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# Liability of an Urgent Care Center for Third-Party Labs

**Urgent message:** While an urgent care center is responsible for the collection and safeguarding of clinical specimens, it's generally not liable for the activities of a third-party lab that it sends a specimen to.

ALAN A. AYERS, MBA, MAcc

Urgent care facilities regularly provide bloodwork and laboratory testing for their patients. These services may include allergy screening, diabetes testing, anemia screening, immunity testing, thyroid screening and monitoring, and hormone testing. Urgent care centers often collect specimens that are sent offsite to third-party labs for processing.

With the coronavirus pandemic, more customers are visiting urgent care locations for COVID-19 testing. This may include antibody testing (Coronavirus COVID-19 SARS-CoV-2 Antibody IgG) or diagnostic testing (an asymptomatic COVID-19 test to confirm negative status and the COVID-19 test when an individual has symptoms or has been exposed to someone with COVID). These two types of diagnostic tests, molecular tests, such as RT-PCR tests, that detect the virus's genetic material and antigen tests that detect specific proteins from the virus are processed on complex equipment.[1]

In diagnostic COVID-19 testing, the urgent care technician swabs the patient, obtains the specimen, and then submits a requisition to a nationally accredited laboratory. That lab reports the test results to the urgent care which, in turn, informs the patient. This process is performed thousands of times a day without incident. However, urgent care owners may question the extent of their liability for labs performed by third parties in the event that issues arise. This article will explore several common scenarios.

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## Urgent Care Collection to Carrier

The urgent care is responsible for collecting the specimen, packaging it along with any required paperwork, and storing it until it is placed in the possession of a courier service or another carrier, such as DHL, UPS, or FedEx. The CDC provides guidelines for the storage and handling of clinical specimens during a respiratory disease outbreak when the pathogen is unknown.[2]

Carriers such as Fed Ex and UPS have terms and conditions of carriage,[3] in addition to government regulations that set out the standard for shipping lab samples.[4] As a result, the urgent care's responsibility for handling the sample generally ends when it is tendered to the carrier.

## Urgent Care Collection to Drop Box

In another daily scenario, the urgent care places the day's specimens in a box outside to be collected by a lab

**Alan A. Ayers, MBA, MAcc** is Vice President of Strategic Initiatives, Experity and is Senior Editor, Practice Management of *The Journal of Urgent Care Medicine*. The author has no relevant financial relationships with any commercial interests.

courier. An urgent care owner may question which party is liable for the specimens and the attached personal health information (PMI) if the box is stolen.

While a lab may provide a "lock box" for specimens awaiting pick-up, the urgent care will generally be responsible for the security of the specimens. Typically, premise liability laws would apply, and the owner of the property and the urgent care would be responsible for theft or damage. The urgent care would have premises liability coverage as part of its commercial general liability policy.[5] This includes coverage for property damage related to the ownership or maintenance of a business premises.

Once the specimen is in the possession of the carrier, it would assume responsibility for safely delivering it to the lab.[6-8]

## The Specimen at the Third-Party Processing Lab

Research shows that the results of common diagnostic tests, such as blood and urine tests, serve as the basis for up to 70% of all medical decisions made by U.S. healthcare providers.[9] However, a lab that is processing an urgent care specimen can make a variety of errors. Negligence can happen in several ways, including the following:

- Failing to take adequate time to perform the lab tests, causing inaccurate results and mistakes
- Lab order paperwork mix-ups
- Use of the incorrect or faulty lab equipment
- Ambiguous or ill-defined results
- Errors in the recording of results
- Losing results or failing to report results to the urgent care
- Delays in delivering results to the urgent care

Negligence at the processing lab may lead to misdiagnosis by the urgent care when interpreting the test results.

## Urgent Care Responsibility for the Quality of the Lab Test Provided by a Third-Party Lab

An urgent care facility may also have concerns for its level of exposure for the quality of the actual lab test of a processing lab, such as in the event that a COVID-19 test performed by a third-party lab produced an erroneous result and the urgent care passed the result on to the patient. Moreover, what is the urgent care's potential liability if the urgent care provider engages in clinical decision making based on the erroneous result?

