Laboratory Proficiency Testing
Welcome to the Laboratory Proficiency Testing (PT) course. This course will help you learn more about some of the key laws and regulations affecting the laboratory healthcare industry and our organization.

As part of our compliance efforts, we are committed to meeting all regulatory requirements. By doing so, we are able to:

- better serve our patients through honest and ethical behavior
- be recognized as a leader in our community by following the law, and
- provide a good working environment for everyone as we always try to "do the right thing"

We welcome your input and comments on this course, and encourage you to talk to your supervisor, manager, or Corporate Responsibility Officer (CRO) if you have any questions or concerns.
Catholic healthcare was built on a foundation of integrity. Our religious sponsors brought a values-based way of living to the communities that they have served since the 1800s. Throughout our history, Catholic healthcare built relationships based upon integrity and trust. Those relationships enable us to assume the challenging role of caring for those most in need, those least able to care for themselves.

Today, the complexity of our world requires that healthcare organizations actively pursue, support and nurture workplace integrity. Workplace integrity is an uncompromising commitment to both legal and ethical principles and behavior. It is critical for Catholic healthcare organizations to reaffirm our total commitment to integrity in our words and actions. Even the perception of fraud or abuse undermines the public’s trust in us and our organization. We are responsible for being good stewards of public and private resources. We are entrusted with government and commercial funds to provide the necessary care and services to beneficiaries. We have a duty to prevent waste or abuse and to prevent or stop fraud of any kind.
The Clinical Laboratory Improvement Amendments of 1988 (CLIA) include standards and requirements for laboratories to be certified to perform testing on human specimens. A laboratory must hold a valid CLIA certificate to bill Medicare and Medicaid for tests and services. In the past, the Office of Inspector General (OIG) and Center for Medicare and Medicaid Services (CMS) has identified CLIA certificates and the testing performed under those certificates as an area of concern.
The laboratory’s level of certification determines the type of testing that may be performed. The testing authorized by each certification is broken down into two different testing categories.

**Waived Testing**
- Some examples include:
  - Bedside glucose monitoring
  - Urine dipsticks
  - Hemoccult Slides

**Non-waived Testing**
- Moderate Complexity
- Provider Performed Microscopy Procedures (PPMP)
- High Complexity

We'll cover each of these types of testing in the next few screens.
Waived testing is defined as:
• simple laboratory tests that have been cleared by the Food and Drug Administration (FDA) for patient testing.
• these tests must be simple and accurate to use and have a low risk for error. Even if performed incorrectly, there is generally no harm to the patient.

Errors in waived testing can occur throughout the testing process, particularly when the manufacturer's directions for testing are not followed and when testing personnel are not familiar with all aspects of the test system.

Waived tests have the potential for serious health impacts if performed incorrectly. Staff performing waived testing must be trained and qualified to perform such testing.
According to the Centers for Medicare and Medicaid Services (CMS):

- more than 67% of all laboratories enrolled in the CLIA program are Certificate of Waiver laboratories (as of January 2012).
- the number mentioned above includes laboratories in states that are considered "CLIA Exempt."

While these tests are easy to perform, CMS conducted a study and found that a large number of laboratories performing waived tests did so incorrectly.
There are three types of non-waived testing.

- High Complexity Tests
- Provider Performed Microscopy Procedures (PPMP)
- Moderate Complexity Tests
Laboratories must maintain the level of testing authorized under their CLIA certificate including items such as:

• implementing quality assessment and quality control programs
• maintaining staff qualifications and training
• publishing recordkeeping procedures, and
• performing proficiency testing.

Failure to maintain these standards may result in sanctions, including loss of certification and loss of the ability to bill Medicare and Medicaid.
The OIG conducts investigations to make sure laboratories only perform those tests authorized within the scope of the laboratory’s CLIA certification. Performing tests that are not authorized under the laboratory’s CLIA certificate is a violation of federal regulations and may result in penalties and fines.
As part of the CLIA certificate application process for moderate and high complexity testing, laboratories must enroll in a CMS-approved proficiency testing program for each testing area where certification is desired. Even though not required by CLIA, some waived testing laboratories are also required to perform proficiency testing challenges if mandated by their Accrediting Agency (i.e., The College of American Pathologists (CAP)) or by their local State Department of Health.
What is proficiency testing?

Proficiency testing or PT is the testing of unknown specimens sent to the laboratory by a CMS approved PT program. Most sets of PT specimens are sent to participating laboratories three times per year. After testing the PT specimens in the same manner as its patient specimens, the laboratory reports its specimen 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 accrediting organizations routinely monitor their laboratories’ performance.
What is the purpose of PT?

