



Clinical Laboratory Improvement Amendments (CLIA)

PROFICIENCY TESTING and PT REFERRAL

DOs and DON'Ts



Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988, establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results, regardless of where the test was performed. Final CLIA regulations were published in the Federal Register February 28, 1992. The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed. Final CLIA Quality Systems laboratory regulations, published by the CDC and CMS, became effective April 24, 2003. Updated CLIA PT Referral regulations, published by CMS, became effective May 2, 2014 and May 12, 2014.

IMPORTANT INFORMATION FOR LABORATORIES PERFORMING NON-WAIVED TESTS

Frequently Asked Questions about CLIA Requirements for Proficiency Testing (PT) and PT Referral

The following information applies only to CMS inspected laboratories. If your laboratory is accredited, you MUST follow the proficiency testing requirements of your accreditation organization. This does not apply to cytology PT.

What is proficiency testing?

Proficiency testing, or PT, is the testing of unknown samples sent to a laboratory by an HHS-approved PT program. Most sets of PT samples are sent to participating laboratories on a scheduled basis (usually three times per year). After testing, the laboratory reports its sample results back to their PT program. The program grades the results using the CLIA grading criteria and sends the laboratory their scores. CMS and accreditation organizations routinely monitor their laboratories' performance.

Why is PT important?

PT is important because it is a tool the laboratory can use to verify the accuracy and reliability of its testing, and can also be used to validate the entire testing process, including competency of your testing personnel. Routine reviews of PT reports by the laboratory staff and the laboratory director will alert them to areas of testing that are not performing as expected as well as indicate subtle shifts and trends that, over time, would affect their patient results.

If I only perform waived testing, am I required to perform PT?

PT is not required for any test classified as waived. However, enrolling in a PT program and performing PT on your waived test(s) will provide you with an excellent indication of the accuracy and reliability of your waived test results thus improving the quality of testing you provide for your patients. It also serves to demonstrate the accuracy of your testing if it is ever questioned. You may check the FDA web site to determine whether your test(s) are waived: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>.

Please note: *If your laboratory enrolls in PT for waived testing, all regulations related to PT referral apply.*

Is PT required for all non-waived testing?

PT is required for only the limited number of tests found in Subpart I, Proficiency Testing Programs for Non-Waived Testing, of the CLIA regulations. If your laboratory

performs any of the tests found in Subpart I, you must enroll in a CMS-approved PT program and perform PT on **each** of the tests. We refer to the tests listed in Subpart I as “regulated” analytes.

A listing of these tests may be found on pages 10-11 of this brochure or can be found on the CLIA website link at the end of this brochure.

Can I enroll in any program that offers PT?

You must enroll in a CMS-approved PT program. A detailed listing of these programs along with their contact information and the tests for which they are approved is available at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html>. Click on “Proficiency Testing Programs”.

What must I do to enroll in PT?

Using the list on the CLIA web site, choose one (more than one, if your director wishes) of the approved PT program(s) that offer(s) the tests you perform in your laboratory. The PT program will assist you with your enrollment. Call your PT program; the PT representatives will help you enroll properly. Assisting you with proper enrollment is a CLIA requirement for approved PT programs. If more than one PT program is chosen for any given test, the lab must designate which PT program will be used to meet CLIA requirements. The program will notify CMS of your enrollment and the PT testing you have signed up to perform.

If I have more than one testing site, do I need to enroll in PT for each site?

PT enrollment and participation is required for **each** CLIA certificate, i.e., PT per certificate (excluding certificate of waiver). If you offer non-waived testing at more than one site, but the testing is all included under one certificate, you must enroll in an approved PT program(s) for all the “regulated” analytes covered under that certificate, **not** for each site. However, PT testing should be rotated through all of the sites under the single CLIA certificate. For example, one event is performed by Site “A”, then the next event would be tested at Site “B”, and so on until all sites have participated. Continue to rotate events between sites. PT events should never be shared between sites (e.g., each PT event should not be given to all of the sites to be tested and produce results which are then compared or averaged for submission to the PT program). **If you have a separate certificate for each site, you must enroll in PT for the tests performed at each site.** It also may be helpful to enroll each site in a different PT provider to avoid any appearance of PT referral.

