Laboratories have been doing proficiency testing (PT) for the last 50 years. A lot has changed during that time, including the reasons for doing PT. Optional at first, PT is now a federal requirement for hospital and independent laboratories. The role of PT has changed as well in the last 50 years—from one of assessing analytical accuracy to that of evaluating the entire testing process. But, is PT keeping up with the times, or is further evolution necessary?

Proficiency Testing Turns 50
F. William Sunderman, MD, a founding fellow of the College of American Pathologists (CAP, Northfield, Ill) and past president of the ASCP who recently celebrated his 100th birthday, began investigating laboratory test quality in 1947 (Fig 1). He found that the laboratories’ results were poor, an embarrassment that led CAP to begin supplying standard reference solutions to pathologists in order to improve accuracy (Fig 2).

Clinical Pathology Standards
College of American Pathologists

- Inexpensive
- Available to All Physicians
- Use as Daily Standard

STANDARD SOLUTIONS
Uniformity—
In all Laboratories
Constancy—
In small ampule unit
Reliability—
In checking techniques

Fig 1. F. William Sunderman, MD, began investigating laboratory test quality in 1947.

In 1949, CAP offered its first proficiency test, the forerunner of the multisample CAP survey. That same year, Sunderman launched the first PT service, and the American Association of Bioanalysts (AAB) started its PT program. The Sunderman Proficiency Test Service was in use for 36 years, before the American Society of Clinical Pathologists (ASCP) incorporated it into the clinical chemistry portion of its Check Sample program.

The first comprehensive CAP survey was offered in the 1960s (Fig 3), with equivalency granted for the CAP survey under the Clinical Laboratory Improvement Amendments of 1967 (CLIA '67); deeming authority was granted to CAP for Inspection and Accreditation in 1978 by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO, Oakbrook, Ill). During this time, “the College [CAP] always has required that laboratories use CAP surveys to assess performance between inspections, but that is changing,” says Ronald B. Lepoff, MD, University of Colorado Health Sciences Center, Denver, and commissioner of the CAP Laboratory Accreditation Program. Now, laboratories can purchase survey materials from other CAP-approved programs and use them instead of CAP survey materials for CAP accreditation purposes. “Four programs have already been accepted and that is just the beginning,” says Lepoff. The four programs are:

- ASCPSTAR program for cervicovaginal cytopathology;
- Current Education in Pathology (CEIC) Cytoquest program in cervicovaginal cytopathology;
- Southeastern Organ Procurement Foundation (SEOPF) program for histocompatibility; and
- State of Maryland Cytology Proficiency Testing Program in cervicovaginal cytopathology.

Lepoff also points out that CAP has formed a task force to explore ways to integrate its various survey products and to improve its quality of responsiveness to customers. “There are many aspects being studied right now and the results should come out next spring,” he predicts. One of the issues that the task force is reevaluating is electronic transfer and/or fax transmission of data. The AAB and ASCPSTAR program already accept completed PT forms electronically.

Why We Perform Proficiency Testing
Over the years, PT has assumed a regulatory and potentially punitive role, in addition to that of ensuring accuracy. The Health Care Financing

Announcing
1964
NATIONAL COMPREHENSIVE LABORATORY SURVEY

The College of American Pathologists will conduct its second annual National Comprehensive Laboratory Survey this spring with the first official invitation for participation in the 1964 Survey being mailed to the Pathologists after March 1, 1964.

The Survey will be provided in 3 KITS, which may be purchased individually or collectively in a Series of three

KIT 1 — CHEMICAL
Bilirubin
Chloride (2 samples)
Total Protein
Uric Acid (3 samples)
Amylase
Alkaline Phosphatase
Glutamic Oxalacetic Transaminase
Urea Nitrogen

KIT 2 — BLOOD BANK, HEMATOLOGY & URINALYSIS
Blood Smear Evaluation (3 slides)
Hemoglobin
Blood Grouping—Typing—Crossmatch (3 samples)
Urinalysis

KIT 3 — BACTERIOLOGY, PARASITOLOGY & SEROLOGY
Bacteria Identification (2 samples)
Parasite Identification
Serologic Tests for Syphilis
Anti-Streptolysin Titer
Febrile Agglutinin Titer

KIT 1 — Chemical .................................................. $10.00
KIT 2 — Blood Bank, Hematology & Urinalysis ......................... 12.00
KIT 3 — Bacteriology, Parasitology & Serology ......................... 15.00

KITS 1, 2, 3 purchased at the same time in a Series (a savings of $4.25) .... $32.75

Administration (HCFA) now requires compliance with the requirements of CLIA, stipulating that laboratories performing moderate- or high-complexity testing must enroll in and successfully complete a PT program. CLIA '88 requires laboratories to review PT data, document the review, and to perform and document remediation of problems identified by PT.

