



## THE ROLE OF UNLICENSED PERSONNEL IN CALIFORNIA LABORATORIES

Under California law, “physician office laboratories” (POLs) are defined as those laboratories owned and operated by a partnership or professional corporation which performs clinical laboratory testing only for patients of five or fewer physicians.

Laboratories meeting this definition can employ “any person” to perform testing provided the individual qualifies to perform testing under the CLIA requirements (COLA Fast Fact #6, “California Law & Your Laboratory Personnel,” outlines personnel requirements). In addition, the physician(s) needs to properly supervise testing personnel sufficient to comply with the law’s stipulations.

All other laboratories, including those performing testing for the patients of six or more physicians, must continue to employ state licensed personnel such as licensed medical technologists, physician assistants, and registered nurses to perform laboratory testing.

Personnel who are not specifically licensed by the state are considered “unlicensed” (e.g., medical laboratory technicians and high school graduates).

When unlicensed personnel are working in a clinical laboratory, other than a POL as defined above, they are only permitted to perform certain functions in the laboratory. These functions are identified in the chart shown at right.

Should you have any questions regarding this issue, other general laboratory personnel issues in California, or CLIA, please call the COLA Information Resource Center toll-free at (800) 981-9883.

### ROLE OF UNLICENSED PERSONNEL IN A CLINICAL LABORATORY (other than a POL)

#### Activities that may be performed are:

- Biological specimen collection, including patient preparation, labeling, handling, preservation or fixation, processing or preparation, and transportation and storage of specimens.
- Assistance in preventive maintenance and troubleshooting.
- Preparation and storage of reagents and culture media.
- Assistance in performance of quality control procedures.

#### Unlicensed personnel—other than a trainee—may do either of the following under the supervision and control of a physician or person licensed under this chapter:

- Perform venipuncture, arterial puncture, or skin puncture as part of specimen collection if he or she meets the requirements of Sections 1242, 1242.5, or 1246\*, and the regulations adopted thereunder.
- Perform specimen labeling, handling, preservation or fixation, processing or preparation, transportation, and storing if he/she has a high school diploma or its equivalent as determined by HCFA under CLIA, and has documentation of training appropriate to ensure the individual has all the skills required to perform these tasks.

**\* Section 1246 of the California Business and Professions code** provides that unlicensed personnel employed by a licensed clinical laboratory may perform venipuncture or skin puncture upon specific authorization from a licensed physician if: he/she works under the supervision of licensed personnel; licensed personnel are physically available to be summoned to the scene of the venipuncture within five minutes during the performance of the procedure; and he/she has signed documentation by the instructing physician, or instructing clinical laboratory bioanalyst, that he/she has been trained in the proper procedure to be employed when withdrawing blood in accordance with training requirements established by the State Department of Health Services.

**Unlicensed personnel may not do any of the following:**

- Record test results, but he/she may transcribe results that have been previously recorded, either manually by a physician or licensed personnel, or automatically by a testing instrument.
- Perform any test or part thereof that involves the quantitative measurement of the specimen or test reagent, or any mathematical calculation relative to determining the results or 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.

**When any of the following manual methods are employed, the activities of unlicensed personnel shall be limited as follows:**

- In the case of qualitative and semi-quantitative “spot, tablet, or stick” tests, the personnel may add the test reagent to the specimen or vice-versa, but the results must be read by a physician, or licensed personnel.
- In the case of microbiological tests, the unlicensed laboratory personnel may make primary inoculations of test material onto appropriate culture media, stain slide preparations for microscope examination, and subculture from liquid media.

**When any of the following mechanical or electronic instruments are employed, unlicensed laboratory personnel shall not perform any of the following activities:**

- Standardizing or calibrating the instrument or assessing its performance by monitoring results of appropriate standards and control.
- Reading or recording test results, except that the personnel may transcribe results that have been previously recorded automatically by a testing instrument.
- 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/dispensers.