When irreplacable specimens are inadequate

In general, I agree with not testing inadequate samples — like those that are hemolyzed — but what should we do when an irreplacable sample is less than adequate? If, for example, we receive an unlabeled pleural biopsy or a blood sample from a patient who is extremely ill or was otherwise difficult to collect, can we run the test in those circumstances if the physician gives us a waiver?

In the many inquiries and comments I receive about testing unacceptable, but unique, specimens, most contend that, to spare the patient another difficult or invasive collection procedure, the test should be run based on a combination of hospital policy, confirmation procedures (if the specimen were unlabeled or could be considered marginally adequate for some purposes), and physician waiver. None of these considerations changes the fact that an unreliable specimen is being tested and that the patient’s care may suffer as a result.

Running a test based on a physician’s waiver probably is not legally sufficient. For a waiver to effectively insulate the laboratory from liability based on questionable test results, it must come from the patient rather than the physician. If the patient is unable to make an informed choice about testing, his legally recognized surrogate must make the decision on his behalf; the physician’s waiver alone will not suffice. In the absence of the consent of the patient or his surrogate, the inadequate sample should not be tested without a legal opinion to the contrary, and the reason for proceeding (or not) with the ordered test should be documented in the patient’s medical record.

The same principles apply to testing difficult-to-collpel specimens that are unacceptable either because of the failure to centrifuge promptly, hemolysis, or inadequate sample size. Document the reason why the sample is inadequate, then explain to the patient the risks and benefits of running and relying on the test and the degree of reliability of the results. Again, if the test is to be run on the inadequate sample, either the patient or his legal surrogate should sign the waiver.

Such a process is unattractive to most physicians and laboratories because it involves admitting a mistake, which triggers lawsuit fears. Although a patient could seize the opportunity to sue the physician, lab, and hospital, most patients will appreciate honesty and be understanding of the mistake. Any legal problems arising from the incident will be based on the actual collection error — not the admission — and will be easier to defend than an incorrect diagnosis resulting from testing an inadequate sample.

Last, but not least, any situation involving inadequate samples should prompt a review of specimen-collection and handling processes. Because most inadequate specimens are a result of “operator error” rather than inadequate policy safeguards, supervisors should take the opportunity to re-educate staff about how to avoid such mistakes.

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