“All proficiency-testing specimens must be processed in the same way as other samples.”
—Irina Lutinger, MPH, MT(ASCP)DLM

Currently 20 PT programs are approved by CLIA (Table) but all of the half-dozen laboratories from large clinical centers that were interviewed for this article use the CAP survey for PT. Some also enroll in other proficiency programs, either because they operate in a state like New York that has its own PT program, or because CAP does not offer PT for an analyte they assay.

CLIA-approved PT programs generally consist of three testing events per year that each consist of five samples for each analyte in a laboratory’s test menu. Satisfactory performance on five of the five samples for an analyte gives a score of 100%, which is what many laboratories strive to accomplish. A score of 80%, which represents satisfactory performance on four of five samples for an analyte is sufficient for CLIA-approved programs, but that means that one of the five results was unacceptable. Several of the people interviewed for this article, say their laboratory is more strict than CLIA '88. They investigate tests with a score of 80% to determine how they can improve performance so that five out of five results are within the acceptable range.

In addition to showing acceptable performance for four of the five challenges, each laboratory must pass at least two of three consecutive testing events for each analyte during a 12-month period. There are two exceptions to this rule:
1. Cervical cytology laboratories must pass 90% of challenges.
2. Laboratories involved in ABO typing, D typing, and histocompatibility testing must pass 100% of challenges.

How Are Proficiency-Testing Specimens Handled?

Because getting correct results on these surveys is so important, how do laboratories handle proficiency specimens? In the past, and to some degree even now, PT samples were not treated as routine clinical specimens. Twenty-five years ago, when I worked in special chemistry, I was asked to verify some of the chemistry department's PT results using a second instrument. I was not alone. In a 1988 survey of 190 hospitals, 17% to 32% of participants were analyzing PT samples on more than one instrument, while 5% to 18% assigned special people to perform PT, 23% to 42% analyzed controls just before PT samples, and 52% to 88% performed replicate analyses on one instrument.1 CLIA '88 regulations stipulate that PT samples be analyzed in the same manner as patient samples, but no studies of compliance have been published since passage of the regulations.

“All proficiency-testing specimens must be processed in the same way as other samples,” says Irina Lutinger, MPH, MT(ASCP)DLM (Fig 4), assistant administrative director, Pathology, The
Proficiency-Testing Programs Currently Approved by CLIA*

Accutest, PO Box 999, Westford, MA 01886-0031, (800) 356-6788

American Academy of Family Physicians (AAFP), 8880 Ward Pkwy, Kansas City, MO 64114-2797, (800) 274-7911

American Academy of Pediatrics, 141 Northwest Point Blvd, Elk Grove Village, IL 60009, (847) 981-7662

American Association of Bioanalysts (AAB), Proficiency Testing Service, 205 West Levee St, Brownsville, TX 78520-5596, (800) 234-5315

American Proficiency Institute (API), 1159 Business Park Dr, Traverse City, MI 49686, (800) 333-0958

American Thoracic Society (ATS), 1740 Broadway, New York, NY 10019-4374, (212) 315-8700

California Thoracic Society (CTS), 202 Fashion Lane, Suite 219, Tustin, CA 92680, (714) 730-1944

College of American Pathologists’ Surveys, College of American Pathologists, 325 Waukegan Rd, Northfield, IL 60093-2750, (847) 832-7000

External Comparative Evaluation for Laboratories (EXCEL), College of American Pathologists, 325 Waukegan Rd, Northfield, IL 60093-2750, (800) 323-4040

Idaho Bureau of Laboratories, Proficiency Testing Program, 2220 Old Penitentiary Rd, Boise, ID 83712, (208) 334-2235

State of Maryland, Office of Licensing and Certification Programs, Division of Laboratory Licensure, 4201 Patterson Ave, 4th Floor, Baltimore, MD 21215, (410) 764-4688 (The State of Maryland’s Cytology Proficiency Testing Program is available to any cytology laboratory possessing a valid Maryland State License. The laboratory must ensure that each individual engaged in the examination of gynecologic preparations is enrolled in PT, if available in the State in which he or she is employed.)

