COLA
Clinical Laboratory Accreditation

COLA Primers
Accreditation

COLA PRIMER 17

Being an Effective Technical Consultant/ Technical Supervisor

● Introduction ●

This COLA Primer focuses on the required positions of **Technical Consultant (TC)** for a moderate complexity laboratory and **Technical Supervisor (TS)** for a high complexity laboratory. Having a qualified Technical Consultant or Technical Supervisor who is effective at carrying out their defined responsibilities is key to a compliant and high functioning laboratory. Their technical knowledge, experience and skills are important for ensuring accurate and reliable test results. Laboratory directors can use this primer to aid in selection and training of suitable staff to hold these important roles in their laboratories. Technical Consultants and Technical Supervisors are encouraged to review the responsibilities outlined in this primer and use the information provided as a framework for fulfilling the role.

__Technical Consultant__ is the required position in a moderate complexity laboratory and __Technical Supervisor__ is the required position in a high complexity laboratory

● Personnel Qualifications ●

The CLIA requirements define specific qualifications a person must meet to hold the position of Technical Consultant or Technical Supervisor. For the position qualifications, see the Personnel Requirements charts included at the end of primer 4, the COLA Accreditation Manual, or the CLIA requirements in Subpart M. If your state has more stringent personnel requirements than CLIA or COLA, or if your state requires personnel licensure, you must ensure that all personnel meet those additional requirements.

To fill the required position of Technical Consultant or Technical Supervisor, the laboratory must employ one or more individuals who are qualified by education and training or experience to provide technical oversight for each of the specialties and subspecialties of testing performed.

● Necessary Training or Experience ●

Let's look at the training or experience that is necessary for individuals with the acceptable educational degrees to qualify as Technical Consultant or Technical Supervisor. It is important to note that when the requirements include "laboratory training or experience," this means actual **hands-on laboratory testing experience** in the specialty/subspecialty of service. This is different than having experience directing a laboratory or supervising testing performed by others. Therefore, an individual who qualifies as the Laboratory Director may not be qualified to hold the position of Technical Consultant or Technical Supervisor. The personnel files for the Technical Consultant or Technical Supervisor must include documentation of the necessary years of hands-on laboratory training and/or experience. Training or experience in different specialties or subspecialties can be acquired concurrently. A laboratory may also employ more than one Technical Consultant or Technical Supervisor, each with training and experience in different specialties of testing performed at the laboratory.

For the **Technical Consultant** in a moderate complexity lab:

- The **minimum** level of education required is a Bachelor's degree in a laboratory science.

- Individuals with a qualifying BS degree must have 2 years of lab training or experience in non-waived testing, and it must be in each specialty/subspecialty of testing performed at the laboratory.
- For individuals with a qualifying Master's or PhD, and for physicians who are not pathologists, the requirement for training or experience is reduced to one year in each specialty/subspecialty of testing performed.
- For a physician who is a pathologist, there is no additional training or experience required to be the Technical Consultant.

*The **minimum** level of education required is a bachelor's degree in a laboratory science, PLUS specified years of defined training or experience*

For the **Technical Supervisor** in a high complexity lab:

- The **minimum** level of education required is a Bachelor's degree in a laboratory science.
- Individuals with a qualifying BS degree must have **4 years** of lab training or experience in high complexity testing, and it must be in each specialty/subspecialty of testing performed at the laboratory.
- For individuals with a qualifying Master's degree, the requirement for training or experience is reduced to two years in each specialty/subspecialty of testing performed.
- For individuals with a qualifying PhD, and for physicians who are not pathologists, the requirement for training or experience is reduced to one year in each specialty/subspecialty of testing performed.
- For a physician who is a pathologist, there is no additional training or experience required to be the Technical Supervisor.

The subspecialties of **Microbiology** require at least 6 months of experience that is *specifically in the subspecialty.* For example, the Technical Supervisor in a lab that performs high complexity Bacteriology must have 4 years of high complexity Microbiology experience including at least 6 months of experience in the subspecialty of high complexity Bacteriology.

There are also some specific points for labs that perform **Immunohematology**:

- If testing performed is for non-transfusion purposes, it is moderate complexity and a Technical Consultant is required.
- If testing performed is for transfusion purposes, it is high complexity and a Technical Supervisor is required. There is a unique single qualification pathway for the Technical Supervisor of Immunohematology:
    - *Board certified Pathologist OR other licensed physician with 1 year hands-on training/experience in high complexity immunohematology.*

COLA has additional qualification requirements for the Technical Supervisor for **Mass Spectrometry** testing and for **non-FDA approved Molecular Diagnostics** testing. Please see the latest COLA Accreditation Manual for details.