May I change my PT program whenever I wish as long as it is CMS-approved?

You may **not** randomly change from one approved PT program(s) to another during the first year of participating with a program. Laboratories must enroll and participate in one approved program or programs for one year before designating a different program. You must also notify CMS before any change in PT program.



If my laboratory is new or if I add a new “regulated” specialty, subspecialty or analyte in the middle of a calendar year, how quickly must I enroll in PT?

Laboratories operating under a new certificate and/or adding new “regulated” testing must enroll in PT as soon as possible and complete the PT for the remainder of the year.

If I perform “unregulated” testing (tests for which PT is not required), am I required to check the accuracy and reliability of those tests?

CLIA requires laboratories to take steps to assure the accuracy of testing in lieu of testing PT samples. CLIA requires that, at least twice annually, you verify the accuracy of any test or procedure that you perform that is not listed in Subpart I.

How do I verify the accuracy of the tests that do not have PT required?

A few examples of ways to check the accuracy of testing not listed in Subpart I are as follows:

- Split a **patient’s specimen** (*never split a PT sample*) with another laboratory that offers the same test(s). Your director should review your results and the other laboratory’s results for acceptability.
- Enroll in PT with a CMS-approved program (**Note:** *If you enroll and participate in PT with a CMS-approved PT program, all regulations related to PT referral apply regardless if the analyte is listed in Subpart I or certificate type*).

Are there ever circumstances in PT that require my laboratory to verify the accuracy of “regulated” tests?

Yes there are. There are times when the PT program cannot fully evaluate your samples and you must verify accuracy of those results. You must verify the accuracy of tests for which PT is required if any of the following occur:

- When your results are submitted to the program after the deadline and are considered a late submission, your laboratory grade will be zero.
- If you did not test your PT samples at all, your laboratory grade will be zero.
- There are instances when your grade does not reflect your performance because there was no consensus among all laboratories performing the PT sample(s). You will see this identified by the PT program on your results report as “Not Graded” or with a code to indicate the reason the sample was not graded. You will be assigned an artificial score of “100%”, but that does **not** reflect your actual performance or the accuracy of your laboratory’s testing.

If I perform the same test using two different test systems, must I perform PT on both test systems?

PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

How long do I have to test and report the PT samples?

The instructions that accompany the PT samples will state the exact date by which you must return your PT results to the program. It is very important to return them on time. A late submission will result in a score of zero (0 %) for the testing event.



What steps should I take after I have received my PT results from the PT program?

Always review your results with your co-workers and your director. Your PT program will include an evaluation for each of the five challenges for each test or analyte in the PT event and will detail the performance of each test system used by the laboratories enrolled with their program. You must evaluate your PT results against the scores published by the PT program.

This should be done for **all** PT results, even those with passing scores. If you receive an 80% score, you should investigate why one of the five samples was outside the acceptable range of results. Document your investigation and what you did to correct the problem that caused the challenge failure. If you discover the issues which led to the 80% score, it could lead to more serious failures in the future.

What must I do if I do not get a passing score when the PT program grades my results?

Re-review the results that were submitted to the PT program for scoring for any obvious errors (this should have been done prior to submitting your results to the program). Clerical or transcription errors are considered incorrect results. The director of your laboratory, as well as the personnel who performed the testing of the PT samples, should compare their PT results with the inter-laboratory comparison evaluations provided by the PT program. **You must take remedial actions**, i.e., determine the cause of the error or errors, correct it (them), **and document your actions**. You must also look back at your patient results reported during the period when your PT was unsatisfactory or unacceptable. If the review identifies that patients were affected, or potentially affected, during this period of time, **you must address the patient results**. Continually monitor the test system performance, review the results of the quality control materials, and discuss with your director to be certain the test system is operating properly and producing accurate results. Depending upon the test system's performance and your director's decision, you may need to contact the manufacturer of the test system for assistance.

What does unsatisfactory PT performance mean?

Unsatisfactory PT performance means failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event. This may also be referred to as "unacceptable" performance.

What does unsuccessful participation in PT mean?

