*Effective Date: 10/12/2022*

# COLA Technical Bulletin

## 2022-6: COLA Criteria for Meeting California Requirements

*With updates for Pathology, 2022*

California Laboratory Field Services (LFS) approved the COLA Laboratory Accreditation program in 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. LFS approved COLA for the specialty of Pathology in September 2022.

Your COLA accreditation 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. Please note that if you are a new laboratory, the initial survey for compliance with California regulations will still be performed by LFS.

***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.

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.

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).

ALL supervisory personnel (TC, TS, GS) must be licensed in POLs and non-POLs alike.

**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.

Cytology records must be retained for a minimum of five 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.

**4. Quality Control**

As of July 2015, California has adopted the QC requirements as outlined in subpart K of the CLIA regulations, and will allow the use of IQCP as an equivalent quality alternative to the regulatory QC requirements described above. COLA Primer #53 contains detailed information about IQCP and is available on COLAcentral®. Call COLA for assistance with COLAcentral®.

**5. 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."

**6. Autoverification**

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

**7. 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:

https://www.cdph.ca.gov/Programs/CID/DOA/Pages/HIVLaws.aspx

**8. 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:

https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/ReportableDiseases.pdf

**9. 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.

**10. Cytology Workload**

A Cytotechnologist performing manual gynecologic slides may not examine more than 80 slides in a 24-hour period. For automated or semi-automated pap methods, the limit is 100 per 24 hours.

**11. Cytology Quarterly Reports to Providers**

Cytology laboratories must send each provider quarterly reports requesting follow-up histological information for correlation of abnormal gynecologic cases.