination. (See 29 CFR 1977.12(b)(2)).
- The mere existence of COVID-19 is not sufficient.
- Remember vulnerable populations.
- OSHA workplace evaluation tool:
<https://www.osha.gov/Publications/OSHA3990.pdf>
- Always check your state’s local OSHA laws and guidance.



STATE COVID-19 LEGAL IMMUNITY PROTECTIONS

- Check your state for potential emergency or special legislation providing employer legal immunity.
- For example, during its recent Special Session, the Utah legislature passed Utah Code §78B-4-517, providing civil immunity related to COVID-19:
 - Immunity from **liability** and **damages** resulting from exposure of an individual to COVID-19
 - On the premises owned or operated by the person;
 - During an activity managed by the person
 - Immunity does not extend to willful misconduct, reckless infliction of harm, or intentional infliction of harm.
 - Does not modify the application of: WCA, UOSHA, Governmental Immunity Act, or other applicable immunity protections under state or federal law.

UTAH'S COVID-19 CIVIL LIABILITY IMMUNITY LAW

- Applies **broadly** to individuals, associations, institutions, corporations, companies, trusts, limited liability companies, partnerships, political subdivisions, government offices, departments, divisions, bureaus, or other body of government, and any other organization or entity.
- Applies **broadly** to “real property and any appurtenant building or structure.”
- Effective May 4, 2020.



CONSIDERATIONS FOR EMPLOYERS IN UTILIZING TEST RESULTS IN DECISION-MAKING

- **CONSENT**
 - Informed
 - In writing
 - Limited use
 - Limited access in organization
- **HIGH RISK v. LOW RISK POSITIONS**
 - Objective criteria
 - Must offer to everyone
 - Should not include testing requirement
 - Compensation Considerations
 - Develop an objective matrix

QUESTIONS?

[Holland & Hart COVID-19 Resources for the Healthcare Industry](#): Alerts, Webinar Recordings, National and State Resources

[Holland & Hart Coronavirus Resource Site](#)

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THANK YOU



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