Medical Laboratory Evaluation (MLE), 2011 Pennsylvania Ave, NW, Suite 800, Washington, DC 20006-1808, (800) 338-2746, (202) 835-2746

New Jersey Department of Health, Proficiency Testing Program, CN 360, Trenton, NJ 08625-0360, (609) 292-5605

New York State Department of Health, State of New York, Department of Health, The Governor Nelson A. Rockefeller State Plaza, PO Box 509, Albany, NY 12201-0509, (518) 474-8739 (Any laboratory located outside the State of New York that holds a valid New York State permit may choose to use the New York State PT program to fulfill federal requirements for PT enrollment and participation in the specialties of bacteriology, diagnostic immunology, chemistry, hematology, and immunohematology.)

Ohio Department of Health, 1571 Perry St, PO Box 2568, Columbus, OH 43216-2568, (614) 466-2278

Pacific Biometrics, 110 Eastlake Ave East, Seattle, WA 98109, (206) 298-9838

Commonwealth of Pennsylvania, Department of Health, Bureau of Laboratories, PO Box 500, Exton, PA 19341-0500, (215) 363-8500

Puerto Rico Department of Health, Laboratory Services Program, Department of Health of Puerto Rico, Bldg A Call Box 70184, San Juan, PR 00936, (809) 274-7735

Solomon Park Research Institute, 12815 NE 124th St, Suite 1, Kirkland, WA 98034, (800) 769-7774

Wisconsin State Laboratory of Hygiene, 465 Henry Mall, Madison, WI 53706-1578, (800) 462-5261

*Laboratories should contact the proficiency testing (PT) provider directly to obtain explicit information pertaining to any particular company's services. Laboratories that are Clinical Laboratory Improvement Amendments (CLIA) certified to perform testing that requires PT enrollment should also contact their state agency and/or approved accreditation organization for additional specific assistance regarding PT enrollment and PT-testing CLIA requirements.
This is a regulation, not an option, we must handle PT samples the same way as patient samples. However, a PT sample is not in a tube and it looks different, so it is hard to have a blind PT sample. You can’t transfer them into other tubes because the volume is too small. We cover the name of the agency on the vial and give it to the person to run as if it was a blood sample, but he or she suspects that it is either a QC [quality control] or PT sample” says Lutinger.

“We have a PT protocol that clearly defines the way specimens are to be handled, who is to review the results, how samples are to be stored, and how to handle an out-of-range result. It’s a strictly defined policy. After analysis, we review the results, just as we verify patient results, and the report is printed for filing,” says Lutinger. All of the sources interviewed for this article agreed that PT samples are treated no differently than other samples in their institutions.

“PT continues to provide good assessment of laboratory-to-laboratory consistency for total test systems. However, fresh biological specimens provide better assessments of repeatability, as well as accuracy.”

—Shahram Shahangian, PhD

Proficiency Testing Identifies Least-Frequent Errors
An inaccurate result can occur for many reasons, and most of them have nothing to do with the actual analysis. PT is not an assessment of the total testing process and does not directly address some important preanalytical steps such as specimen collection, processing, and storage, or postanalytical steps such as data transcription and reporting. It has been reported that 90% to 93% of laboratory errors occur before analysis (the preanalytical phase) or after analysis (the postanalytical phase).2

In a review of PT studies since 1987, Shahram Shahangian, PhD, of the Laboratory Practice Assessment Branch of the Centers for Disease Control and Prevention, Atlanta, concluded that PT mainly appears to be a measure of the analytic performance and that current PT practices provide an incomplete assessment of the total testing process.3

Another type of PT error may result from the sample composition itself. Some instruments, for example, analyze processed PT material differently from other analyzers, producing the “matrix effect.” This has been defined by the International Federation of Clinical Chemistry, Hamilton, Ontario, Canada, as “the effect of compounds other than the analyte on the measurement of the analyte.”3 Today's automated instruments were designed to analyze blood or plasma, not PT samples that react differently than biologic samples. Nonetheless, when laboratories use the same method or instrument for analyses and their results are compared, there is no problem. The problem arises when a laboratory uses a different method or instrument and its results are compared to a group mean.