Proficiency testing is performed to validate the quality of the test results generated by the lab. Routine review of PT results will alert the lab staff and director to areas of testing that are not performing as expected.
Is PT required if you only perform waived testing?

Generally, PT is not required by CLIA for any test that is waived. However, some states and Accrediting Agencies require that PT be performed on certain types of CLIA waived testing.

Additionally, as a matter of good laboratory practice, your laboratory may also require PT testing for certain types of CLIA waived testing. If you have questions on the PT testing requirements for your laboratory, contact your laboratory manager or medical director.
PT specimens must be processed in the same manner as all other patient specimens. However, PT specimens may NEVER, under any circumstances, be sent out of your laboratory even to one located in or owned by your hospital or CHI.
This means that PT specimens:

• Must be incorporated into the routine workflow and not treated any differently than routine patient specimens

• Must be tested the same number of times as patient specimens;

• Must be tested at the same time as patient specimens;

• Must be tested by the same personnel that routinely test patient specimens;

• Must be tested using the same test system that is routinely used for patient specimens; and

• Must be rotated among the testing personnel in your laboratory
NEVER send PT specimens out of your laboratory for any reason, even if you routinely send out patient specimens for additional or confirmatory testing. This would include other laboratories within Catholic Health Initiatives or your facility.

Contact your laboratory supervisor or director for any issues with PT specimens.
What happens if I send a PT specimen to another lab for testing?
The consequences of sending a PT specimen to another lab for testing are severe. The penalties include:

- loss of your laboratory’s CLIA certificate for one year or more
- your medical director cannot direct a laboratory for two years
- your laboratory owner may not own or operate a laboratory for two years resulting in your lab being unable to process any type of testing
- all of the related laboratories of an organization could lose their CLIA certificates as well

In accordance with policy, adverse employment action, up to and including termination of employment, may be taken against any person(s) that improperly sends a PT specimen to another laboratory.
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 due date set by the testing agency for reporting results. This applies even to a laboratory located in or owned by your hospital or CHI.
May I send my PT specimens to another laboratory to see if they get the same results as I do?

**NEVER** send your PT specimens to another laboratory even if you send your patient specimens to another laboratory for confirmation testing. **Even to a laboratory located in or owned by your hospital or CHI.**
What do I do if I receive a PT specimen from another laboratory for testing?

As soon as you identify the specimen as a PT sample, notify your lab department director or manager. He or she will take the appropriate steps to report this issue to the appropriate agency. **DO NOT TEST** the specimens!
What do I do if I get an error result message on a PT sample?

If you receive an error result message on a PT specimen you should:

• Follow your laboratory policy for handing this situation except under no circumstances should you send the PT specimen to another laboratory for testing. Typical troubleshooting normally would include the following:

  • Repeat the sample
  • Check to see if the daily controls were within allowable limits
  • Trouble-shoot the process as described in your procedure manual
  • Contact your supervisor if the above steps are not successful
Proficiency Testing (PT) Key Points:

• Proficiency testing is performed to validate the quality of the test results generated by the laboratory. Under the PT program, a laboratory must successfully perform testing on the PT sample.

• When performing proficiency testing, laboratories must:
  ▪ Process specimens in the same manner as all other patient specimens, and
  ▪ Not communicate with other laboratories regarding the testing results,
  ▪ Not have another laboratory perform testing on the specimen
Proficiency Testing (PT) Key Points:

- The laboratory must immediately notify the Centers for Medicare and Medicaid Services (CMS) if proficiency testing specimens are received from another laboratory.

- A laboratory’s CLIA certificate may be revoked for one year or more for sending proficiency testing specimens to another laboratory for testing. In addition, the laboratory director cannot direct a laboratory for two years and your laboratory owner may not own or operate a laboratory for two years.
Remember:

PT specimens may **NEVER**, under any circumstances, be sent out of your laboratory.

• **NEVER** enter into discussion with another laboratory about PT results before the due date set by the testing agency for reporting results.

• **NEVER** analyze a PT specimen sent to you from another laboratory - **even if the laboratory is located in or owned by your hospital or CHI**.
Thank you for completing the Laboratory Proficiency Testing course.

If you have any questions about PT and/or this course, please speak with your lab director, manager or Corporate Responsibility Officer.
Click here for the Laboratory Proficiency Testing Acknowledgment and Certification