COLA
Clinical Laboratory Accreditation

COLA Primers
Accreditation

COLA PRIMER 8

Proficiency Testing

• Overview•

Proficiency Testing (PT) is an independent, external assessment providing feedback on your laboratory performance and how it compares to other laboratories using the same instrument or kit. Laboratories gain significant information about their performance as a result of participation in a PT program.

The CLIA-approved PT program sends sets of unknown samples to your laboratory. The laboratory tests the samples and reports their results back to the PT program. The PT program grades the results and sends them back to the laboratory for review.

Proficiency Testing is an important component to the laboratory's overall quality. It provides a check to verify the accuracy and reliability of your laboratory's test results. A list of CLIA-approved Program providers can be found on the CLIA Website:
https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ptlist.pdf

• Proficiency Testing Enrollment•

The Laboratory Director and/or Technical Consultant/Supervisor must verify that the laboratory is enrolled in PT for all regulated analytes the laboratory is performing each year. Once enrolled the PT provider sends an order confirmation. This should be reviewed to ensure it is correct. If changing to a different PT provider, notify COLA with the new PT provider's information. COLA notifies CLIA of any test menu changes that affect the addition or deletion of a subspecialty or specialty.

COLA laboratories are required to notify COLA within 30 days of any PT provider or test menu changes. Once enrolled with a CLIA-approved PT provider, the laboratory may not change to a different provider for one year. If adding a new regulated specialty, subspecialty or analyte in the middle of a calendar year the laboratory must enroll in PT as soon as possible and complete the PT for the remainder of the year.

NOTE: *COLA does not provide proficiency testing samples as part of its services. COLA monitors the laboratory's performance in proficiency testing as part of the accreditation process.*

• Regulated Analytes•

CLIA regulations state that laboratories must enroll in PT for all ***regulated analytes*** and must authorize the forwarding of their PT results to CLIA. If COLA accredits the laboratory, they must notify the PT provider to forward results to COLA as well as CLIA. Make sure to include your CLIA number and COLA number on your enrollment. A list of the regulated tests can be found in COLA Primer 7 – *Regulated Analytes*; in the CLIA regulations under Subpart I, *Proficiency testing Programs for Non-Waived testing;* or in CLIA brochure #8 - *Proficiency Testing Dos and Don'ts*. Both can be found on the CLIA Website. See Other Resources at the end of this document.

Enrollment for regulated analytes provides five PT samples (challenges) three times a year for each specialty. For regulated analytes under the specialty of Bacteriology, proper enrollment requires a

minimum of five challenges per subspecialty for each event. Select modules that cover the methods/procedures performed in your laboratory (e.g., antigen detection, gram stain, bacterial identification and susceptibility testing).

Additionally,

- If a regulated analyte is performed using more than one instrument or method, the primary method must be designated for CLIA PT compliance. COLA requires that method comparisons (e.g., split sample testing) be performed, between the instruments or methods, twice a year. (See COLA Primer on Split Specimen Analysis)

- In any state where the State Department of Health requires laboratories to enroll in the state-offered PT program for particular analytes (i.e., syphilis and gonorrhea), COLA accepts the results from those programs even if the state program is not a CLIA-approved PT program. The laboratory must notify COLA of their participation in the state program and provide written authorization for the state to release results to COLA.

● Unregulated Analytes●

CLIA requires laboratories to take steps to assure the accuracy of ***unregulated analytes***. This can be accomplished through split specimen analysis with another laboratory or enrollment in PT with a CLIA-approved program. COLA strongly recommends that laboratories perform PT on unregulated analytes as an added measure of external quality assessment. The PT programs offer modules with 2-5 challenges.

If the laboratory is not enrolled in PT for unregulated analytes, then some form of external comparison, such as split specimen analysis, must be performed on five samples twice yearly. See COLA Primer 9 on Split Specimen Analysis.

● Waived Tests●

CLIA does not require PT for ***waived tests***. COLA believes that waived testing is also important to patient care. COLA encourages participation in PT for waived testing. Most of the PT providers offer a waived testing module. A list of waived tests can be found on the CLIA website. See Other Resources at the end of this document.

● Proficiency Testing Events ●

Once you have enrolled in a PT program, you receive a shipping schedule for the PT events. This provides you with the dates the samples are shipped to your laboratory. It is important to note the shipping dates. If your shipment does not arrive by the expected date, you need to contact your PT provider.

● Receiving Your PT Events ●

In your shipment there are step-by-step instructions for the storage, preparation and testing of the PT samples.

