Clinical Laboratory Improvement Amendments (CLIA)

PROFICIENCY TESTING AND PT REFERRAL

The following information only applies to CMS-inspected laboratories. It may not apply to accredited laboratories or cytology proficiency testing. Accredited laboratories must follow the accreditation organization's proficiency testing requirements.

PROFICIENCY TESTING

What's proficiency testing?

Proficiency testing, or PT, is the process used to evaluate a laboratory's performance. PT is a useful tool to:

- Verify testing accuracy and reliability.
- Validate the entire testing process, including the testing personnel competency.

Why is PT important?

PT reports can alert laboratory staff and the laboratory director to testing phases (for example, pre- or post-analytical) that aren't performing as expected. Routinely reviewing PT reports can also indicate subtle shifts and trends that, over time, could affect patient results.

How does PT work?

A HHS-approved PT program sends samples to your laboratory on a regular basis (usually 3 times each year) and then compares your laboratory's test results against CLIA grading criteria. When testing is complete, your laboratory reports its results to the PT program, which then grades the results and sends you a score. CMS and accreditation organizations routinely monitor your laboratory's score and overall performance.

Is PT required if I only perform waived tests?

No. PT isn't required for any tests that are categorized as waived because they're considered "low-risk" tests. However, enrolling in a PT program and performing PT on your waived test(s) can offer some benefits. For example, you'll better understand the accuracy and reliability of your waived test results, which can improve testing quality for your patients.

Check the Food and Drug Administration's (FDA) test complexity categorization website: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm.

Note: *If your laboratory enrolls in a PT program for waived tests, all regulations related to PT referral apply.*

Is PT required for all nonwaived tests?

PT is only required for the limited number of tests found in Subpart I, Proficiency Testing Programs for Nonwaived Testing, of the CLIA regulations. We refer to the tests listed in Subpart I of the CLIA regulations as "regulated" analytes. You must enroll in a HHS-approved PT program and perform PT on **each** of the regulated analytes your laboratory tests.

For a listing of the regulated analytes, go to pages 10-12 or visit the CLIA website: www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/proficiency-testing.

Can I enroll in any program that offers PT?

You must enroll in a HHS-approved PT program.

Visit the CLIA website for a detailed listing of these programs, contact information, and tests they're approved for at: www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/proficiency-testing.

How do I enroll in a PT program?

To enroll, follow these steps:

1. **Visit the CLIA website** for a detailed listing of these programs: www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/proficiency-testing.
2. **Choose a PT program(s)** that offers the test(s) you perform in your laboratory. If needed, you may select an additional PT program to cover all types of tests you perform in your laboratory. If you choose more than one PT program for any given test, you must designate which PT program you'll use to meet CLIA requirements.
3. **Call or email the PT program(s)** you'd like to enroll in to get started.

Note: *CLIA requires that approved PT programs assist you with your enrollment. The PT program will notify CMS of your enrollment and the PT testing you signed up to perform.*

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

PT enrollment and participation is required for **each** CLIA certificate, meaning one PT program per certificate (except if you have a certificate of waiver).

If you offer nonwaived testing at more than one site using the multiple-site exception (MSE) and all testing is under one certificate, you must enroll in an approved PT program for all regulated analytes covered under that certificate.

If I have more than one testing site, how should I perform PT at each site?

You should rotate PT through all of the sites under the single CLIA certificate. For example, test one event at Site "A", then test the next event at Site "B", and so on until all sites participate. Continue to rotate events between sites.

Never share PT events between sites or order the same PT event for multiple sites or instruments under one CLIA certificate. If you have a separate certificate for each site, you **must** enroll in PT for the tests performed at each site. It may be helpful to enroll each site with a different PT program provider to avoid any appearance of PT referral.

Can I change my PT program whenever I wish as long as it is HHS-approved?

No, you may **not** change from one approved PT program to another during the first year of enrolling in the program. Laboratories must enroll and participate in an approved program for **one calendar year** before they can change to a different HHS-approved program. You must notify CMS before you make any change to your 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 a PT program?

Laboratories must enroll in a PT program as soon as possible if they're:

- operating under a new certificate
- adding new regulated tests (which include specialties, subspecialties, or analytes)

Once enrolled, you must complete the PT program for the remainder of the calendar year.

If I perform "unregulated" testing (tests where PT isn't required), am I required to check the accuracy and reliability of those tests?

Yes. CLIA requires laboratories take steps to assure the accuracy of testing, even if PT isn't required. To comply with CLIA requirements, you must verify the accuracy of any test or procedure you perform at least 2 times each year.

How do I verify the accuracy of the tests that don't require PT?

