



COLA Primers
Accreditation

COLA PRIMER 5

***Finding a Qualified Technical Consultant or
Technical Supervisor for Your Laboratory***

• What is a Technical Consultant, What is a Technical Supervisor, and... What is the difference? •

The Clinical Laboratory Improvement Amendments (CLIA) regulations require specific types of personnel for non-waived clinical laboratories. For each required position, CLIA defines qualifications and assigns responsibilities.

In laboratories where the highest test complexity is **moderate complexity**, a Technical Consultant (TC) is required. Typically moderate complexity laboratories have only one TC, but more than one person can be designated as a TC. The important thing to remember is that the TC qualifications and responsibilities, defined by CLIA, must be met.

In laboratories where the highest test complexity is **high complexity**, a Technical Supervisor (TS) is required for each high complexity specialty and subspecialty. Each high complexity laboratory must have one or more persons qualified to fill the TS role. Again, the important thing to remember is that the TS qualifications and responsibilities, defined by CLIA, must be met.

Note that although Provider Performed Microscopy (PPM) is considered a sub-category of moderate complexity testing, a TC is not required for laboratories with a PPM CLIA certificate.

Both Technical Consultants and Technical Supervisors are required to have a minimum of a Bachelor's degree in a relevant science. The number of years of training or experience required is greater for a TS than for a TC, but both are required to have training or experience in the type of testing that they will oversee. Commonly these positions are filled by Clinical Laboratory Scientists (formerly called Medical Technologists), but can be filled by others with the appropriate education and training or experience.

A question that is commonly asked is "Can a physician Laboratory Director serve as the TC or TS?" The answer is **yes, if qualified**. Licensed physicians will typically meet the education requirements for these positions, but the training and experience that is required needs to be actual hands-on laboratory experience. Most physician Laboratory Directors have not had enough direct laboratory experience to meet the qualifications of a TC or TS. In addition, the TC and TS positions require a significant time commitment. Practicing physicians, even if qualified, may find it difficult to meet the responsibilities of a TC or TS.

For detailed information on the required qualifications for the TC and TS, see COLA Primer 4, Clinical Laboratory Personnel Requirements. If you have questions about qualifications or are not sure if a particular person is qualified, please contact COLA for assistance.

• Why do I need a Technical Consultant or Technical Supervisor? •

Besides being required by the CLIA regulations for non-waived laboratories, the TC and TS can provide the expertise necessary to help your laboratory provide accurate and reliable test results. They can also help investigate and resolve problems in the laboratory when they occur.

CLIA gives the following responsibilities to the TC and the TS:

- Selection of appropriate test methods and instrumentation
- Verification / establishment of test performance characteristics
- Enrollment in an HHS-approved (U.S. Department of Health and Human Services) Proficiency Testing (PT) program
- Establish a Quality Control Plan that is appropriate for the testing performed and establish acceptable levels of performance throughout all phases of testing
- Resolve technical problems and ensure that remedial actions are taken and documented
- Identify training needs for laboratory staff and make sure that regular continuing education is provided and documented
- Evaluate the competency of all testing personnel, semi-annually the first year of testing and annually thereafter.

In addition to these CLIA defined responsibilities, the TC or TS can also help with:

- Start-up of a new laboratory
- Writing procedures (to be approved by the Laboratory Director)
- Establishing and implementing a Quality Assessment program
- Laboratory Information Systems
- Laboratory records organization
- Preparation for an onsite survey and correction of any identified deficiencies
- Required safety training for laboratory personnel.

Considering all of these responsibilities, it is no surprise that the TC and TS are very important positions in a clinical laboratory.

• So I need a Technical Consultant or Technical Supervisor... What do I look for in a TC or TS? •

A TC or TS must meet the CLIA-defined qualifications for the position. In addition, it is helpful to find a consultant who is familiar with the type and size of your laboratory, and who is accessible to the laboratory staff. The TC or TS does not need to be on-site at the laboratory at all times, but must be accessible to provide consultation, via face-to-face interaction, telephone, or electronic means. A TC or TS who is located a long distance from the laboratory may have a difficult time overseeing the technical aspects of the laboratory. Typically, the TC or TS, if not a regular employee of the laboratory, will visit the laboratory on a regular basis to keep all technical requirements in compliance.

CLIA does not define a maximum number of laboratories that a TC or TS can oversee. But having too many laboratories to oversee can prevent the TC or TS from being in tune with what is happening at the laboratory. This may be something to consider when hiring a TC or TS.

Be sure that the TC or TS that you hire is licensed by the state where the laboratory is located, if required. For laboratories performing very specialized high complexity testing, such as mass spectrometry or molecular diagnostics, the TS must have experience in these areas. COLA requires specific technology-related experience for the TS overseeing these two types of testing.

If your laboratory has testing personnel who are qualified to serve as TC or TS, you may want to promote them to TC or TS, but consider that:

- They may not be familiar with all of the regulatory requirements
- You can provide them with a mentor, such as an outside consultant, until they have mastered the position of TC or TS.

• Where Do I Find a Qualified TC or TS? •

A good place to start is your local hospital or regional reference laboratory. These facilities may know of available and qualified professionals who can serve as TC or TS on a consulting basis.

Another option is to go to myconsultantcentral.com, which lists professional consultants and consulting companies that provide TC and TS services.

In addition, you can contact your state or regional chapter for laboratory professional organizations, such as:

- **ASCLS** — American Society for Clinical Laboratory Science (<https://www.ascls.org>)
2025 M Street NW, Suite 800 | Washington, DC 20036
Phone: (202) 367-1174
- **CLMA** – Clinical Laboratory Management Association (www.clma.org)
330 N. Wabash Ave., Suite 2000, Chicago, IL 60611
Phone: (312) 321-5111.

• Now that I have found a Consultant...Do I need a contract? •

If you hire an outside professional TC or TS, it is recommended that you agree on expectations and record these in a contract. Important things to consider:

- What are the fees to be paid to the TC / TS? Identify a schedule for payment on a schedule that is mutually agreed upon.
- Will the consultant have travel expenses to visit the laboratory? Will these be paid by the TC / TS; or reimbursed by the laboratory?
- How often is the TC / TS expected to be on-site to review documentation and address issues in the laboratory?

- Are written reports on laboratory status and progress to be delivered to the Laboratory Director and how often?
- How will the Laboratory Director and/or laboratory staff contact the TC/TS when needed? What is the expectation for response time?
- The contract should delineate the CLIA defined responsibilities of the position, and any specific duties assigned or delegated by the Laboratory Director.
- Since lack of competency assessment continues to be a top citation among accrediting organizations, it is recommended that competency assessment expectations be included in the contract.
- What is the duration of the contract and is it renewable? What circumstances would allow either party to terminate the contract?

• The Significance of Competency Assessment •

We have mentioned that the TC / TS is responsible for competency assessment for laboratory staff. Nevertheless, it is important to note that the TC / TS must also be evaluated for competency. This is typically documented by the Laboratory Director, and should focus on the how the TC / TS has met the responsibilities of the position. The responsibilities outlined in the contract can be a good guide for evaluating competency. COLA has a template for competency assessment of the TC / TS that is available to all COLA laboratories.

The complete CLIA personnel requirements are (Subpart M) can be found at:
<https://www.ecfr.gov/cgi-bin/textidx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.com>