● Technical Consultant/Technical Supervisor Responsibilities ●

The Technical Consultant or Technical Supervisor is responsible for technical and scientific oversight of the laboratory. They are not required to be on-site at all times, but must be available to provide needed consultation either in-person, by telephone, or electronically.

Included at the end of this primer is a table describing how a Technical Consultant or Technical Supervisor can effectively meet the following CLIA-defined responsibilities:

- Select test methods that are appropriate for the clinical use of the test results.
- Verify the test procedures performed and establish the laboratory's performance criteria, including the accuracy and precision of each test and test system.
- Enroll and ensure participation in an approved PT program commensurate with the services offered by the laboratory.
- Establish a quality control program appropriate for the testing performed, establish the acceptable levels of analytic performance, and ensure these levels are maintained throughout the testing process.
- Resolve technical problems and ensure corrective actions are taken whenever test systems deviate from the laboratory's established performance specifications.
- Ensure that patient test results are not reported until all necessary corrective actions have been taken and the test system is functioning properly.
- Identify training needs and ensure testing personnel receive regular in-service training and education.
- Evaluate the competency of all testing personnel and assure that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.
- Evaluate and document testing personnel performance at six and twelve months during the first year of employment and yearly thereafter. Reevaluate performance using the new test methodology or instrumentation prior to reporting patient test results, if test methodology or instrumentation changes.

  (There are additional responsibilities for the Technical Supervisor in a lab that performs cytology. Please refer to the CLIA requirements in Subpart M)

The Technical Consultant or Technical Supervisor is responsible for technical and scientific oversight of the laboratory.

● Delegating Responsibilities ●

In a high complexity laboratory, the Technical Supervisor may delegate, in writing, these responsibilities to the General Supervisor

- Ensuring that all corrective actions are taken whenever test systems deviate from the laboratory's established performance specifications.
- Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly.
- Providing orientation to all testing personnel.
- Annually evaluating and documenting the performance of testing personnel.

• Working with the Laboratory Director •

The Laboratory Director and the Technical Consultant or Technical Supervisor work closely together and have responsibilities that overlap in the areas of test selection, performance specifications, quality control, PT and personnel. Collaboration between the Lab Director and the Technical Consultant/Technical Supervisor is vital and can lead to better communication and teamwork among all lab staff. An effective Technical Consultant/Technical Supervisor will recognize the importance of this collaboration and work with the Lab Director to ensure accurate and reliable testing.

Some responsibilities of the Laboratory Director can be delegated to the Technical Consultant/Technical Supervisor. Delegation of responsibilities will be specific to your lab and must be documented in writing. The Lab Director remains responsible for assuring that the Technical Consultant/Technical Supervisor fulfills any additional responsibilities that have been delegated to them.

•Competency Assessment for Technical Consultant/Technical Supervisor•

To evaluate the performance of their CLIA-defined responsibilities, the Technical Consultant/Technical Supervisor is expected to undergo annual competency assessment. This competency assessment is to verify that the responsibilities are being met, and it is performed by the Laboratory Director. This competency assessment must also include any additional responsibilities that the Lab Director has delegated to the Technical Consultant/Technical Supervisor.

If the Technical Consultant/Technical Supervisor performs any testing, then the individual also holds the position of Testing Personnel and is therefore required to undergo competency for that role, utilizing the six required methods of assessment. See COLA Primer 6.

Laboratory inspections will check that the Technical Consultant/Technical Supervisor is qualified and adequately fulfills the responsibilities of the position.

Laboratory inspections will check that the Technical Consultant or Technical Supervisor is qualified and adequately fulfills the responsibilities of the position. Work with the Laboratory Director to strive for more than just “adequate”! Effective technical and scientific oversight of the laboratory has a positive impact on day-to-day operations, test results, and consequently, patient care.