Unsuccessful participation in PT means any of the following:

- Unsatisfactory performance for the same analyte in two consecutive or two out of three testing events.

- Repeated unsatisfactory overall testing event scores for two consecutive or two out of three testing events for the same specialty or subspecialty.
- An unsatisfactory testing event score for those subspecialties not graded by analyte (that is, bacteriology, mycobacteriology, virology, parasitology, mycology, compatibility testing, unexpected antibody detection, antibody identification) for the same subspecialty for two consecutive or two out of three testing events.

What does unsuccessful PT performance mean?

Unsuccessful PT performance means a failure to attain a satisfactory score for an analyte, subspecialty, or specialty for two consecutive or two of three consecutive testing events.

**Please note: Unsuccessful performance and unsuccessful participation are interchangeable. CMS inspectors generally will use unsuccessful performance.*

If I do not successfully participate in PT, what happens?

If your laboratory has not had a prior unsuccessful performance for any PT analyte, subspecialty, or specialty, the CLIA regulations, under certain circumstances, may permit technical assistance and training to take place, rather than a more serious sanction. However, repeated unsuccessful PT performance for that same analyte, subspecialty, or specialty may result in your laboratory no longer being allowed to perform the failed testing.

You may decide to **voluntarily stop** testing the unsuccessful analyte, subspecialty, or specialty. As soon as you receive your PT results indicating an unsuccessful performance, you must notify your State Agency and Regional Office CLIA consultant* that testing of the unsuccessful analyte, subspecialty, or specialty has been stopped voluntarily.

**Note: The notification that you have ceased testing must be made before you receive a letter from your CMS Regional Office imposing a cease testing sanction. If you voluntarily cease testing and then successfully perform two consecutive PT events for the analyte, subspecialty, or specialty that was unsuccessful, your Medicare and Medicaid reimbursement may not be affected.*

My laboratory has been required to cease testing an unsuccessful analyte, subspecialty, or specialty. What must I do to be able to resume testing?

First, you must demonstrate that your laboratory has identified the reason(s) for your unsuccessful performance and has corrected it (them). Be sure to document this process. Secondly, when you are certain you have corrected the problem(s), your laboratory must perform two consecutive PT events (re-instatement PT) successfully, which will demonstrate correction of the problem(s).

If sanctions have been imposed and you have been required to cease testing, your Medicare and Medicaid reimbursement and your CLIA certificate will be suspended or limited for a six month period. However, you may purchase your re-instatement PT events at any time after you have identified and corrected the problem(s) that caused the unsuccessful performance. You should purchase these samples from your PT program, but you may obtain them from any CMS-approved PT program.

Do I need to keep records of my PT testing?

Yes, you must keep a copy of all your records, such as the step by step PT sample preparation and handling, all the steps taken in the testing of the sample, instrument printouts, a copy of the PT program results form used to record and submit your PT results (includes the attestation statement), a print screen if results are entered electronically, and the PT program's evaluation of your laboratory's performance, etc. These copies must be maintained for a minimum of **two years** from the date of the PT event. If any corrective actions are taken as a result of an unsatisfactory or unacceptable score, records of these actions must also be maintained for two years.

Do I test my PT samples any differently than I test patient specimens?

PT samples must be tested in the same manner you test patient specimens. This means testing the PT samples the same number of times as you would patient specimens, at the same time as patient specimens, by the same personnel that routinely test the patient specimens, and using the same test system, including analyzer and reagents, that is routinely used for the patient specimens. PT samples should be rotated among the testing personnel in your laboratory.

Please note that some PT sample preparation may be necessary before testing. It is important for your staff to read the specimen handling and preparation sections of the PT booklet that comes with each event to determine if PT samples require special treatment prior to testing. In other words, after preparation, PT samples must be treated in the same manner as patient specimens. However, as stated below, **never send PT samples out of your laboratory for any reason**, even if you routinely send out patient specimens for additional testing. Your laboratory should only test the PT sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing (i.e., distributive, confirmatory, reflex testing).

What is PT Referral?