1. Record the date you received the shipment and document the condition of the shipment.
2. Check to ensure all the samples required are present and that there are no leaking or broken vials. If problems are identified, notify the PT provider immediately. They may be able to supply you with replacements.
3. Take note of the deadline set by the PT provider. for the submission of your results. Your results must be submitted by the date provided. Failure to submit on time results in a 0% score for all analytes.
4. Samples are to be rotated among the testing staff, when applicable. Assign the samples to your testing staff along with copies of the directions. It is a good idea to develop a method to keep track of what tests are being performed by each of the testing personnel. A spreadsheet is a good way to monitor this process and assists you later when doing your competency evaluations.

● Preparation For Testing ●

Follow the instructions from the PT provider for proper storage, preparation and testing of the PT samples. Different types of samples may be shipped. They may include but are not limited to:

1. Liquid samples: these samples are ready to use.
2. Lyophilized (freeze-dried) samples: these require reconstitution using specified solutions (which may be provided). When reconstituting PT samples, always use pipettes that are certified for accuracy. **Do not** use syringes for reconstitution. They are not designed for use in the laboratory for accurate dispensing, reconstituting or diluting of PT samples.
3. Dry loop samples: for bacteriological identification and susceptibility testing.
4. Color photographs: for some microscopic tests (e.g., urine sediment, pinworm, wet prep, WBC differentials).
5. Prepared glass slides: for tests such as gram stains and KOH preps.

● Testing PT Samples ●

PT is used to evaluate the quality of the test results that your laboratory obtains every day you report patient results.

- PT samples are to be treated in the same manner as patient specimens. It is important that you do not take extra steps, such as running extra QC or additional calibration, to ensure you get the correct results.
- Test PT samples along with the regular patient workload using routine methods.

- Test PT samples the same number of times as routine patient specimens are tested. The laboratory must not repeat testing or take an average of test results unless this policy also applies to patient specimens.
- There may be no inter-laboratory communication of results until after the PT submission date. If the laboratory shares employees with another laboratory, comparison or sharing of results between laboratories is strictly prohibited. If shared employees have performed a PT event in one laboratory, they should not perform the same event in another laboratory.
- The laboratory must not send PT samples or portions of samples to another laboratory, even if the normal patient procedure is to send reflex, distributive, or confirmatory testing to another laboratory. Any laboratory that CMS determines intentionally referred its PT samples to another laboratory for analysis will have its CLIA certification revoked for at least one year. COLA will deny accreditation to a laboratory if it intentionally refers a PT sample to another laboratory for analysis. COLA will not accept reapplication for one year.
- Any laboratory receiving PT samples from another laboratory for testing must notify CMS or COLA of the receipt of those samples. Failure to notify CMS or COLA may result in revocation of the laboratory's CLIA certificate. COLA will deny accreditation to a laboratory if it intentionally accepts a PT sample from another laboratory for analysis. COLA will not accept reapplication for one year.
- If you are not able to test the PT samples by the deadline (e.g., instrument broken, lack of reagents, etc.), call the PT provider to be "excused" from the event to avoid failing the event. In addition, you must indicate this information on your PT result form (paper or PT website) and submit the form before the deadline to avoid an unsatisfactory score. COLA should be notified of the situation.

Once testing is complete, properly store leftover PT sample material until the results for the event are received.

● Submission of Data ●

After testing is completed, fill out the data submission forms included in the shipment or enter your results electronically on the PT provider's website. If mailing results, make sure they are mailed before the deadline set by the PT program. Retain copies of the following for at least 2 years (10 years for immunohematology):

1. Copies of the instructions provided in the PT shipment.
2. Raw data for tests performed (e.g., instrument printouts, patient logs, worksheets).
3. Copies of the results submitted, whether paper or electronic, and the date submitted.
4. Copies of the Attestation forms, either paper or electronic, with the signatures of the Laboratory Director or qualified designee and all testing personnel participating in the PT event. If the Attestation form is electronic, the Laboratory Director or qualified designee and all testing personnel participating in the event must physically sign the attestation form.

●Review of Results●

When your PT results arrive, document the date received and submit the results to the Laboratory Director or qualified designee for review.

1. Review for results that are not graded or given 100% due to lack of consensus or lack of a peer group. These results should be compared with the information provided by the PT program in the Data Summary Report. The laboratory must perform a self-evaluation of those results and document their findings. Take appropriate corrective action if required.
2. Review for results that are given a passing score of less than 100%. The laboratory should perform a self-evaluation of those results and document their findings. Take appropriate corrective action if required.
3. Failure to submit results for grading to the proficiency testing provider by the cut-off date results in a grade of 0% for all analytes involved. Any analyte that is not graded should be compared to the information provided by the PT Program in the Data Summary Report. The laboratory should perform a self-grading of those results and document their findings and any corrective actions taken. A Quality Assessment (QA) review of the reporting process should be evaluated, and action taken to prevent this from happening in the future.
4. Review for unacceptable results. The criteria for satisfactory performance are a minimum score of 80% for all analytes (except a minimum score of 100% for unexpected antibody detection, ABO/Rh and compatibility testing). For analytes in the same specialty, the scores are averaged to obtain an overall specialty score. The laboratory should investigate the failures and document the outcome of the investigation and corrective action taken.

