

LabGuide 8

Proficiency Testing

INTRODUCTION

Proficiency testing (PT) is an important aspect of an overall quality assurance program. PT serves as an external check to verify the accuracy of a laboratory's results by providing samples with unknown values for the laboratory to test.

Laboratories test the PT samples in the same manner as a patient specimen* and report the results to the PT provider by a specified due date. When results are received by the PT provider, they are grouped and analyzed, and then scores are reported back to the participating laboratories.

*Important note: Labs should treat PT samples in the same manner as a patient specimen ***up until the point when the laboratory would normally send a patient specimen to another laboratory, such as for confirmatory, reflex, or distributive testing.***

Labs should never send PT samples to another laboratory for testing.

ENROLLMENT REQUIREMENTS

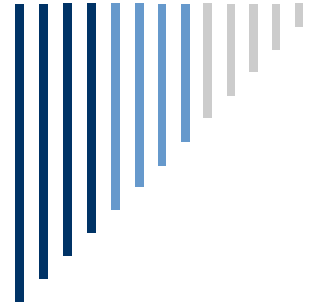
CLIA regulations and COLA policy state that laboratories must enroll in PT for all regulated analytes and must authorize that their PT results be forwarded to CMS and their accrediting agency (if applicable). For regulated analytes, enrollment provides five PT samples (challenges) three times a year for each specialty. For regulated analytes which fall under the specialty of Bacteriology, proper enrollment requires a minimum of five challenges per subspecialty for each event. It's important to select modules which offer appropriate challenges for the methods/procedures performed in your laboratory (i.e., gram stain, antigen detection, bacterial identification, susceptibility testing).

Laboratories must also enroll in PT or perform split-specimen analysis (see LabGuide #9) as an external validation of all non-regulated analytes. Proficiency Testing for waived tests is highly recommended but not required by CLIA. PT providers offer economical 2-challenge PT modules for waived tests and other non-regulated analytes.

PT EVENTS

Each specialty (i.e., Chemistry, Hematology) has three PT events each calendar year. Sample kits are sent to the participant laboratory with information and instruction sheets, and an attestation form. Shipping schedules for PT events are available from your PT program and it is important to note the shipping dates. If your samples do not arrive in a timely manner, contact your provider.

CLIA regulations and COLA policy state that laboratories must enroll in PT for all regulated analytes.



TYPES OF SAMPLES

Types of samples provided by PT programs may include:

- Liquid samples such as urine, plasma, serum, whole blood, and other body fluids.
- Lyophilized (freeze-dried) samples which require reconstitution using specified solutions (which may be provided). Lyophilized samples are not as common as in the past, but some PT providers still use them for certain analytes.
- Dry loop samples for bacteriological identification.
- 35 mm color transparencies which simulate microscopic samples.

PREPARATION

It is important to follow the exact step-by-step instructions for the storage, preparation and analysis of PT samples. The accuracy of your laboratory's PT results depends on it! When it is necessary to reconstitute PT samples, always use pipettes of certified accuracy. Class A volumetric pipettes for the reconstitution of PT samples are available through some PT programs or may be purchased through your laboratory supply distributor. Syringes are not acceptable for reconstitution. They are not designed for use in the laboratory and are not accurate enough for dispensing, reconstituting, or diluting PT samples.

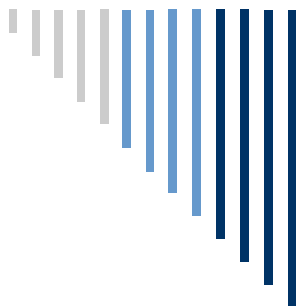
REQUIREMENTS FOR PERFORMING PT

You must perform PT in the same manner as your patient specimens, except when specifically instructed by the PT provider. Under no circumstances should the laboratory repeat testing and average results to “improve your chances.” If you test patient specimens once and report, you must do the same with the PT samples. If you repeat abnormal patient specimens before reporting, you may repeat abnormal PT samples before reporting. Personnel who routinely test patients should test the PT samples, and everyone who tests patients should rotate performing the PT during the year. Carefully check the result form for clerical errors. Sign the attestation statement and submit the results by the due date.