To check these tests' accuracy, you can:

- Split **a patient's specimen** (never split a PT sample) with another laboratory that offers the same test(s). Your laboratory director should review your results and the other laboratory's results for acceptability.
- Enroll in a HHS-approved PT program.

Note: *If you enroll and participate in a HHS-approved PT program, all regulations related to PT referral apply regardless of certificate type or whether the analyte is listed in Subpart I of the CLIA regulations.*

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

Yes, there are times when the PT program cannot fully evaluate your samples and you must verify the accuracy of those results. You must verify the accuracy of tests for which PT is required in these situations:

- When you submit your results to the PT program after the deadline. This is considered a late submission, and your laboratory grade will be zero.
- If you didn't test your PT samples at all, your laboratory grade will be zero.
- When your grade doesn't reflect your performance because there wasn't consensus among all laboratories performing the PT samples. When this happens, your PT program will either state "Not Graded" or include a code to indicate the reason the sample wasn't graded on your results report. You'll get an artificial score of "100%", but that **doesn't** 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 only required for the test system, assay, or examination that you use as the primary method for patient testing.

For the Hematology specialty, should I enroll in the "cell identification" or "white blood cell differential" PT module?

- If you're performing **manual** cell identification, enroll in the cell identification PT module.
- If you're performing **automated** cell identification, enroll in the white blood cell differential PT module.
- If your laboratory performs both manual and automated cell identification, enroll in **both** PT modules.

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

The instructions that accompany the PT samples will include the exact date by which you must return your PT results to the PT program. It's very important to return them on time. Late submission will result in a score of zero for the testing event.

What should I do after I receive my PT results from the PT program?

Always review your results with your co-workers and your laboratory director. Your PT program will:

- Include an evaluation for each of the five samples for each test or analyte in the PT event.
- Detail the performance of each test system that the participating laboratory uses.

You must evaluate your PT results against the scores published by the PT program for **all** PT results, even those with passing scores. For example, if you receive 80%, you should investigate why one of the five samples was outside the acceptable range of results. Be sure to document your investigation and what you did to correct the problem that caused the sample failure. If you don't identify the issue(s) that led to the 80% score, it could lead to more serious failures in the future.

What should I do if I don't get a passing score when the PT program grades my results?

Make sure you re-review the results for any obvious errors (you should've already reviewed your results before submitting them to the PT program). Remember, clerical or transcription errors are considered incorrect results. Your laboratory director and personnel who tested the PT samples should compare their PT results with the inter-laboratory comparison evaluations the PT program provided.

If you didn't pass, **you must** take remedial action to determine the cause of the error(s) and correct them. Make sure you document your actions. As part of your remedial action(s), **you should:**

- **Monitor your test system.** Continually monitor the test system performance, review the results of the quality control materials, and discuss with your laboratory director to be certain the test system is operating properly and producing accurate results. You may need to contact the manufacturer of the test system for assistance.
- **Address the patients' results.** Also, look at past patient results and identify affected or potentially affected results during the timeframe that your PT was unsatisfactory.

What does "unsatisfactory" PT performance mean?

It means you failed to get the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event.

What does "unsuccessful participation" mean?

It means any of the following:

- Unsatisfactory performance for the same analyte in either 2 consecutive testing events, or 2 out of 3 testing events.
- Repeated unsatisfactory overall testing event scores for either 2 consecutive testing events, or 2 out of 3 testing events for the same specialty or subspecialty.
- Unsatisfactory testing event score for the same subspecialties not graded by analyte* for either 2 consecutive testing events, or 2 out of 3 testing events. *bacteriology, mycobacteriology, virology, parasitology, mycology, compatibility testing, unexpected antibody detection, antibody identification

What does "unsuccessful performance" mean?

It means failing to get a satisfactory score for an analyte, subspecialty, or specialty for either 2 consecutive testing events, or 2 out of 3 testing events.

What happens in "unsuccessful participation" or "unsuccessful performance" situations?

If your laboratory hasn't had previous unsuccessful participation or unsuccessful performance for any PT analyte, subspecialty, or specialty, CLIA regulations may permit technical assistance and training, versus a more serious sanction in certain situations. However, repeated unsuccessful participation and unsuccessful performance for that same analyte, subspecialty, or specialty may result in your laboratory no longer being allowed to perform the failed testing.

If you receive PT results indicating unsuccessful performance, you may decide to **voluntarily stop** testing the unsuccessful analyte, subspecialty, or specialty. In this situation, notify your State Agency (who will work with the CMS Enforcement Branch) that you voluntarily stopped testing the unsuccessful analyte, subspecialty, or specialty.

If you voluntarily stopped testing due to unsuccessful performance and then successfully perform 2 consecutive PT events for the analyte, subspecialty, or specialty that was previously unsuccessful, your Medicare and Medicaid reimbursement may not be affected.

