ENROLLING IN PROFICIENCY TESTING

Laboratories performing non-waived testing are required to enroll every year in a proficiency testing program for all regulated analytes on the test menu. See *Fast Facts 10: CLIA Regulated Analytes* for the list of regulated analytes.

Performing PT and evaluating your results is good laboratory practice and an important means to assess quality. This fact sheet contains some helpful tips on enrolling in PT and the regulatory requirements that affect your enrollment.

Regulatory Requirements

The CLIA regulations require laboratories to enroll in proficiency testing for all regulated analytes. PT programs provide five challenges per regulated analyte per event, and there are three events per year. CLIA requires laboratories to either enroll in PT for unregulated analytes or to perform twice-yearly split-sample analysis or other scientifically defensible external comparison of these analytes.

CLIA also requires that laboratories permit PT providers to release their scores to regulatory or accrediting agencies. To do this, provide the following information to your PT provider:

- CLIA ID number (required for PT providers to report scores to CMS for CLIA compliance purposes)
- Where to send copies of PT scores:
  - Regulatory or accrediting agencies (e.g.,CMS/State/COLA)
  - State agency, if required by state laboratory licensure law
  - Consultants, if applicable

PT Programs

It pays to shop around. Prices, analytes available, and analyte combination modules will vary. Different providers also target their program to meet different customer needs. If you are a member of a professional society, you may receive discounted registration fees for a particular PT program.

All PT programs enroll on a calendar year basis. The enrollment period begins in October for the next year. You should enroll early - providers have a limited number of specimens available.

Also, consider the timing and shipping schedule of the PT program and decide which works best for your laboratory's workload. Some programs send multiple shipments (one specialty at a time) for each event. While other programs send one shipment containing specimens for all specialties together for each event.

Enrolling in PT

First, determine the analytes needed. Then, consider combination modules. PT providers often allow additional modules to be added at a discount. You may also want to consider voluntary enrollment for unregulated analytes and waived tests.

For duplicate test methods, if more than one method is used to perform the same analyte, then designate one of the methods to be used for regulatory scoring purposes and perform PT by that method.

If you want to enroll both methods in PT, understand that only one score per analyte is allowed. You must specify which method is to be scored. You are only required to enroll in PT for the primary method of analysis.

Special Circumstances

WBC Differential

This regulated analyte may be performed manually or by automated hematology instruments. PT is required even if the instrument only provides a partial differential. Make sure the PT module you select includes specimens that are compatible with your method or analyzer. For manual differentials you will receive 35mm slides or photographs to identify. Blood samples are sent for analyzer (autodiff) differentials. If your lab performs both methods, then choose one to use for regulatory scoring purposes.

Microbiology

Microbiology is comprised of the following subspecialties: bacteriology, mycobacteriology, mycology, parasitology, and virology. PT is required for the regulated organisms within each subspecialty.

Laboratories are scored at the subspecialty level, not by individual test types. Only one score is given for each subspecialty even though there are many different tests a lab may perform within an individual subspecialty. Each type of test (e.g.,culture, direct antigen, ID systems) requires PT. When multiple types of tests are performed in the lab, the results of each are averaged by the PT provider to obtain the one score that is reported to regulatory and accrediting agencies for CLIA compliance purposes.

The laboratory must perform a total of five specimens per subspecialty. These five specimens can be a combination of all types of regulated testing performed within the subspecialty, as long as each type of testing has a PT challenge. For example, if your laboratory performs three different bacterial antigen detection tests and three different cultures or ID methods, then you have the option of choosing which antigen detection test(s) and which cultures or ID methods to include within the five required challenges per subspecialty.

To ensure that all procedures necessary for culture identification are evaluated by PT, your laboratory should enroll in modules that provide a sufficient variety of organisms and specimen types.