Never send PT samples to another laboratory for testing, even in cases where your normal procedure for patient specimens includes sending to another laboratory for confirmatory, reflex, or distributive testing. In addition, CLIA regulations and COLA policy prohibit laboratories from communicating with another laboratory to discuss PT results prior to the cutoff date for submission of test results.

The whole point of PT is to evaluate the quality of the test results your laboratory produces every day for your patients. If you take extra steps to ensure that you get the right result for the PT samples so you can pass PT, but don't take these same measures when performing your routine testing, nothing is gained. Integrate the PT samples into your normal daily workflow to demonstrate that your routine methods, testing staff, and policy for repeat testing produce accurate and reliable test results every day.

It is important to follow the exact step-by-step instructions for the storage, preparation and analysis of PT samples. The accuracy of your laboratory's PT results depends on it!



If you are unable to test the PT samples when they arrive (instrument broken, reagents backordered), call the PT provider to be "excused" from the event so you don't fail for not participating. In addition, you must indicate on your PT result form your inability to perform testing and submit the PT result form back to your PT provider by the listed due date to avoid an unsatisfactory score.

YOUR PT RESULTS

Your PT scores are sent to you in an individualized PT report. Along with the results report, each laboratory receives a Participant Summary Report which provides results from all participants for each analyte, grouped by the methodology used. Thoroughly review your PT scores to see how you performed. Then review the participant summary to see how your results compare to other labs. Call your PT provider or COLA if you need help interpreting your report.

REPORT TERMINOLOGY

Proficiency Testing providers use several different mechanisms to determine the range of acceptable results for a PT sample. Here are some definitions of the different concepts used to evaluate PT data. Depending on the provider, you may see these, or similar, terms on your result report:

1. **Regulated Analyte:** Those analytes designated by the Federal Government as requiring PT enrollment. The Regulated Analyte list is included at the end of this LabGuide.
2. **Mean:** The average (the sum of all values divided by the number of values) of all of the results for a PT sample obtained by the comparison group. This is the "correct" result for the sample that your results are being compared to. In most cases, this "target" mean is your peer group mean. You want your result to be as close as possible to the mean.
3. **Standard Deviation (SD):** A way of determining how much variation from the mean there is in the results. Standard deviation (SD) measures the degree of precision of a method – the smaller the SD, the more precise the method.
4. **Accuracy:** How close a test result is to the true value of the quantity being measured.
5. **Precision:** The degree to which repeated test results on the same sample agree; the reproducibility of the test.
6. **Reliability:** A test method's capacity to maintain both accuracy and precision.
7. **Coefficient of Variation (CV):** The relative standard deviation, which is the standard deviation expressed as a percentage of the mean. CV is a measure of precision that is used to compare the amount of error or variation of two or more different sets of results. The smaller the CV, the more precise the results. By comparing the CVs of different instruments from the Participant Summary Reports, it may be possible to determine which instruments provide the most precise results.
8. **Peer Groups:** The participants' results are sorted into groups of laboratories using comparable methods or instruments called "peer groups." When the peer group is large enough, the results obtained from a participant are evaluated against results obtained by the peer group. When the number of participants using a particular

Integrate the PT samples into your normal daily workflow to demonstrate that your routine methods, testing staff, and policy for repeat testing produce accurate and reliable test results every day.

instrument or method is below a cut-off level established by the PT provider, or when a method not listed on the PT program answer sheet is reported, the participant is put into a similar group or is evaluated by a comparative method.

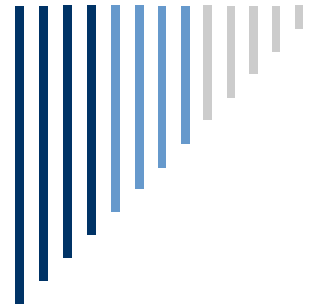
9. **Comparative Method:** A commonly used acceptable method that is considered widely compatible with most current methods. It is used to compare the various peer groups with a good historically acceptable method. It is also used as the target value for evaluation of some chemistry analytes and for evaluating participant results for those methods designated by insufficient numbers of participants to generate a separate peer group. If no comparative method has been designated, results will not be evaluated.
10. **Fixed Limits:** Used for evaluation of quantitative data. A mean value and SD are calculated for the peer group. Acceptable performance is established based on the target value +/- fixed limits. The target values are determined from either the peer group or comparative method mean.