● Unacceptable PT Results ●

1. If your laboratory fails a single testing event, it receives a performance score of "**unsatisfactory**" for that analyte, subspecialty, or specialty and your laboratory must take appropriate action to identify the problem, correct it, and document the corrective action in the laboratory records. These records are reviewed by the surveyor during your laboratory's on-site survey.
2. If your laboratory fails to achieve a minimum satisfactory score in two consecutive, or two of three consecutive testing events for an analyte, subspecialty, or specialty, you receive a performance score of "**unsuccessful**" for that analyte, subspecialty, or specialty. Unsuccessful performance means your laboratory is at risk of having to cease testing that analyte, if you fail again within the next two consecutive testing events, or if you have repeated unsuccessful performance within 12 events. You must seek consultation to remedy the causes of the failures. COLA requires you to submit written documentation of the corrective action taken.
3. CLIA and COLA monitor each of their laboratories' performance for regulated analytes and specialties and contact the laboratory in the event of PT failure with information on corrective action and troubleshooting tips.
4. Please note that laboratories receive scores from their proficiency testing providers prior to COLA receiving them. Laboratories should review their scores and begin to perform and document corrective action immediately once they receive their graded results rather than waiting for notifications from COLA.

• Cease Testing •

As a result of the CLIA regulations, proficiency testing failures are a major concern to laboratories. Laboratories that demonstrate "unsuccessful" PT performance a second time over 12 PT events. for the same regulated analyte, subspecialty or specialty are directed to cease testing the regulated analyte, subspecialty, or specialty for a minimum of six months, and until the laboratory demonstrates satisfactory performance for two consecutive graded PT testing events.

For unregulated analytes with repeated unsuccessful PT, COLA requires the laboratory to cease testing the unregulated analyte, subspecialty, or specialty until the laboratory demonstrates satisfactory performance for two consecutive graded PT testing events.

• Troubleshooting •

PT failures may be an indication of problems with the instrument, personnel training, or quality control procedures. The laboratory should retain and properly store the remaining PT samples (if stable) to use for troubleshooting.

1. Review documents for clerical errors. If the error is in the proficiency testing provider's results, notify the PT provider as soon as possible for a corrected report.
2. Repeat testing, if possible. If samples fall within range on repeat, the problem could be a sample handling problem. Observe testing personnel for problems with technique and determine whether they are correctly following the procedure.
3. Review QC records for shifts and trends, maintenance logs for any maintenance performed, and calibration records to confirm calibrations were performed as required and passed.
4. Review instrument service records to see if any service was performed before or after the results were submitted.

• Remedial / Off-schedule Samples •

Remedial, also referred to as off-schedule samples, are additional samples separate from your regular scheduled PT samples that may be used for troubleshooting and reinstatement purposes. You may obtain remedial PT samples from any of CLIA-approved PT provider.

NOTE: *Remedial samples may not be used in lieu of PT performance or to replace a missed event.*

NOTE*: If remedial samples are being used for reinstatement purposes, they must be graded by the PT Provider. COLA does not accept self-graded PT results.*

● Result Review Documentation ●

Once the review is completed, the results are to be shared with the testing staff. There should be documentation indicating this information was shared with each participating testing person. Documentation could be in the form of laboratory meeting minutes, a sign-off sheet, or documentation on the result report. All documentation is to be kept for a minimum of 2 years (10 years for immunohematology).

● Proficiency Testing QA Review ●

The laboratory needs to perform a QA review of proficiency testing at least annually. This review helps the laboratory ensure all documentation is available for the surveyor during their survey.

1. Is the laboratory enrolled in PT for the coming year?
2. Are all the regulated analytes enrolled in PT?
3. Are unregulated analytes enrolled in PT or is split specimen analysis performed?
4. For each PT event look for:
    a. Copies of raw data, PT instruction booklets, copies of data entered online or mailed.
    b. Attestation form signed by LD and testing personnel.
    c. Copy of graded results reviewed by the Laboratory Director or qualified designee and testing staff.
    d. Documentation of corrective action taken for failures, passing results less than 100%, and not-graded results given a 100%.
    e. Copy of PT enrollment for the coming year.

Other Resources:

1. COLA Accreditation Manual
2. COLA client portal, COLAcentral® offers free resources to COLA laboratories
3. CLIA Regulations, Subparts H, I, K *https://www.CMS.gov/Regulations-and-Guidance/Legislation/CLIA*
4. CLIA-Approved PT Programs *https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ptlist.pdf*
5. CLIA Brochure #8: Proficiency Testing *https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures*
6. CLIA categorization of waived tests *https://www.cms.gov/Regulations-and-guidance/Legislation/CLIA/Categorization_of_Tests*