

**CALIFORNIA CLINICAL
LABORATORY LAWS AND
REGULATIONS FOR UN-
LICENSED PERSONNEL
TRAINING**

Presented by:
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Welcome

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Objectives

- Understand what California Laws and Regulations apply to clinical laboratory testing personnel
- Understand the differences between CLIA personnel regulations and California laws and regulations
- Understand who can perform clinical laboratory tests in a California Licensed Clinical Laboratory
- Understand what unlicensed personnel may do in a California Licensed Clinical Laboratory

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Why do Lab People want to work in a CA laboratory?

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- It's a great place to live
- Lab people get paid more than in other states
- California license laws and regulations ensure higher test quality



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How are California lab laws and regulations different from other states?

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- Most States use CLIA personnel standards
 - California, New York, Florida, Hawaii, Oregon and several other States have requirements exceeding CLIA
- California Business and Professions Codes and Health and Safety Codes define clinical laboratory personnel standards
- California issues licenses to qualified persons to perform clinical laboratory tests

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Classification of Clinical Lab Tests

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- California Follows CLIA Classification
 - Waived
 - Provider performed microscopy (PPM)
 - Moderate complexity
 - High complexity
 - Lab developed tests (LDT)

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Who Can Perform What Test(s)?

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High Complexity

- MD/DO (applies also to a licensed Dentist or licensed Podiatrist if result can be lawfully used in his or her practice)
- CLS & Laboratory Directors (Specialist license limited to tests relative to their specialty)
- PHM (Public Health Microbiologist; limited to microbiology and/or immunology testing for infectious disease)
- PA (Physician Assistant)
- Perfusionist (when authorized by and performed in compliance with CBPC §2590)
- RCP (Respiratory Care Practitioner; limited to blood gas analysis and as specified in CCR Title 17 §1054.1)
- NMT (Nuclear Medicine Technologist; limited to testing authorized by scope of practice)
- POL personnel (physician office personnel with onsite physician supervision)

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Who Can Perform What Test(s)? Cont'd

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Moderate Complexity

- MD/DO (applies also to a licensed Dentist or licensed Podiatrist or if result can be lawfully used in his or her practice)
- CLS & Laboratory Directors (Note: A person licensed as a "clinical chemist scientist," or "clinical microbiologist scientist," or "clinical toxicologist scientist," or "clinical immunohematologist scientist," or "clinical genetic molecular biologist scientist," or "clinical cytogeneticist scientist," or a "clinical histocompatibility scientist" may perform any clinical laboratory test or examination classified as waived or of moderate complexity under CLIA. CBPC §1210(a).)
- MLT (Medical Laboratory Technician; must have onsite supervision as described in CCR Title 17 §1032.5.b.3)
- PHM (Public Health Microbiologist; if the test or examination is within a specialty or subspecialty authorized by the person's certification. CBPC §1206.5(c)(4))

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Who Can Perform What Test(s)? Cont'd

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Moderate complexity cont'd

- PA (Physician Assistant)
- Perfusionist (when authorized by and performed in compliance with CBPC §2590)
- RCP (Respiratory Care Practitioner;; limited to blood gas analysis)
- NMT (Nuclear Medicine Technologist; limited to testing applicable to practice)
- Pharmacist (if ordering drug therapy-related laboratory tests)

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Unlicensed Personnel Qualifications

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- High School diploma or the equivalent with the following documented training and competency:
 - ▣ The skills required for proper specimen collection, including patient preparation, labeling, handling, preservation or fixation, processing or preparation, and transportation and storage of specimens.
 - ▣ The skills required for assisting a licensed physician and surgeon or personnel licensed under BPC chapter 3, other than trainees, in a licensed clinical laboratory.

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Unlicensed Personnel Qualification Cont'd

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- ▣ The skills required for performing preventive maintenance, and troubleshooting.
- ▣ A working knowledge of reagent stability and storage.
- ▣ The skills required for assisting in the performance of quality control procedures, and an understanding of the quality control policies of the laboratory.
- ▣ An awareness of the factors that influence test results.

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Activities That an Unlicensed Person can Perform

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- Unlicensed Laboratory Personnel are not authorized to perform clinical laboratory tests or examinations and are not considered testing personnel under California law.
- CBPC §1269 specifies that Unlicensed Laboratory Personnel are authorized to **assist** a licensed physician and surgeon or personnel licensed under CBPC, Chapter 3.

