PT failures: steps to preventing a cease testing

September 2015—When the Clinical Laboratory Improvement Amendments of 1988 were implemented in the early 1990s, a number of significant changes to proficiency testing, or PT, were required. For the 83 tests or analytes (and microbiology subspecialties) defined as CLIA regulated, the law imposed requirements on both PT providers and laboratories. Regulations require participation in at least three PT events per year (each with five specimens) for each analyte, subspecialty, or specialty (mycobacteriology requires two events per year). CLIA regulates how PT providers score PT challenges for these analytes, and mandates that all laboratories that fail to achieve satisfactory scores be reported to the Centers for Medicare and Medicaid Services and initiate corrective action for issues related to poor PT performance.

As a result of a recent CMS clarification and communication on the requirements that have to be met to resume testing after a cease-testing period, the CAP is ensuring enforcement of an additional consequence: The laboratory must cease testing for a full six months after a cease testing for a regulated analyte.

We will discuss here this consequence and how the CAP oversees PT performance for regulated analytes, but first it will be useful to define terms, as used by the CMS:

- An occurrence of PT is an event. As mentioned above, for most tests or analytes, the regulations require five specimens in three events each year. Mycobacteriology requires two events per year.
- The correct result of an individual PT sample is referred to as acceptable; an incorrect result is unacceptable.
- Failure to attain at least 80 percent (ABO, Rh, and compatibility testing require 100 percent) correct results for a regulated analyte, subspecialty, or specialty is considered unsatisfactory PT performance. Unsatisfactory PT performance due to clerical errors or data omissions is not given special consideration.

Example: 2015/1 80% | 2015/2 100% | 2015/3 60%

- Failure to attain at least 80 percent (ABO, Rh, and compatibility testing require 100 percent) correct results for a regulated analyte, subspecialty, or specialty for two out of three testing events is unsuccessful PT performance. The terms unsuccessful PT performance and unsuccessful PT participation are interchangeable.

Example: 2015/1 20% | 2015/2 100% | 2015/3 60%

- A subsequent unsuccessful PT performance within six or fewer PT events is called repeat unsuccessful PT performance and requires the laboratory to cease testing for that analyte, subspecialty, or specialty for six months. Note that for most analytes, six events constitute two years in a PT program. Repeat unsuccessful performance can be three consecutive failures, three out of four failures, or two sets of two out of three failures within the six events.

Example 1 (three out of four failures): 2015/1 20% | 2015/2 60% | 2015/3 100% | 2016/1 20% | 2016/2 100% | 2016/3 100%

Example 2 (two sets of two out of three): 2015/1 20% | 2015/2 60% | 2015/3 100% | 2016/1 100% | 2016/2 20% | 2016/3 0%

The CAP monitors PT performance continually. The timeframe does not stop nor does it reset annually. Thus, if a laboratory performed unsuccessfully on PT in the second or third events of 2014, or the first event of 2015, it would currently be at risk for repeat unsuccessful PT performance.

As mandated by CLIA, the CAP requires laboratories to cease patient/client testing in response to any repeat unsuccessful PT performance for a regulated analyte, specialty, or subspecialty. The PT performance of CAP-accredited laboratories is
true outstanding. In 2014, among more than 7,000 accredited laboratories (more than 1 million analyte challenges), only 23 laboratories were sent cease-testing directives for regulated analytes and no laboratory received more than one cease-testing directive. Among the analytes involved in the 2014 cease-testing directives, 16 were chemistry, four were hematology/coagulation, two were bacteriology, and one was transfusion medicine. Of note, seven cease-testing directives were for blood gas measurement, specifically pO2. This is likely related to the importance of PT specimen handling. The CAP provides information for laboratories on troubleshooting PT failures, in the Proficiency Testing Toolbox that can be found at http://j.mp/pt_troubleshooting.

**The director of a laboratory that receives a cease-testing directive** is required to sign an affidavit ensuring that patient/client testing has ceased for that analyte. To be reinstated, the laboratory must:

- complete a root-cause analysis detailing the cause of the repeat unsuccessful PT performance.
- detail the corrective actions that have been put in place to prevent recurrence.
- provide an analysis of the impact of the PT failure on patient testing.
- provide documentation of any required personnel training/retraining.
- successfully complete two events of reinstatement PT for the analyte.
- ensure that the laboratory is in compliance with the cease-testing directive.

In the past, when a laboratory completed steps for reinstatement and submitted acceptable documentation to the CAP, the CAP would often find that it had all the information necessary to decide whether a laboratory was in compliance and could resume testing. Now, as a result of the recent CMS clarification, the CAP is enforcing the additional consequence that a laboratory cease testing for six months before being allowed to resume patient/client testing.

For a number of regulated analytes (blood gas, electrolytes, compatibility testing, hematology testing), the option of sending out this testing during the six-month cease-testing mandate will pose a challenge to providing good patient care. The CAP will work with laboratories that experience a cease-testing directive for a critical analyte to minimize the impact on patient care. Of course, the best way to minimize the impact on care is to prevent PT failures and address all instances of unacceptable PT results so they do not recur.

Because of the serious nature of a cease-testing directive and its effect on laboratories and patients, the CAP Laboratory Accreditation Program has put together a tip sheet on the escalation process for PT failures (http://j.mp/pt_tips). The tip sheet is intended to help laboratories better understand the process and consequences of a repeat unsuccessful PT performance. If your laboratory does reach the point of an unsuccessful PT performance, you will need to exercise increased vigilance over several PT events to ensure that you don’t have a repeat unsuccessful PT performance. As in the past, an unsatisfactory PT performance must be investigated and, for inspection purposes, documentation of corrective action must be maintained by the laboratory even though a formal response to the CAP is not required. An unsuccessful PT performance will continue to require the laboratory to complete and return to the CAP a proficiency testing compliance notice (PTCN) response form, documenting the corrective action taken to prevent further PT failures. This process will not change and serves to alert the laboratory that it is at risk if an unsuccessful PT performance were to occur again. In all cases of unsatisfactory PT performance, the laboratory must assess the impact on patient testing. The PT failure may be an indicator of problems with patient testing, requiring a look-back at patient results to determine if the patient testing has been valid.

The CAP requires enrollment in formal proficiency testing for about 300 nonregulated analytes. It will continue to monitor PT performance for these nonregulated analytes as it has in the past. The process for monitoring nonregulated analytes is different, and repeat unsuccessful PT performance does not require testing to be ceased for a full six months. Information about the monitoring and escalation process for nonregulated analytes can be found online in the Proficiency Testing Toolbox. The information in this CAP TODAY article relates to the monitoring of regulated analytes only. As a reminder for nonregulated analytes, the laboratory must demonstrate its proficiency using an alternative assessment method at least two times per year.

In conclusion, laboratories and laboratory directors need to be aware of the consequences of unsatisfactory, unsuccessful, and repeat unsuccessful PT performance. If an unsuccessful PT performance should occur, every effort should be made to understand and correct the testing process to prevent a repeat unsuccessful PT performance. The CAP will continue to work closely with laboratories to improve performance and avoid the consequences of PT failure.

A “Focus on Compliance” webinar on this topic was presented July 15 and can be viewed at https://vimeo.com/134230415.

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Dr. Olson is a member and Dr. Karon is the chair of the CAP Continuous Compliance Committee. Dr. Olson is a professor emeritus, Department of Pathology, University of Texas Health Science Center at San Antonio, and director of clinical laboratories, South Texas Reference Laboratories. Dr. Karon is associate professor of laboratory medicine and pathology,
Mayo Clinic, Rochester, Minn.