References:

COLA Accreditation Manual 2020
CLIA Requirements, 42 CFR, Part 493, Subpart M, 493.1411-1413 and 493.1449-1451
CMS Interpretive Guidelines

Meeting Technical Consultant/Technical Supervisor Responsibilities

General Duties and Responsibilities	How to effectively meet these responsibilities
Provide technical and scientific oversight of the laboratory *Must be available to provide consultation either on-site, by telephone, or electronically* *Ensure that any duties delegated to the General Supervisor (GS) are properly performed (applies to the Technical Supervisor only)*	▪ Review and understand the CLIA regulations, the requirements of your accrediting agency (if applicable), and any state or local laboratory regulations that apply to your laboratory for the testing performed. ▪ For the most effective oversight, being on-site is ideal. When that is not possible, check in regularly, provide your contact information to all lab staff and make sure that you are accessible during lab operating hours. ▪ Utilize any self-assessment tools available and operate as if every day is inspection day. ▪ Welcome a laboratory inspection as an educational experience. Be present and ask questions. Make any needed corrections promptly and maintain those improvements. ▪ Regularly communicate with the laboratory director about lab operations. Setting up a monthly (or more frequent, if needed) meeting is recommended, and you may periodically want to include all lab staff in the meeting. Always address urgent matters right away, rather than waiting for the next meeting. ▪ Stay informed of latest technologies and trends through laboratory publications and conferences. ▪ Never stop learning! ▪ For the TS (high complexity lab), delegating some responsibilities the General Supervisor (GS) may allow you to be more effective other areas that have more impact in your lab.
Technical Oversight Responsibilities	**How to effectively meet these responsibilities**
Select test methods that are appropriate for the clinical use of the test results *Verify the test procedures performed and establish of the laboratory's test performance characteristics, including the accuracy and precision of each test and test system*	▪ Select test systems carefully and work with the lab director to ensure they are appropriate for the patient population, testing volume, and diagnostic needs of the laboratory. ▪ Work with suppliers and manufacturers to select test methods with proven accuracy that meet your needs. ▪ Work with the lab director to establish adequate test verification procedures and use them to verify that the manufacturer's stated performance characteristics are achieved in your lab. Specify the remedial actions to take when performance characteristics are not met. ▪ Work with the lab director to ensure the procedure manual is up-to-date and ensure all package inserts in use are current. ▪ Periodically follow a specimen through the entire path of workflow to confirm that policies and procedures are effective and being followed by all staff.

Resolve technical problems and ensure that corrective actions are taken whenever test systems deviate from the laboratory's established performance specifications	▪ Review quality control for each test and monitor the test accuracy and reliability over time.
	  ○ Review daily QC logs.
	  ○ Review L-J charts weekly.
	▪ Ensure that personnel follow the manufacturer's directions and use good laboratory practices.
	▪ Create a Problem Log and instruct staff when and how to use it. Closely monitor for entries, investigate problems as they arise and look for patterns over time.
	▪ Evaluate the frequency and appropriateness of corrective actions. Investigate further when corrective actions are repetitive or not effective.

Personnel Responsibilities	**How to effectively meet these responsibilities**

Identify training needs and ensure that testing personnel receive regular in-service training and education
 	
Evaluate the competency of all testing personnel and assure that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently
 	
Evaluate and document testing personnel performance at six and twelve months during the first year of employment and yearly thereafter.
	▪ Work with the lab director to hire qualified individuals and provide the training they need.
	▪ Provide personnel with initial orientation and training for the duties and testing they will perform. Ensure that training was effective and verify competency before patient testing begins.
	▪ Provide training on any new or changed procedures, test kits or instrumentation.
	▪ Observe personnel as they perform pre-analytic, analytic and post-analytic phases of testing.
	▪ Establish standards for personnel performance and conduct personnel competency assessments (every 6mo for 1st year & annually thereafter).
	▪ Develop a process to ensure on-time competency assessments that are meaningful and documented including the outcome. Include the six required evaluation methods for each test the individual performs.
	  ○ Observe the performance of routine patient testing to ensure that each step is being performed according to procedure, noting the date of the observation for each test and any need for retraining.
	  ○ Review test records to ensure that recording and reporting of results follows your laboratory's procedure. Document which records and lab reports were reviewed, the date reviewed, and include copies of the reports reviewed.
	  ○ Review log sheets, maintenance records, calibration records, QC & PT records, patient worksheets, and any other records completed by the individual to ensure they are present, accurate, and completed as required by your laboratory's procedure. Document which records were reviewed, the date, and include copies of the records reviewed.