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Required Supervision of an Unlicensed Person

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- **S&C = Must be performed under Supervision and Control**
- **Supervision and control**, as it relates to Section 1269 of the Business and Professions Code, means that the unlicensed person is supervised by a licensed physician and surgeon, or a person licensed under Chapter 3 of the Business and Professions Code, other than a trainee, who is either physically present in the laboratory or available by telephone or other electronic means,

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Required Supervision of an Unlicensed Person Cont'd

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- **D&C = Must be performed under Direct and Constant Supervision**
 - Supervision CBPC§1206(a)(9)
- "Direct and constant supervision" means personal observation [**direct line of sight**] and critical evaluation of the activity of unlicensed laboratory personnel by a physician and surgeon, or by a person licensed under this chapter other than a trainee, **during the entire time that the unlicensed laboratory personnel are engaged in the duties specified in Section 1269.**

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Required Supervision of an Unlicensed Person Cont'd

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- No laboratory testing can be performed without a licensed person on-site.
- A California Licensed Medical Technician [MLT] has to have a California Clinical Laboratory Scientist or other qualified licensee onsite whenever they are performing laboratory tests that they are licensed to perform.

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Unlicensed Personnel Can Perform These Examples with Supervision & Control

- Labeling
- Handling
- Preservation or Fixation
- Processing or Preparation
- Transportation
- Storage
- Load patient samples into centrifuges and start the centrifuge.
- Load patient samples onto robotic sorting/aliquoting system in the pre-analytic phase and start the system

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Unlicensed Personnel Can Perform These Examples with Direct and Constant Supervision

- Place QC and calibration verification material [not calibrators] on an instrument.
- Assist in performance of Quality Control procedures.

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Unlicensed Personnel Can Perform These Examples with Direct and Constant Supervision

- Manually record digital temperature and humidity results
- Pre-analytically load patient samples, reagents, QC material and calibration verification material [not calibrators] onto analytical instruments
- Start/operate the instrument
- Assist in preventive maintenance and troubleshooting

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Unlicensed Personnel Can Perform These
Examples with Direct and Constant Supervision

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- Biological Specimen Collection (except for Blood)
- Patient Preparation
- For qualitative tests only, once the analytical process has begun, load patient samples into shakers, incubators and automated washers and start the system
- For qualitative tests only, once the analytical process has begun load patient samples into centrifuges and start the centrifuge
- Load patient samples onto automated diluting systems and start the system

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Unlicensed Personnel Can Perform These
Examples with Direct and Constant Supervision

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- Use fixed volume pipettes to dispense material when the fixed volume pipettes have been previously calibrated by a person licensed under Chapter 3 of the CBPC.
- For manual qualitative and semi-quantitative (spot, tablet, or stick) tests, add the test reagent to the specimen or vice versa.

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Unlicensed Personnel Can Perform These
Examples with Direct and Constant Supervision

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- Preparation and storage of reagents and culture media.
- In the case of microbiological tests, the personnel may:
 - make primary inoculations of test material onto appropriate culture media
 - stain slide preparations for microscopic examination, and
 - subculture from liquid media.

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Unlicensed Personnel Can Perform These Examples with Direct and Constant Supervision

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- Preparation and storage of reagents and culture media
- Load premeasured reagents that do not require any further quantitative measurement onto any automated instrument or system and start the instrument or system
- Unload and store reagents

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Unlicensed Personnel Can Perform These Examples with Direct and Constant Supervision

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- Transcribe results that have been previously recorded [electronically or on a paper print out] either manually by a CLS or automatically by an instrument.

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Unlicensed Personnel Cannot Perform These Examples with Supervision & Control

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- Manually measure the quantitative volume of any specimen or reagent
- Quantitatively measure any sample unless done automatically by an instrument in the course of its normal operation or by the use of previously calibrated and approved automatic syringes or other dispensers.
- Collect blood samples unless they are a Limited Phlebotomy Technician/Certified Phlebotomy Technician
- Select any automated instrument or system program or setting

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Unlicensed Personnel Cannot Perform These Examples with Direct and Constant Supervision

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- Collect blood samples unless they are a Limited Phlebotomy Technician/Certified Phlebotomy Technician
- Select any automated instrument or system program or setting
- Select the temperature, timer or program used for shakers, incubators and automated washers.
- Set the time or speed of centrifugation during the analytical phase of testing.
- May not perform any test or part thereof that involves the quantitative measurement of the specimen or test reagent [[CBPC §1269 (d)(2)]

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Unlicensed Personnel Cannot Perform These Examples with Direct and Constant Supervision

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- Prepare any control that requires the use of a pipet or other manual quantitative measurements.
- Evaluate QC, calibration or patient results for acceptability.
- Place calibration materials on an instrument.

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Unlicensed Personnel Cannot Perform These Examples with Direct and Constant Supervision

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- Standardize or calibrate an instrument.
- Quantitatively measure any sample unless done automatically by an instrument in the course of its normal operation or by the use of previously calibrated and approved automatic syringes or other dispensers.
- Select any automated instrument or system program or setting
- Select the temperature, timer or program used for shakers, incubators and automated washers

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Unlicensed Personnel Cannot Perform These Examples with Direct and Constant Supervision

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- Set the time or speed of centrifugation during the analytical phase of testing
- May not perform any test of part thereof that involves the quantitative measurement of the specimen or test reagent [(CBPC §1269 (d)(2)]
- When any of the following mechanical or electronic instruments are employed:
 - Standardizing or calibrating the instrument or assessing its performance by monitoring results of appropriate standards or controls.