Shahangian says that despite the shortcomings of processed PT materials, “PT continues to provide good assessment of laboratory-to-laboratory consistency for total test systems. However, fresh biological specimens provide better assessments of repeatability, as well as accuracy.”3 Working toward that goal, CAP is conducting a study with the Veterans Administration in which both lyophilized and fresh biologic samples are being used for PT. The Laboratory Proficiency Testing Program, Toronto, Ontario, Canada, has used both fresh and lyophilized PT samples and reported that consistency was significantly better when fresh serum was used.3

Another controversy in PT is the type of calculation used to assess satisfactory performance. The PT grading criteria used most commonly are based on the $1_{2S}/1_{3S}$ rule ($\pm 2SD$ or $\pm 3SD$ from the peer group mean) or fixed limits. Ehrmeyer and Læssig have said that the $1_{2S}$ rule correctly identifies acceptable performance 90% of the time, but fails to uncover unacceptable performance about 25% of the time.4 As the number of laboratories in a peer group decreases, peer group statistics may misidentify good laboratories.5 Conversely, when the population SD increases, fewer laboratories fail PT. Fixed limits around a group mean are sometimes used to address the problem caused by the increased precision of today’s instruments. Alternatively, clinical significance is used to determine acceptable limits of some analytes, such as hemoglobin.
Few Laboratories Fail, But What If Yours Does?

In a 1987 study of CAP PT results, less than 1% of hospital and independent laboratories had unacceptable results. In 1994, HCFA reported that the percentage of unsatisfactory test results for the 30 most common tests in hospital and independent laboratories was 1.3% to 5.6%. Of the 17,058 laboratories reporting to HCFA in 1994, 97% of hospital and independent laboratories had overall satisfactory PT performance.

Pass or fail, procedures need to be in place in case of failure. NCCLS has published sample forms for documenting unacceptable PT investigations (Fig 5).

Whenever a PT or QC sample is out of range, action must be taken. According to Lutinger,

We review all our QC data before, during, and after the time period when we performed the PT for shifts, trends, and errors. If the error or problem is determined by that review, then corrective action is implemented and documented. We have a PT report that is reviewed by the director of the laboratory, the supervisors, and if need be, the technologists. The entire quality improvement process is reassessed, so that all tests performed by the laboratory will conform to specified performance criteria. The next step would be discussions with employees regarding the result and ways to improve the process. These discussions are educational, not punitive. The reports and pertinent comments are then filed, and copies are reviewed regularly by the director of the laboratory. Even acceptable results are reviewed during an in-service meeting with the staff, particularly urinalysis, body fluid, and hematology surveys, because they offer 35-mm transparencies for interpretation. This review process definitely provides good educational opportunities for the staff.

To determine if a postanalytical transcription error occurred, Lutinger takes the original printout generated when the PT sample was analyzed and compares it with the result that was manually entered on the PT forms sent by the agencies. A second individual also verifies that the result was accurately transcribed. “One of the first questions we ask is whether there is a transcription error. If there is none, then we go back and review all the QC records,” says Lutinger.

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**Fig 5. Sample form for documenting unacceptable proficiency-testing (PT) investigations. SOURCE: Continuous Quality Improvement: Essential Management Approaches and Their Use in Proficiency Testing; Proposed Guideline GP22-P. Wayne, Pa: NCCLS; 1997. Used with permission.**
Proficiency Testing and Competency Assessment

Diane Krienitz, DLM(ASCP), manager in clinical pathology, Lovelace Health Systems, Albuquerque, NM, explains that competency assessment is a large and important part of accreditation by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO, Oakbrook Terrace, Ill, see table below), the College of American Pathologists (CAP, Northfield, Ill), and the Clinical Laboratory Improvement Amendments (CLIA). “You have to create programs that show that employees are competent to perform the tests and related functions that they perform. Competency assessment is mandatory for accreditation and CLIA states that competency can be assessed by three measures: proficiency testing (PT), quality control (QC), and observation. You can also expand it to include how well an employee can troubleshoot and how well he or she spots errors. It is important that you not just look at one area. There is a lot more involved in competency assessment than doing a test.”