CRITERIA FOR SATISFACTORY PT PERFORMANCE

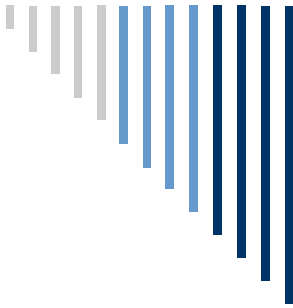
The grading criteria that PT providers use to evaluate PT results are defined by CMS in the *Federal Register*. A minimum overall testing event score of 80 percent for each regulated analyte, specialty, and subspecialty is required to pass and achieve satisfactory PT performance. The exception is ABO/Rh and compatibility testing, which have a minimum score of 100 percent for each testing event.

The following definitions are provided to help you interpret your laboratory's PT reports and performance:

1. **Testing Event:** The time period during which the laboratory receives their PT kit, performs the testing, and returns their results to the PT provider. There are three events per specialty, spaced throughout the calendar year, in which the laboratory must participate.
2. **Challenge:** The actual sample provided for PT testing. A minimum of five challenges per testing event are required for each regulated analyte.
3. **Satisfactory:** A “passing” score. A minimum score of 80 percent (except for ABO/Rh and compatibility testing, which have a minimum score of 100 percent) must be achieved for each testing event to achieve satisfactory PT performance. Also called “acceptable” by some PT providers.
4. **Unsatisfactory:** A failure to achieve a minimum satisfactory score for an analyte, specialty, or subspecialty for a single testing event. Also called “unacceptable” by some PT providers.
5. **Unsuccessful:** A failure to achieve a minimum satisfactory score for an analyte, specialty, or subspecialty for two consecutive or two of three testing events. Unsuccessful performance means your laboratory is at risk of losing your ability to test that analyte (if you fail again) until you pass two consecutive testing events.
6. **Consecutive (Repeated) Unsuccessful:** Unsuccessful PT performance followed by another unsatisfactory performance in either of the next two testing events. The laboratory will be directed to cease patient testing for the analyte, specialty, or



A minimum score of 80% (except for ABO/Rh and compatibility testing, which have a minimum score of 100%) must be achieved for each testing event to achieve satisfactory PT performance.



subspecialty for at least six months and obtain two consecutive passing scores before resuming patient testing.

- 7. Reinstatement of an Analyte:** The corrective action process followed to demonstrate that a laboratory is prepared to successfully begin retesting an analyte, specialty, or subspecialty after a period of cease testing.

TROUBLESHOOTING

Keep in mind that PT failures may be an indication of problems with instrumentation, personnel training, or quality control procedures. It is a good idea to retain and properly store remaining PT samples (if stable) to use for retesting if troubleshooting becomes necessary.

If your laboratory's PT result for an analyte is outside the range of "acceptable values," then there is a problem that must be identified and corrected. Use the following questions as a guide to identifying the root cause of the problem.

What is the scope of this problem?

- Is a single or are several analytes affected?
- Is a single or are several samples affected?
- Is a single or are several instruments affected?
- Are all ranges or just a certain range of test results affected?

Narrowing the scope of the problem may lead you in the direction of where corrective action is needed.

Can you identify any clerical errors?

- Copied onto answer sheet correctly?
- Numbers reversed on answer sheet?
- Was the proper method code used?
- Did the PT program enter your answer correctly?

If clerical errors are the cause of the problems, document your findings and take corrective action to avoid these types of errors in the future. If the PT program made a mistake, contact them immediately to have the error corrected. If this was not the source of the problem, continue:

Can you identify any technical processing errors or instrument failures?

- Quality Control acceptable at time of testing event?
- Misidentification of samples?
- Sample preparation error?
- Results accepted outside linearity of instrument?
- Are calibrations up to date?
- Has maintenance been performed appropriately?

Keep in mind that PT failures may be an indication of problems with instrumentation, personnel training, or quality control procedures.

- Have there been shifts, trends or other changes in the Quality Control results since the testing event?
- Were all reagents, controls, and samples stored properly and not expired?

If any of these questions identifies a possible problem, take appropriate corrective action, document and proceed to verify your corrective actions have worked by retesting frozen PT samples, requesting additional PT samples or using another form of external validation. Remember to document all corrective action and retain this in your laboratory's records.

DOCUMENTATION

It is very important to maintain accurate records of PT data during each testing event. The following items highlight some key points for successful documentation of PT performance.

