CMS
CENTERS for MEDICARE & MEDICAID SERVICES

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

Clinical Laboratory Improvement Amendments (CLIA)

Brochure # 8

PROFICIENCY TESTING

DOs and DONT's

NOTE: 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. The final CLIA regulations were published in the Federal Register on February 28, 1992. The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April, 24, 2003.

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IMPORTANT INFORMATION FOR LABORATORIES PERFORMING NON-WAIVED TESTS

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

NOTE: This brochure information applies 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 a CMS approved PT program. Most sets of PT samples are sent to participating laboratories three times per year. After testing the PT samples in the same manner as its patient specimens, 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 scores reflecting how accurately it performed the testing. 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. Routine reviews of PT reports by the laboratory staff and director will alert them to areas of testing that are not performing as expected and also 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 that is waived. (Check the FDA web site to determine whether your test(s) are waived: *www.FDA.gov/cdrh/CLIA*) However, enrolling in a PT program and performing PT on your waived test(s) will provide you with an excellent indication of the accuracy of the waived test(s) and thus improve the quality of testing you provide to your patients. It also serves to demonstrate the accuracy of your testing if it is ever questioned.

Is PT required for all nonwaived testing?

PT is required for only the limited number of tests found in Subpart I, Proficiency Testing Programs for Nonwaived Testing, of the CLIA regulations. If your laboratory performs any of the tests found in subpart I, you must perform PT on **each** of the tests. We refer to the tests listed in subpart I as "regulated" analytes.

Review the specialty, subspecialty and analytes listed and determine which specialties, subspecialties and analytes you perform in your laboratory. Enroll in a CMS approved PT program for each of those tests.

A listing of these tests may be found on the last page 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 with their contact information and the tests for which they are approved is available at ***www.cms.hhs.gov/clia***; click on "PT providers".

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 if you ask. The program will notify CMS of your enrollment and the PT testing you have signed up to perform.

How do I enroll for bacteriology? Must I enroll for five PT samples for each test I do in bacteriology; Gram stain, direct antigen, identification of organisms, and/or susceptibility testing?

Your laboratory must enroll for a total of five PT samples per testing event and those five samples must include at least one of the types of testing your laboratory performs – Gram stains, direct antigen, identification of organisms, and/or susceptibility testing. If you perform one or two of these procedures, the five samples must include the one or two tests you perform. 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 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. If you have a separate certificate for each site, you must enroll in PT for the tests performed at each site.

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. Laboratories must enroll and participate in one approved program for one year before designating a different program. Laboratories should enroll in the fall for the next calendar year. However, if you apply for a new CLIA certificate mid-year or add a "regulated" specialty, subspecialty, or analyte in the middle of a year, you may change PT programs at the next PT enrollment period.

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.

- Perform PT on the tests (many PT programs offer a limited number of PT samples for "unregulated" tests), but **NEVER** send the PT samples out of the laboratory for any reason. Depend on the scoring by the PT program to determine accuracy.

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 (a few ways to accomplish this are listed above). 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 as "ungradable" on your results report. You will be assigned an artificial score of "100%", noted as "ungradable", but that does **NOT** reflect your performance.

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 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 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. 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 or confirmatory testing.

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 cause you to lose 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 for confirmation or identification testing. (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 actions to be taken against your laboratory, your laboratory director, and the laboratory owner. The penalties include loss of your laboratory's CLIA certificate for at least one year, your director cannot direct a laboratory for two years, and your laboratory owner may not own or operate a laboratory for two years.

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 **"reflex" test.** (A "reflex" test is a test procedure routinely added-on to a patient specimen when the test results are at a level that meets the clinician's threshold to automatically add specific tests. This is usually done by a "standing" order.)

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.

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, 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, maintain records of these actions for two years also.

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 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.

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.

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. 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. Your director may want to review the results of the patients tested during the unsatisfactory or unacceptable testing event. 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.

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 never had an unsuccessful performance for any PT analyte, subspecialty, or specialty, the CLIA regulations, under certain circumstances, 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.

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 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 you have been required to cease testing, your Medicare and Medicaid reimbursement will be suspended 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.

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 regional office CLIA consultant that testing of the unsuccessful analyte, subspecialty, or specialty has been stopped voluntarily.

This notification **must** be made before you receive a letter from your CMS regional office imposing a cease testing sanction. You will need to successfully perform two consecutive PT events for the analyte, subspecialty, or specialty that was unsuccessful. Your Medicare and Medicaid reimbursement will not be affected.

Be sure to read to the CLIA regulations for proficiency testing (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 Nonwaived 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 or SGPT)

Albumin

Alkaline Phosphatase

Amylase

Aspartate Aminotransferase (AST or 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

Where can I find additional information and guidance?

Assistance for meeting the requirements is provided in Appendix C of the State Operatons Manual (CMS Publication 7), which is posted on CMS's CLIA website.

www.cms.hhs.gov/clia

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