All labs must comply with federal and state statutes and regulations, such as the Clinical Laboratory Improvement Amendments (CLIA).[10] CLIA regulations establish the quality standards for lab testing performed on human specimens for diagnosis, prevention, or treatment of disease, or assessment of health.[11,12] If the third-party lab failed to comply with standards for quality, it would be generally be liable for its violations. Many labs warrant that the testing they perform for their clients will be performed in accordance with standard methodologies and professional standards. For instance, a lab will provide:

> In the event of error, omission, or other professional negligence or any breach of the […] warranty, the sole and exclusive responsibility of [the lab] shall be to re-perform the deficient work at its own expense, *and the laboratory shall have no other liability.*[12]

Further, continuing with the above example, the lab states that all costs associated with the laboratory's compliance to any subpoena for documents and/or court testimony for purposes relating to the client's samples are the client's responsibility.[13]

However, it's unlikely that this would prevent an urgent care or other healthcare provider from joining the lab in any litigation it was forced to defend based on an error with the third-party lab's testing of the specimen.[14,15] In fact, some states will not recognize waivers of liability. For example, under Massachusetts law, exculpatory contract clauses cannot shield a party from claims for gross negligence or responsibility for a statutory or a regulatory code violation.[16,17] Thus, an urgent care may bring a third-party complaint against the lab.[18]

## Urgent Care Responsibility for Business Processes at a Third-Party Lab

In addition to actual mistakes with the testing, an urgent care facility may have concerns for its level of exposure for the back-office integrity of a third-party processing lab. These processes can include quality assurance, IT systems, and billing. If the third-party lab fails to comply with nationally defined standards for quality and is out of compliance in its data security, it would generally be liable for its violations.[19]

Again, an urgent care may bring a third-party complaint against the lab if it is named in a lawsuit for the negligence of the lab.

## The Elements of Negligence

It is also important to point out that a plaintiff must prove all four elements of negligence in such a case against an urgent care facility.

The elements of a negligence claim law are (i) duty; (ii) breach; (iii) causation; and (iv) injury.[20] The failure to prove even one of the four elements will cause a negligence claim to be dismissed.[21] Further, a complaint must allege sufficient facts to show a claim that is plausible on its face.[22]

The plaintiff, critically, must establish *damages*. That means failure to demonstrate any quantifiable monetary damage—"an essential element of a negligence claim in our civil justice system—" requires that the case be dismissed.[23]

## The PREP Act

As a part of this discussion as it pertains to COVID-19 and a pandemic, it's critical to understand that the Public Readiness and Emergency Preparedness, or PREP Act,[24] provides almost total immunity under specific circumstances for manufacturers, distributors, and administrators of certain drugs, medical devices, and biologics designed to counteract an epidemic or pandemic.[25,26]

> Immunity means that courts must dismiss claims brought against any entity or individual covered by the PREP Act. Claims that courts must dismiss include claims for any loss that is related to any stage of design, development, testing, manufacture, labeling, distribution, formulation, labeling, packaging, marketing, promotion, sale, purchase, donation, *dispensing, prescribing, administration,* licensing or use of a countermeasure recommended in a Declaration.[27]

## Summary

While an urgent care has certain protections and defenses, this may not stop a party from bringing a lawsuit.[28]

The urgent care must make certain that its procedures for collecting specimens, packaging them with any required paperwork, and storing them until they are placed in the hands of a delivery service or carrier are completed in a safe and organized manner. The urgent care must comply with all state and local regulations concerning specimen collection and handling.

The carrier will have its own rules for the transport of biological substances, and any errors by a third-party lab resulting in action against an urgent care would most likely bring about a third-party complaint against the lab for its negligence, despite its attempts at contractual waver of liability. ■

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