COLA Technical Bulletin

2014-1: COLA criteria for meeting California requirements

Good news for COLA accredited laboratories in California!

California Laboratory Field Services (LFS) approved the COLA Laboratory Accreditation program on September 19, 2013. This deeming authority was granted in accordance with a state law enacted in 2009 that permits private, non-profit accrediting organizations to apply to LFS for approval to inspect California laboratories for compliance with California laboratory regulations.

Your COLA accreditation now allows you to show compliance with federal CLIA *and* the laws and regulations of the State of California. Very practically, this means that you will experience only one ***routine*** survey every two years by a COLA surveyor.

When you apply for your facility license renewal from LFS, because you are a COLA-accredited laboratory, you will be issued a Certificate of Deemed Status at your next renewal. COLA has already provided LFS with a list of our California members to ensure that you receive the proper certificate at your next renewal. As a point of clarity, the Certificate of Deemed Status is equivalent to the State License that you currently hold.

What additional requirements will COLA now be reviewing during the on-site survey?

You have always been required to comply with all state regulations. The difference going forward is that for the biennial surveys, COLA , rather than LFS, will now be reviewing your compliance with state regulations. Please note that if you are a new laboratory, the ***initial*** survey for compliance with California regulations will still be performed by LFS.

For your convenience, we have listed below the areas that are specific to compliance with California state regulations, and that COLA will be reviewing during the on-site survey.

1. Personnel

California has some very specific requirements regarding personnel, especially for non-POLs. COLA has always held you to these expectations, so nothing changes in that regard. For detailed information on California laboratory personnel regulations, see COLA Fast Facts 2 and 7. These can be found on COLAcentral® under the Education/Resources tab. Go to Free Resources, and select Fast Facts.

In California, a POL is defined as a clinical lab that is owned as a partnership, or professional corporation of ***no more than five*** physicians, or by a individual licensed physician, that performs testing ***only for their own patients.*** If a laboratory qualifies as a POL, then the laboratory is exempt from the California laboratory personnel licensure requirements, and only the CLIA personnel requirements apply. However, all other California laboratory regulations apply, and the **Laboratory Director** for any non-waived lab, POL or non-POL, must meet California requirements for Lab Director, (a **CA-licensed** physician/surgeon, master or doctoral scientist, or master or doctoral bioanalyst).

2. Record retention

California requires that all records be maintained for a minimum of three years. This includes discontinued procedures, QC and QA records, calibration and maintenance records, and Proficiency Testing, to name a few. Please note: COLA requires that all Immunohematology records be maintained for a minimum of 10 years.

3. Job descriptions

California requires documentation that specifically describes the responsibilities for each member of the laboratory staff. This documentation should reflect what is permissable under state law. COLA will typically look for this list of responsibilities in the job descriptions for your staff.

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4. Verifying performance specifications for high complexity testing

If your laboratory performs high complexity testing, California has maintained the 1994 CLIA requirement for additional verification of performance specifications for high complexity testing. Therefore, in California, COLA criteria VER (verification) 5 through 11 apply not only to non-FDA approved methods, but to any high complexity laboratory test.

5. Quality Control

California has maintained the 1994 CLIA regulations for Quality Control. There is no allowance for an alternate, equivalent quality option. Therefore, neither Equivalent Quality Control (EQC) nor Individualized Quality Control Plans (IQCP) are allowed in California at this time. The 1994 CLIA regulations, and current California regulations, require that QC be performed each run. A run is defined as an interval within which the accuracy and precision of a testing system is expected to be stable, but cannot be greater than 24 hours or less than the frequency recommended by the manufacturer.

In addition, QC for Hematology analyzers must be run every eight hours of patient testing.

For Microbiology, the 1994 CLIA QC requirements must be followed in California:

- For catalase, coagulase, beta-lactamase, oxidase, and DNA probes, you must run positive and negative controls each day of use.
- For bacitracin, optochin, ONPG, and X and V strips, you must run positive and negative controls each week of use.
- For combination X/V strips, you must run a positive control each week of use.
- For acid fast stains used for mycobacteriology or mycology, you must check reactivity using positive and negative control organisms each week of use.
- For biochemical tests used to identify mycological organisms, you must check reactivity using a positive control organism each week of use.
- For antisera used for Microbiological identification, you must perform positive and negative controls with each new lot, batch, or shipment, and at least monthly.

6. Test reports

California requires that the name of the Laboratory Director be on all laboratory test reports.

Test reports for prenatal blood typing must be stamped or imprinted with the following statement: "State law requires that the woman tested be informed of the rhesus (Rh) typing test results."

7. Autoverification

If your laboratory uses autoverification for the release of test results, you must document and verify the criteria used for autoverification.

8. State requirement for HIV confirmatory testing

California requires laboratories to follow HIV confirmation protocols recommended by the CDC to confirm all reactive or indeterminate HIV test results prior to reporting the result. If your laboratory performs HIV screening, you must define and document a protocol to obtain confirmatory testing of intitial HIV screening results that are postive or indeterminate. For details, please refer to: http://www.cdph.ca.gov/programs/aids/Documents/HIVTestingConfTestiGuidance.pdf.

9. Reportable disease and condition reporting

You must have a written procedure regarding reportable disease and condition reporting requirements. For detailed information, consult the California Department of Public Health website: http://www.cdph.ca.gov/HealthInfo/Pages/ReportableDiseases.aspx.

10. Proficiency Testing

California requires that all laboratories performing HIV testing, even if the test kit is waived, participate in an approved Proficiency Testing program for HIV.