Quite simply, PT referral is when one laboratory (Laboratory A) sends its PT samples to another laboratory (Laboratory B) or multiple laboratories (Laboratories B, C, D, etc.) for any reason. Whether or not acts are authorized or even known by the laboratory's management, a laboratory is responsible for the acts of its employees. Generally, PT referral is considered to be intentional. Over the course of the CLIA program, "Intentional" has been legally interpreted to mean the "intent to act" regardless of motivation. However, in cases of PT referral where one laboratory refers their PT samples to another laboratory for testing, but that testing is limited to distributive, confirmatory, or reflex testing, and if the referring laboratory had an approved procedure in place at the time of the referral and the laboratory had not been sanctioned for PT referral previously, the referral will be considered improper rather than intentional.

Your laboratory will need to have procedures in place and train employees on those procedures to prevent staff from forwarding PT samples to other laboratories even in



instances in which they would normally forward a patient specimen for testing.

Please note: PT referral applies to any PT samples referred to another laboratory for testing regardless if they are analytes found in Subpart I (“regulated analytes”), not found in Subpart I (“unregulated analytes”), or waived tests.

What happens if my laboratory refers PT samples to another laboratory for testing?

The PT referral regulations, effective May 2014, provide a specific framework for application of sanctions for PT referral cases and are based on the severity and extent of the violation. These regulations include three categories of sanctions for a PT referral to be applied under certain specified conditions:

- **Category 1** is for the most egregious violations, encompassing cases of repeat PT referral, regardless of circumstances revolving around the violation, and cases where a laboratory reports another laboratory’s PT results as its own to the PT program on or before the PT event close date.
- **Category 2** is when a laboratory refers its PT samples to another laboratory for analysis and obtains test results for the PT samples from the other laboratory on or before the cut-off date for the PT event, but reports its own PT sample results to the PT program.
- **Category 3** includes cases of PT referral where the laboratory refers its PT samples to another laboratory for analysis and obtains test results for the PT samples from the other laboratory after the cut-off date for the PT event. This category also includes the carve-out for confirmatory, distributive, and reflex testing.

Each case of potential PT referral will be evaluated to determine if PT referral occurred, and if so, which of the three categories is applicable to the specific facts.

Please note: Repeat proficiency testing referral means a second instance in which a proficiency testing sample, or a portion of a sample, is referred, for any reason, to another laboratory for analysis prior to the laboratory’s proficiency testing program event cut-off date within the period of time encompassing the two prior survey cycles (including initial certification, recertification, or the equivalent for laboratories surveyed by an approved AO). This means that if a laboratory has been sanctioned for **any** category of PT referral in the prior two survey cycles, the second, or “repeat” referral will be considered a Category 1.

May I discuss my PT results with another laboratory?

Never discuss your PT results with another laboratory and **never** enter into discussion with another laboratory about their PT results before the PT event cut-off date. This activity may result in sanction(s) taken against your CLIA certificate.

May I send my PT samples to another laboratory to see if they get the same results as I do?

Never send your PT samples to another laboratory even if you send your patient specimens to another laboratory. (Please read the PT results sheet carefully and select “Would refer” or “Test not performed” in these instances.) Sending PT samples to

another laboratory for testing is considered PT referral and will cause serious action(s) to be taken against your laboratory, and may cause adverse actions against your laboratory director and the laboratory owner. The penalties may include loss, suspension, or limitation of your laboratory's CLIA certificate; your director's being unable to direct a laboratory for two years; your laboratory operator/laboratory director/owner losing the rights to own or operate a laboratory for two years; and a directed Plan of Corrections and/or civil money penalty (CMP).

Your laboratory's name will be listed on the CMS Laboratory Registry on the CMS web site.



Be **extremely cautious not** to send PT samples out for a confirmatory, distributive, and reflex testing:

- **Confirmatory testing** means testing performed by a second analytical procedure that could be used to substantiate or bring into question the result of an initial laboratory test.

Example: Pos HIV screen or Pos Lyme → Western Blot

- **Distributive testing** means laboratory testing performed on the same specimen, or an aliquot of it, that requires sharing it between two or more laboratories to obtain all data required to complete an interpretation or calculation necessary to provide a final reportable result for the originally ordered test. When such testing occurs at multiple locations with different CLIA certificates, it is considered distributive testing.