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Unlicensed Personnel Cannot Perform These Examples with Direct and Constant Supervision

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- Read qualitative or semi-quantitative (spot, tablet, or stick) test results.
- Record test results but may transcribe results that have been previously recorded, either manually by a physician and surgeon or personnel licensed under this chapter, or automatically by a testing instrument.
- Perform any test or part thereof that involves quantitative measurement of the specimen or test reagent or any mathematical calculation relative to determining the results of the validity of a test procedure.
- Perform any phase of clinical laboratory tests or examinations in the specialty of immunohematology beyond initial collection and centrifugation.

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Unlicensed Personnel Cannot Perform These Examples with Direct and Constant Supervision

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- Quantitatively measuring any sample or reagents unless done automatically by the instrument in the course of its normal operation or by the use of previously calibrated and approved automatic syringes or other dispensers.

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Unlicensed Personnel Cannot Perform These Examples with Direct and Constant Supervision

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- Release patient results.
- Read or initially record test results.

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Unlicensed Personnel Signatures or Initials on Documents / Records

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- Unlicensed personnel **can** sign or initial the following documents/records
 - ▣ Equipment maintenance
 - ▣ Room Temperature or Humidity [if digital thermometer or hygrometer]
 - ▣ Temperature of heat blocks [if digital thermometer]
 - ▣ Temperature of water bath [if digital thermometer]
 - ▣ Notes on test requisitions regarding missing information, etc., required by SOP

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Unlicensed Personnel Signatures or Initials on Documents / Records Cont'd

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- Unlicensed personnel **cannot** sign or initial the following documents/records
 - ▣ QC records
 - ▣ Calibration records
 - ▣ Patient test results
 - ▣ Validation results
 - ▣ Any task(s) requiring interpretation
 - Making any reagent needing liquid measurements [except using pre-calibrated automatic pipettes]
 - Measuring specimen volumes using a graduate/flask/non-automated pipette

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Reminders

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- There are only two licenses issued to perform clinical laboratory testing in California
 - ▣ Clinical Lab Scientist (CLS)
 - ▣ Medical Laboratory Technologist (MLT)
- Unlicensed personnel require supervision by licensed testing personnel
- A licensed person must be in the lab when any test is being performed

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Reminders Cont'd

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- **Two kinds of supervision of unlicensed personnel are required**
 - ▣ **S&C = Must be performed under Supervision and Control**
 - ▣ **D&C = Must be performed under Direct and Constant Supervision DIRECT LINE OF SIGHT**

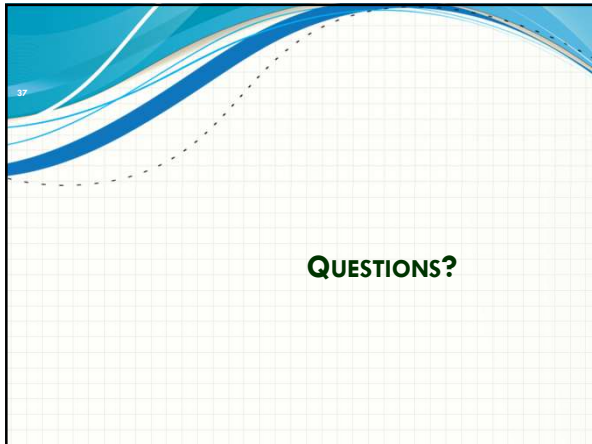
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Reminders Cont'd

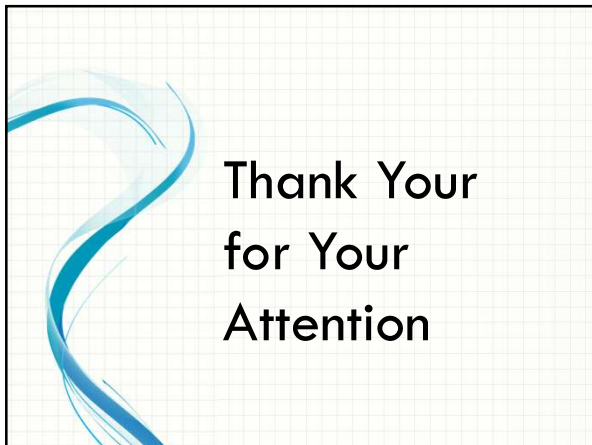
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- Unlicensed personnel performing any un-authorized task may be subject to termination.

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