> ***Note**: You must notify your State Agency that you voluntarily stopped testing **before** you receive a letter from the CMS Enforcement Branch imposing a "cease testing" sanction.*

My laboratory is required to cease testing. What must I do to resume testing?

1. You must demonstrate your laboratory identified the reason(s) for unsuccessful performance and corrected them. Be sure to document this process.
2. When you're certain you corrected the problem(s), your laboratory must successfully perform 2 consecutive PT events (reinstatement PT), which will demonstrate you corrected the problem(s).

If CMS imposed sanctions and you're required to cease testing, your Medicare and Medicaid reimbursement and your CLIA certificate may be suspended or limited for 6 months. However, you may purchase your reinstatement PT samples any time after you identified and corrected the problem(s) that caused the unsuccessful performance. Purchase these samples from your PT program or get them from any HHS-approved PT program.

Do I need to keep records of my PT?

Yes, you must keep a copy of all your records for at least 2 years from the date of the PT event. Records may include:

- The step-by-step PT sample preparation, processing, and handling instructions.
- All the steps taken to test the sample including result reporting.
- Instrument printouts, raw data, and manual entry logs.
- A copy of the PT program results form used to record and submit your PT results (including the signed attestation statement).
- A print screen if results were entered electronically.
- The PT program's evaluation of your laboratory's performance.
- All corrective action documentation, if applicable.

Do I test my PT samples differently than patient specimens?

You must test PT samples the same way you test patient specimens. This means:

- Testing the PT samples the same number of times as you would test patient specimens.
- Testing at the same time as patient specimens.
- Testing by the same personnel that routinely test the patient specimens.
- Using the same test system, including analyzer and reagents, that you routinely use for the patient specimens. You should rotate PT samples among your laboratory's testing personnel.

Note that in some situations, PT sample preparation may be necessary before testing. Your staff needs to read the specimen handling and preparation sections of the PT booklet that comes with each event to determine if PT samples require special preparation or treatment before testing. Once you've prepared the PT sample, you **must** test it in the same manner as patient specimens up until the point you'd refer a patient specimen to a second laboratory for additional testing (i.e., distributive, confirmatory, reflex testing).

Note: *Never send PT samples out of your laboratory for any reason, even if you routinely send out patient specimens for additional testing.*

PT Referral

What's PT Referral?

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.) to test for any reason. PT samples can include: analytes found in Subpart I of the CLIA regulations (regulated analytes), analytes not found in Subpart I of the CLIA regulations (unregulated analytes), or waived tests.

Your laboratory must have procedures in place and train employees on those procedures to prevent staff from forwarding PT samples to, or discussing PT results with, other laboratories even in instances in which they would normally forward a patient specimen for testing.

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

If this happens, your laboratory could be sanctioned based on the severity and extent of the violation. The PT referral regulations include three sanction categories that can be applied under certain conditions.

CMS will evaluate each case to determine if PT referral occurred, and if so, which of the three categories applies to the situation.

Can I discuss my PT results with another laboratory?

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

Can 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. Carefully read the PT results sheet. Select "Would refer" or "Test not performed" in these instances. Remember, sending PT samples to another laboratory for testing is considered PT referral and will result in serious action(s) against your laboratory, laboratory director, and owner. Penalties may include:

- Revocation, suspension, or limitation of your laboratory's CLIA certificate.
- Loss of the laboratory director's ability to direct a laboratory for two years.
- Your laboratory operator/owner losing the rights to own or operate a laboratory for two years.
- A directed Plan of Correction (dPoC) and/or civil money penalty (CMP).

Additionally, your laboratory's name will be listed on the CMS Laboratory Registry on the CMS website.

In addition, **do not** send PT samples out for 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**: Positive HIV screen or Positive Lyme → Western Blot confirmatory
- **Distributive testing** means testing that occurs at multiple locations with different CLIA certificates. In this situation, a laboratory performs testing on the same specimen (or an aliquot of it) and needs to share it with 2 or more laboratories to obtain all required data to complete an interpretation or calculation necessary for a final reportable result for the originally ordered test.
    - **Example**: Protein Electrophoresis – Laboratory A does electrophoresis, Laboratory B does Total Protein
- **Reflex testing** means confirmatory or additional laboratory testing that's 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**: Positive Hep A screen → reflexes to Total Hep A vs Hep A IgM

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

If you receive PT samples from another laboratory, notify your inspecting entity:

- CMS
- State Agency
- Accreditation organization

Make sure you tell them the name of the other laboratory and the test(s) requested, but **do not test** the samples.

NONWAIVED REGULATED ANALYTES

You're required to enroll in a HHS-approved PT program and perform PT on each of these non-waived tests or regulated analytes.

