1. Is Lab Central Connect® required?

Yes, we want you to use the portal to manage certain lab-specific pieces of information that are currently being collected. Please reference the Joint Commission Lab Central Connect Important Information Checklist for the elements that need to be collected. In summary, they are:

- Name and qualifications of the lab director when changes to the director occur. Your current lab director will import from the e application. We will then be able to provide prompt feedback if it appears the lab director does not meet the CLIA requirements, which protects your organization.
- Names of your technical supervisor, general supervisor, technical consultants and clinical consultants as defined by CLIA. You should also provide the experience that qualifies them according to CLIA using the fields provided as the surveyors will need to see that. Please note that one person can fill multiple roles and multiple people can fill any role besides Laboratory Director. It is optional to upload any education, competency or other supporting documents but many of our pilot sites found that to be a useful tool. Pilot sites found it takes approximately 5 minutes or less per person to complete this information.
- Mark the relevant circle "does or does not accept referral testing". Referral testing are samples from an outside organization and may impact the state requirements that the surveyor needs to review.
- "Test Systems" lists the analyzers and tests used by the laboratory. This field has been removed from the application to avoid any redundancy. The FDA database used to build this list will allow you to accurately associate the specialty and complexity needed for your CLIA certificate. This will prevent surprises when the surveyors arrive and the CLIA certificate doesn't match the actual on-site activities.
- If cytology is performed, you must upload your workload and annual statistics for surveyors to readily access. This again will also be valuable during the PPR calls or visits.

2. What are the personnel requirements from CLIA?

Personnel and competency questions are frequent findings on surveys. Lab Central Connect has also prompted a lot of questions regarding the qualifications for the CLIA defined roles. One of the most frequent questions we continue to receive is the personnel requirements. We are asking for the entry of your CLIA required leadership positions:

- Laboratory Director
- Technical Supervisor (high complexity only)
- General Supervisor (high complexity only)
- Technical Consultant (moderate complexity only)
Clinical Consultant (both high and moderate)

For more information on what is required for each of these positions, we have a link on Lab Central Connect to the CLIA regulations, http://wwwn.cdc.gov/clia/regs/subpart_m.aspx.

We are currently developing an FAQ document to help describe these roles, which should be differentiated from job titles. The other important piece of regulation is competency assessment and CMS has just released a brochure that can help you better understand what competence documentation is required for these roles, including providers performing PPMP. The brochure also discusses waived testing.


3. Do the Cytology Workload Requirements apply to non-gyn and FNA samples? Are pathologists required to complete them?

The Joint Commission standards and survey process follow the CLIA regulations for cytology. Workload recording is required for all primary screeners by CLIA regulations for gyn and non-gyn cytology, including fine needle aspirations. This includes the pathologists if they are performing primary screening. The CLIA regulations can be found at this link: http://wwwn.cdc.gov/clia/regs/subpart_k.aspx#493.1274.

4. What is defined as referral testing?

Many states have requirements for organizations accepting samples from outside facilities for testing. To capture this for the surveyors, we are now asking this question in Lab Central Connect. Many of you have asked how this is defined.

Referral testing is testing from an organization that is not functionally and organizationally integrated, i.e. testing that comes from outside of your organization. If any of these samples are coming from out of state, you should be aware of any unique requirements of the state of origin, including actual licensure.

5. Why can you only designate one activity in the personnel qualifications page (direct, supervise or perform)?

The intent of this page is to identify the highest CLIA role performed by the personnel. Lab Directors are reviewed by our Standards interpretation Group to ensure that they meet the CLIA requirements to direct. If the person qualifies to direct, they will qualify to supervise or perform as those are lesser criteria. Likewise, a supervisor will always have sufficient qualifications to perform testing according to the regulations if they can supervise. The qualifications for supervisors and testing personnel will be reviewed on survey.

6. If our pathologists is CP and AP boarded, which do we choose in Lab Central?

When pathologists are dual boarded, you may select either Anatomical or Clinical Pathology. We have submitted an enhancement request to our vendor to add an AP/CP selection.

7. How often should we upload the cytology workload sheets?
The absolute minimum is every 6 months after you do your supervisory review. Preferably, the sheets are uploaded monthly or quarterly. The surveyors will want to check the workload sheets against all primary screeners, including pathologists.

8. Will I get cited on survey if the information isn’t loaded into Lab Central Connect correctly?

The first survey after implementation will be educational and no findings will be issued as long as there is an effort to get the information into the system.

9. Can I upload multiple staff members at once into Lab Central Connect?

Many laboratories have their personnel already documented in a database file or have asked if they could create a master Excel spreadsheet and upload multiple staff members at once into Lab Central Connect. This feature is now available and can be accessed under the Personnel tab of the portal. From this tab, access the User Guide which will walk you through the steps for completing a spreadsheet or how to upload information from a database.

10. What proficiency testing (PT) is now being requested? Do we have to do anything?

The Joint Commission has always received PT information via the Centers for Medicare & Medicaid Services (CMS) database in order to fulfill its regulatory obligations for CLIA. What has changed is that we will soon begin uploading the same PT data directly from the vendors as well. This will provide you with a dashboard of results from all of the vendors in the same format as we now see it, as well as a centralized review spot for surveyors. Nothing will change regarding how you manage the follow-up process for now. It is our intent to eventually upload the non-regulated analytes as well as these represent the laboratory version of performance measures. This again will provide a dashboard for you as well as data for discussion during the Periodic Performance Review (PPR) to assist you with identifying risk points.