The following are questions (and answers!) that lab customers and colleagues frequently ask our lab team. Hopefully you and your organization will find them helpful.

Q. What is required to document competency of independent practitioners for waived testing if no instrument is used?
A. When a licensed independent practitioner performs waived testing that does not involve an instrument and the test falls within his or her specialty, the organization may use the medical staff credentialing and privileging process to document evidence of training and competency in lieu of annual competency assessment. In this circumstance, individual practitioner privileges include the specific waived tests appropriate to the scope of practice that he or she is authorized to perform. At the discretion of the person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate or according to organization policy, more stringent competency requirements may be implemented.

Provider performed microscopy procedures are not waived tests. The use of the credentialing and privileging process is not adequate to document the competence of independent practitioners to perform these tests per CLIA. Competence to perform these non-waived procedures must be documented using the requirement found at Joint Commission Standard HR.01.06.01.

Q. What are the required personnel roles for CLIA other than testing personnel?
A. Based upon the level of testing complexity, CLIA regulations require that certain personnel be identified to fill specific roles. These may not be the exact titles you use in your laboratory but you still need to identify the personnel who fulfill these roles.

- Moderate complexity testing requires the following roles be assigned: Laboratory Director, Technical Consultant, and Clinical Consultant.
- High complexity testing requires the following roles be assigned: Laboratory Director, Technical Supervisor, Clinical Consultant, and General Supervisor.

For additional information regarding the qualifications and responsibilities of these roles, please refer to CLIA Subpart M. This can be accessed from the Support Center/Resources Tab on Lab Central Connect™ if your lab is currently accredited by The Joint Commission or on the CDC website.

Q. Where can educational materials on performing calibration verification be found?
A. Some helpful hints on meeting the standards for calibration verification are located in a new video located on the Joint Commission Lab Central Connect™ portal, located on the extranet site of labs accredited by The Joint Commission. The video is accompanied by PowerPoint slides, a script and the supporting documents to allow customization of the presentation if desired. This is a great tool for conquering one of the most frequent findings for laboratories.
Q. What are the requirements for meeting standard DC.02.03.01, EP 12 when using electronic records?
A. Clarification for date and time test results:
   - DC.02.03.01 The laboratory report is complete and is in the patient’s clinical record.
   - EP12 The date and time the test results were generated as a final report. The date and time cannot be changed on copies of the report that are made at a later date.

The patient’s clinical record is most often owned by the hospital and therefore subject to the hospital conditions of participation (CoPs). Using the CoPs to provide a consistent approach across all programs, The Joint Commission needed to broaden its interpretation of this EP as electronic records became predominant. The Joint Commission has determined that in order to provide clinical relevance to laboratory results, the patient’s clinical record must include a time with the results that provides the best timeline guidance for the clinician. The organization has a choice of what that time could be, including an order time, a draw time, or a final result time. The date and time chosen cannot be changed on copies of the report that are made at a later date.

Q. Does proposed standard QSA.04.06.01 EP 6 (Effective July 2013) require laboratories to culture all stool specimens for O157 Shiga toxin-producing E. Coli (STEC) and also test for non-0157 STEC?
A. If a laboratory performs stool cultures, the specimens from all patients with community-acquired diarrhea must be cultured using selective or differential media to identify 0157 STEC. Additional testing must be performed to identify non-0157 STEC. However, this additional testing may be sent to a reference laboratory. Laboratories which do not perform stool cultures are encouraged to order culture and testing for 0157 and non-0157 STEC on specimens from all patients diagnosed with community-acquired diarrhea.

Q. Is it required to document workload for non-gynecologic cytology and fine needle aspiration readings?
A. Workload recording is required for all primary screeners by CLIA regulations, including fine needle aspirations. This includes the pathologists if they are performing primary screening.

If we can be of further assistance, please contact us at qualitylabs@jointcommission.org