MICROBIOLOGY	
Bacteriology	Bacterial Detection and Identification Detection of the presence or absence of bacteria without identification Antimicrobial Susceptibility Testing Direct Bacterial Antigen Detection Bacterial Toxin Detection Gram Stain
Mycobacteriology	Acid Fast Stain Mycobacteriology Detection and Identification Detection of the presence or absence of mycobacteria without Identification
Mycology	Detection of Fungi and aerobic actinomycetes and Identification Detection of the presence or absence of fungi and aerobic actinomycetes without identification Direct Fungal Antigen Detection
Parasitology	Presence or Absence of Parasites Detection and Identification of Parasites Direct Parasite Antigen Detection
Virology	Viral Antigen Detection Viral Detection and Identification
IMMUNOHEMATOLOGY	**HEMATOLOGY**
ABO Group D (Rho) Typing Unexpected Antibody Detection Compatibility Testing Antibody Identification	Cell Identification (manual) White Blood Cell (WBC) Differential (automated) Erythrocyte Count Hematocrit Hemoglobin Leukocyte Count Platelet Count Fibrinogen Partial Thromboplastin Time (PTT) Prothrombin Time (PT)
DIAGNOSTIC IMMUNOLOGY	

Syphilis Serology	Qualitative and Quantitative Syphilis Testing
General Immunology	Alpha-1 Antitrypsin Alpha-Fetoprotein (AFP tumor marker) Anti-HBs Anti-HCV Antinuclear Antibody (ANA) Antistreptolysin O (ASO) Anti-Human Immunodeficiency Virus (HIV) Complement C3 Complement C4 C-reactive protein (high sensitivity) Hepatitis B Surface Antigen (HBsAg) Hepatitis B Core Antibody (Anti-HBc) Hepatitis Be Antigen (HBeAg) Immunoglobulins: 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 B-natriuretic peptide (BNP) ProBNP Calcium, total Carbon dioxide Chloride Cholesterol, Low-Density Lipoprotein, direct measurement (LDL) Cholesterol, Total Cholesterol, High-Density Lipoprotein (HDL) Creatine Kinase Creatine Kinase, Isoenzyme (CK-MB) Creatinine Ferritin Gamma-glutamyl transferase Glucose Hemoglobin A1c Iron, total Lactate Dehydrogenase (LDH) Magnesium Phosphorus Potassium

	Prostate-specific antigen (PSA), total Sodium Total iron binding capacity (TIBC), direct measurement Total Protein Triglycerides Troponin I Troponin T Urea Nitrogen Uric Acid
Endocrinology	Cancer antigen (CA) 125 Carcinoembryonic antigen (CEA) Cortisol Estradiol Folate, serum Follicle-stimulating hormone (FSH) Free Thyroxine Human Chorionic Gonadotropin (HCG) Luteinizing hormone (LH) Parathyroid hormone Progesterone Prolactin T3 Uptake Testosterone Triiodothyronine (T3) Thyroid Stimulating Hormone (TSH) Thyroxine, (T4) Vitamin B12
Toxicology	Acetaminophen, serum Alcohol (blood) Blood Lead Carbamazepine, total Digoxin, total Gentamicin Lithium Phenobarbital Phenytoin, total Salicylate Theophylline Tobramycin Valproic acid, total Vancomycin

WHERE CAN I FIND MORE INFORMATION?

For more information and resources about the CLIA program and Proficiency Testing, visit:

State Operations Manual (SOM) Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services	https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107ap_c_labpdf.pdf
CDC CLIA Website	https://www.cdc.gov/clia/index.html
FDA CLIA Website	https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia
FDA Test Categorization Website	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm
CMS CLIA Website	https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments?redirect=/clia/
CLIA Regulations	https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/regulations-federal-register

You can also email questions to the CMS Lab Excellence mailbox at: LabExcellence@cms.hhs.gov

Note: *This brochure presents information about proficiency testing and PT referral. It's not intended to replace or substitute CLIA regulatory requirements. Note that state, local, and accreditation requirements may be more stringent.*

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Congress passed the **Clinical Laboratory Improvement Amendments (CLIA)** in 1988 establishing authority to promulgate standards for certain laboratory testing to ensure the accuracy, reliability, and timeliness of test results regardless of where or by whom the test was performed. The CLIA requirements are based on the complexity of the test and the type of laboratory where the testing is performed. The information provided in this brochure is intended only to be a general informal summary of technical legal standards. It is not intended to take the place of the statutes, regulations, or formal policy guidance upon which it is based. This brochure summarizes current policy and operations as of the date it was published. We encourage readers to refer to the applicable statutes, regulations, and other interpretive materials for complete and current information.