Lost specimens

Q We recently got a call from a physician’s office asking about results on a specimen we never received. In fact, we did not even know that something was submitted until that office called several days later asking for results. The physician’s staff is adamant that the specimen was sent. They insist that we lost what was a particularly important test to monitor progress of cancer treatment on a research protocol, which really cannot be replaced. Who is responsible — and does the lab have any legal liability to the patient in this situation?

A Let us start with the easy question first: The person who actually lost the specimen is responsible. Unfortunately, without some investigation, determining whether the physician office or the lab is at fault is going to be difficult. Even with a thorough examination of the circumstances surrounding the loss, establishing exactly what went awry may not be possible. For that reason, legal specimens are handled with a chain of custody that requires samples to be physically passed from one responsible individual to the next with a receipt to document in whose possession a sample is at all times. As a result, few such specimens are lost but, unfortunately, that degree of attention and documentation is generally too great a burden when there are hundreds of specimens a day to track.

In your lab’s case, if it can be established by convincing circumstantial evidence that the specimen actually made it into the possession of the laboratory staff and was subsequently mislaid, the lab, indeed, could be liable for any damage that the patient suffers as a result. Fortunately, though losing a monitoring specimen may not be ideal in following a patient with cancer, it is rarely so important that clinical management is compromised. Most of the time, re-testing will satisfy patient care needs, if not those of research protocols.

Given the number of specimens handled by a clinical laboratory in the course of a year, surprisingly few are lost, though there have been a few high-profile cases. One large national laboratory allegedly lost two boxes of cytology and biopsy specimens in an air shipment several years ago. In such unhappy situations, loss of a specimen can give rise to a lawsuit. Imagine, for example, losing the excisional biopsy of a possible melanoma. Without the specimen, the patient will possibly undergo extensive surgery and considerable personal anxiety, all of which might have been avoided had the specimen been available to be examined.

The reality is that the patient does not really care who lost the specimen — if he sues, he will almost certainly name both the physician and the lab, and could conceivably collect six-figure damages from both. In such a situation, being able to prove that the lab did not receive the specimen in the first place suddenly becomes very important. And without good routines and policies in place for specimen management and transport, that can be nearly impossible.

When specimens are generated from the lab, a tracking system is always in place from the beginning: The order is received, the specimen is drawn or collected, and the resulting material (usually) comes back fully labeled to the lab for processing. It is when specimens are generated by someone other than lab personnel and are delivered outside the laboratory-collection routine, that things most often go wrong.

This incident provides an opportunity to test how well your tracking system audits what is handled. When receiving specimens from outside sources — especially physician offices — the best interests of the lab require confirmation of the specimens received as close in time and geography to the initial contact by lab personnel as possible. Ideally, each specimen should be checked in when it is picked up from the physician office by the courier before he transports it. In that way, a missing specimen can be identified early and clearly before the lab has possession and, therefore, responsibility for it.

Unfortunately, because of time constraints, this often is not practical. A workable alternative is to require a separate log of specimens be sent along with requisition forms to be completed by the submitting physician. In that way, if a physician intends to send a specimen and does not do so, at least the lab has early warning that a specimen is missing and can notify the physician’s office in time to recover the missing material or re-collect it if possible.

How well it trains its couriers and manages its specimen check-in also will determine how likely a laboratory is to be held responsible for a missing specimen. The presence of a policy for managing instances of potentially missing specimens (e.g., empty vials, requisitions with no containers, reports of missing specimens) is essential. Are specimens transported boxes secured? Are couriers required to lock their vehicles to avoid theft or vandalism of specimens? If third-party couriers or shippers are used, how are containers checked in? Is there an inventory of specimens made before the container is handed over? Are there tamper-proof seals? The greater the pre-emptive response of the lab to forestall possible mechanisms of loss, the less likely there will be lost specimens; and, if there are, the less likely that the lab is found liable.

A good idea is to track lost specimen reports, analyze for trends, and design appropriate interventions. Are particular offices more likely to report lost specimens? Are lost specimens associated with a particular shift, technologist, or courier? Is the rate of lost specimens acceptably low and stable? In the absence of absolute proof regarding the fate of a particular specimen, being able to demonstrate a high level of reliability in managing specimens can be convincing both to an upset patient and to a jury.

Barbara Harty-Golder is a pathologist-attorney consultant in Chattanooga, TN. She maintains a law practice with a special interest in medical law. She writes and lectures extensively on healthcare law, risk management, and human resource management.