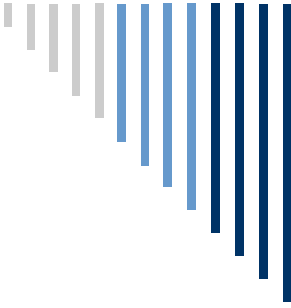
- Document each step of the handling, preparation, processing, and examination of the PT sample.
- The individual testing the PT sample and the laboratory director must sign an attestation statement that PT samples are tested in the same manner as patient specimens.
- The laboratory director should promptly review PT results with the laboratory staff. Document this review and address any unsatisfactory scores.
- Initial and date the PT data to indicate that the results have been reviewed.
- Retain all records of PT participation, including worksheets, instrument tapes or printouts, PT report forms, investigations and corrective actions, and signed attestation statements, for two years, except for immunohematology data which must be retained for ten years.

It is very important to maintain accurate records of PT data during each testing event.

HELPFUL HINTS FOR PROFICIENCY TESTING

Below are some hints to summarize how to comply and obtain optimal PT results:

- Enroll in PT for all federally regulated analytes.
- Give your PT provider your CLIA identification number. If you participate with an accrediting organization, provide the name of the accrediting body and your ID number. If you have a State ID number, provide this information as well.
- If your practice has satellite labs, each must be enrolled in PT and perform their own PT. Provide the unique CLIA number, and any other applicable ID numbers, for each physical location to your PT provider. This will ensure that PT results from satellite labs are identified correctly by your PT provider and forwarded correctly to CMS, the State, and other applicable agencies.
- If you do not receive your PT samples, refer to the shipping schedule provided by your PT program and alert them within the allotted time if a shipment has been missed. They will send a replacement shipment promptly if notified in time.
- Check PT kits immediately upon receipt. Contact the PT program promptly if PT samples are missing or damaged so that you can receive a replacement.
- If you cannot perform PT for any analyte normally tested in your laboratory due to circumstances beyond your control, notify your PT provider in writing. List the



analyte(s) affected and give the reason for lack of performance. Your PT provider may grant an exclusion if they feel the situation warrants it. This will result in your laboratory receiving a passing for the analyte for that event rather than a failing score. **Note:** PT providers will not grant multiple requests for exclusions!

- Strictly follow the PT provider's storage and handling requirements for the PT samples.
- Do not send PT samples to another laboratory, and test the PT samples in the same manner as patient specimens.
- Use a volumetric pipette to reconstitute lyophilized PT samples. Syringes are not accurate enough, and will markedly increase your chances of unsatisfactory PT performance.
- Analyze PT samples within the time frame provided by the PT provider.
- Avoid clerical errors when completing PT answer forms. Be sure to enter the correct result in the correct space on the form. Institute a quality assurance measure of having another staff person double check the answer sheet before submitting it to your PT provider.
- Identify and enter the correct instrument or method code so you are graded among your peer group. If you are not sure which method code to use, telephone your PT program's Customer Service area for help.
- If you do not perform a particular analyte listed on the answer form, use the correct code for "Test Not Performed" to indicate this. Answer forms left blank could be considered as a failure to participate, reflecting negatively on your score.
- Make and retain copies of all answer forms before submitting your results to your PT provider.
- Be sure that the attestation form is signed and submit your results by the due date.
- When results are received, carefully review your scores and participant summary reports, follow up on reasons for PT failures, correct them, and document all corrective actions in your lab's records.
- Perform a self-evaluation of any 100% scores that do not reflect your lab's actual performance. This can happen when there is no consensus in grading.
- Promptly notify CMS and/or your accrediting agency of any changes to your test menu and enroll in PT for any new analytes at the first opportunity.
- If you report your PT results to the PT provider electronically via a website, you must still print, sign, and maintain the attestation page.

Additional Resources:

COLA Accreditation Manual

The COLA Client Portal, *COLAcentral* offers free Resources to COLA labs.

CLIA Regulations , Subparts H, I, K <http://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5>

CLIA-approved PT Programs

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html

CMS Brochure #8: Proficiency Testing

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html

LabUniversity online courses at www.labuniversity.org :

Proficiency Testing

QSE Assessments

Improving Proficiency Testing Performance (free to COLA labs on COLAcentral)