Reevaluate performance using the new test methodology or instrumentation prior to reporting patient test results, if test methodology or instrumentation changes	○ Observe the performance of instrument maintenance and function checks, when applicable, to make sure that the maintenance is being performed correctly, documenting the date of observation for the specific maintenance procedures. ○ Set up blind samples to run for each test performed and evaluate results for acceptability. PT performance can be used for this purpose, or you can use previously tested patient samples with known values. PT materials can be used to assess additional staff members AFTER the scores have been received from the PT provider. Include a copy of the PT or blind patient sample testing results and evaluation. ○ Review problem logs and QA activities to assess problem solving skills. Or provide "what if" scenarios to assess if testing personnel know what to do when issues occur, such as an incorrect specimen type or how to investigate a physician complaint. Include copies of documents used in this exercise with your documentation. ▪ Focus competency assessments on the individual's ability to perform assigned tasks according to procedure to produce accurate and reliable laboratory results, whether they meet the duties and responsibilities of their position, and assessment of actual test performance and result interpretation. ▪ Look for and encourage these qualities when evaluating competency: ○ Attention to detail. ○ An understanding of the importance of consistently following procedures exactly, every time. ○ Ability to recognize and resolve problems. ▪ Competency assessment procedures can be done over the course of the year rather than all at once by incorporating competency assessment procedures into routine activities. ▪ If the TS in a high complexity lab has delegated the performance and documentation of competency assessments to the General Supervisor (GS), ensure that this delegation is in writing and that competency assessments are on time and properly performed by the GS. ▪ Require and provide remedial training when needed. ▪ Encourage and provide opportunities for continuing education.

PT Responsibilities	How to effectively meet these responsibilities
Enroll and ensure participation in an approved proficiency testing program commensurate with the services offered by the laboratory	▪ Select an approved PT provider that meets your needs and work with the lab director to maintain continuous enrollment in appropriate PT modules for all regulated analytes. ▪ Develop a split-sample testing protocol for non-regulated analytes, or enroll in suitable PT. ▪ Promptly enroll new tests in PT as they are added to the test menu. ▪ Make sure lab staff understands all the rules and requirements for testing PT samples, and the importance of submitting results on time. Post the shipment schedule so staff knows when samples will arrive and when results are due. ▪ Keep left-over, storage-stable PT samples for follow up testing and competency assessment. ▪ Review, initial, and date all PT reports and evaluate your lab's performance. ▪ Investigate any unacceptable results and any results that do not reflect the lab's performance and take corrective action when needed. ▪ Get more out of PT performance and prevent future problems by looking closely at passing results. Check for all results on one side of the mean, SDIs greater than 2, or patterns that could indicate a developing problem. And, always self-evaluate any ungraded results. ▪ Investigate the one unacceptable result for 80% scores. Yes, you passed, but even one incorrect result should be a concern. ▪ Share and discuss PT performance with the staff and lab director and make sure that periodic reviews of PT policies, procedures and performance are included in your QA plan.

QC Responsibilities	How to effectively meet these responsibilities
Establish a quality control program appropriate for the testing performed, establish acceptable levels of analytic performance and ensure these levels are maintained throughout the entire testing process *Ensure that patient test results are not reported until all necessary corrective actions have been taken and the test system is functioning properly*	▪ Work with the Lab Director to develop comprehensive policies and procedures for the performance and acceptability of quality control that meets regulatory & manufacturer requirements. Specify for each test: o number and type of controls to run, o frequency of running controls, o proper storage and handling of controls, o how you will determine if controls are acceptable, o what corrective actions to take when controls are not acceptable, and o how QC will be documented and reviewed. ▪ For each non-waived test on the lab menu, work with the laboratory director to decide whether to follow the CLIA default QC requirement or to develop and implement IQCPs. ▪ Review and initial QC logs and charts weekly to ensure that test systems are "in control" and providing accurate and reliable results. Look for: o Compliance with lab policies. o The correct number, type and frequency of QC. o Acceptability of QC results. o Shifts and trends. o Corrective actions taken for out of range results, including their appropriateness and effectiveness. ▪ Make sure laboratory policy states that patient results are not to be reported when the test system is not functioning properly (i.e., QC is out of range). Verify that all staff follow this policy. ▪ Review and initial problem logs regularly and verify that appropriate corrective actions are performed and documented. ▪ Make sure that QA reviews are effective at identifying and preventing errors, and that follow up reviews are performed to evaluate the outcome and effectiveness of corrective actions.