She continues, “External PT specimens, because of their small sample size, don’t lend themselves to competency assessment for a large group of employees. They can be used for this purpose only if a small number of staff is involved in testing that particular analyte. Internal PT must be used in large laboratories. In addition, if a person reports a PT result that turns out to be unacceptable, action must be taken to determine how the error occurred. If the error is due to individual performance, remedial action must be taken. We have a performance improvement plan for such cases.”

Krienitz explains that everyone goes through annual recredentialing. “This competency assessment includes areas like leadership and ability to work with others, as well as technical expertise. You have to have technical competency, of course, but you have to be able to adapt and work as part of a team as well. This also is an important part of competency,” she says.

Top Standards Cited by JCAHO Before and After CLIA ’88 Implementation

Before CLIA ’88

1. No daily review of patient testing, QC, and preventive maintenance results (QC.1.3)*
2. No corrective action for outliers, ie, PT, QC, waived testing (QC.1.1.1, QC.1.4, WT.1.5)
3. No evidence of preventive maintenance of equipment (EC.2.1.f)
4. No performance of QC or appropriate frequency (QC.7.1, QC.8.7, WT.1.4)
5. No adequate PT program (QC.1.1)

4 Years After CLIA ’88

1. No corrective action for outliers, ie, PT, QC, waived testing (QC.1.1.1, QC.1.4, WT.1.5)
2. No correlation of multiple test methods for same analytes across the organization (QC.1.2.1)
3. No daily review of patient testing, QC, and preventive maintenance results (QC.1.3)
4. No adequate PT program for regulated analytes (QC.1.1)
5. No adequate competency assessment program (HR.7, WT.1.2)

*Numbers following a deficiency identify the standard.


None of the laboratorians interviewed had ever had a PT failure by CLIA’s definition. Marianne C. Watters, MT(ASCP), director, Department of Pathology, Parkland Health and Hospital System, Dallas, explains, “We never have had a failure by the definition used by HCFA, which is to fail two out of three challenges. However, we will research any analyte that we tested and got the wrong answer to find out what happened so that it doesn’t happen again. A good part of the time it has been because something was wrong with the specimen. Nonetheless, we review the QC records and check for clerical error. Sometimes we determine that there is no answer, and that it must have been a random error that we cannot pinpoint.”

“We never have had a failure by the definition used by HCFA, which is to fail two out of three challenges.”

—Marianne C. Watters, MT(ASCP)

Helen Ogden-Grable, MT(ASCP)PBT, laboratory supervisor, DSI Laboratory, Naples Community Hospital Healthcare System, Naples, Fla, explains:

PT is certainly a wonderful tool for assessing quality, but it is only as good as the action that you take if you have a problem. Laboratories need to implement a system of handling PT errors and it needs to be in writing and documented. Without documentation, you have no proof. As important as documentation is, however, the stress should be placed on the action taken when there is a failure and how you handle it. Laboratory staff must be educated as to the handling of PT errors. There should be an initial orientation into your laboratory protocol followed by periodic reviews.
What Proficiency Testing and Accreditation Mean to the Laboratory

Successful PT results and subsequent accreditation demonstrate to everyone that a laboratory offers quality results, ensuring quality patient care. Comparing PT results with peers and becoming accredited enable you to say on a legal basis, that you provide quality patient care. Because we have such extensive QC programs, we can always justify that checks and balances have been in place,” says Lutinger.

Ogden-Grable adds that, “laboratory accreditation by CAP and hospitalwide accreditation by JCAHO are promoted by the hospital. We have large signs throughout the hospital that the public can see. The signs are even in our parking garage stating that we passed our JCAHO accreditation with commendation. Institution-wide there is some degree of pride in being accredited by these agencies. I think it has a very positive impact” (Fig 6).

Proficiency Testing: Limited but Effective

As important as PT is, it has shortcomings and does not address the total testing process. The challenge for the future is to develop a systematic approach: one that addresses not only the analytical procedure, but pre- and postanalytical steps as well. The introduction of biological specimens that are more like patient samples and electronic capture of PT results would help meet this goal, but may be difficult to achieve. Can PT be made to mimic patient testing? Organizations are currently working on these changes. Let’s hope they succeed so that PT will fulfill its true mission—to ensure quality throughout the testing process.

Janet Hodnett, MS, MT(ASCP), is a freelance writer in Rye, NY.

References