Example: Protein Electrophoresis – Lab A does electrophoresis, Lab B does Total Protein

- **Reflex testing** means confirmatory or additional laboratory testing that is automatically requested by a laboratory under its standard operating procedures for patient specimens when the laboratory's findings indicate test results that are abnormal, are outside a predetermined range, or meet other pre-established criteria for additional testing.

Example: Pos Hep A screen → Total vs IgM, Pos E.coli → serotyping

What do I do if I receive PT samples from another laboratory for testing?

As soon as you identify them as PT samples, notify your inspecting agency (your accreditation organization if your laboratory is accredited or your State Agency inspectors) that you have received PT samples from another laboratory. Tell them the name of the other laboratory and the test(s) requested, but **do not test** the samples.

Be sure to read the CLIA regulations for proficiency testing and PT referral (available on the CMS web site). This brochure is not intended to replace or be a substitute for the CLIA regulatory requirements. It is intended only to present most of the proficiency testing requirements in layman's terms.

LIST OF NON-WAIVED TESTING FOR WHICH PT IS REQUIRED

MICROBIOLOGY

Bacteriology

Aerobic/Anaerobic Culture & Identification

Antibiotic Susceptibility Testing

Direct Bacterial Antigen Detection

Gram Stain

Mycobacteriology

Acid Fast Stain

Mycobacteriology Identification

Mycobacteriology Susceptibility Testing

Mycology

Culture and Identification

Parasitology

Presence or Absence of Parasites

Identification of Parasites

Virology

Direct Viral Antigen Detection

Viral Isolation and Identification

DIAGNOSTIC IMMUNOLOGY

Syphilis Serology

General Immunology

Alpha-1 Antitrypsin

Alpha Fetoprotein (tumor marker)

Antinuclear Antibody

Antistreptolysin O

Anti-Human Immunodeficiency Virus (Anti-HIV)

Complement C3

Complement C4

Hepatitis B Surface Antigen (HBsAg)

Hepatitis B Core Antibody (Anti-HBc)

Hepatitis Be Antigen (HBeAg)

Immunoglobulins, total:
IgA, IgG, IgM, IgE

Infectious Mononucleosis

Rheumatoid Factor

Rubella

CHEMISTRY

Routine Chemistry

Alanine Aminotransferase (ALT/SGPT)

Albumin

Alkaline Phosphatase

Amylase

Aspartate Aminotransferase (AST/SGOT)

Bilirubin, total

Blood Gases:
pH, pCO₂, pO₂

Calcium, total

Chloride

Cholesterol, total

Cholesterol, HDL
Creatine Kinase, total
Creatine Kinase, Isoenzyme (CK-MB)
Creatinine
Glucose
Iron, total
Lactate Dehydrogenase (LDH), total
LDH Isoenzymes (LDH1/LDH2)
Magnesium
Potassium
Sodium
Total Protein
Triglycerides
Urea Nitrogen
Uric Acid

Endocrinology

Cortisol
Free Thyroxine
Human Chorionic Gonadotropin
T3 Uptake
Triiodothyronine
Thyroid Stimulating Hormone
Thyroxine, total

Toxicology

Blood Alcohol
Blood Lead
Carbamazepine
Digoxin
Ethosuximide
Gentamicin

Lithium
Phenobarbital
Phenytoin
Primidone
Procainamide and Metabolite
Quinidine
Theophylline
Tobramycin
Valproic acid



HEMATOLOGY

Cell Identification
WBC Differential
Erythrocyte Count
Hematocrit
Hemoglobin
Leukocyte Count
Platelet Count
Fibrinogen
Partial Thromboplastin Time
Prothrombin Time

IMMUNOHEMATOLOGY

ABO Group
D (Rho) Typing
Unexpected Antibody Detection
Compatibility Testing
Antibody Identification



For additional information and guidance

Assistance for meeting the requirements is provided in Appendix C of the State Operations Manual, which is posted on CMS' CLIA website, shown below, under "Interpretive Guidelines for Laboratories". You can find a list of Regional Office and State Agency contacts there as well.

<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html>