

PHYSICIAN OFFICE LABORATORIES OR CLINICS - FREQUENTLY ASKED QUESTIONS
ABOUT CLINICAL LABORATORY LICENSING AND REGISTRATION

Q: What is clinical laboratory?

A: A clinical laboratory is defined in state and federal law as any place where testing is done on human specimens for diagnostic purposes.

Q: Would a physician office laboratory (POL) be considered a clinical laboratory?

A: Yes, a POL is considered a clinical laboratory if any patient testing is done (e.g., urine dipstick tests, fingerstick blood tests or Pap smear review and reporting).

Q: Why do clinical laboratories need to be licensed or registered?

A: State law requires it. The licensing and registration of clinical laboratories helps assure that quality standards are maintained in clinical laboratories. Licensure or registration is part of the process that may include inspections, complaint review and proficiency testing oversight.

Q: What is the difference between laboratory licensure and registration?

A: Laboratories doing non-waived testing are required to be inspected and licensed. Laboratories doing waived or provider-performed microscopy only need to be registered, although some waived laboratories may also be inspected.

Q: Are there some laboratories that are exempt from licensure or registration?

A: A few types of laboratories are exempt from licensing and registration requirements. These include veteran's hospitals, public health laboratories, forensic laboratories, and research or teaching laboratories.

Q: Are POLs exempt from licensure or registration requirements?

A: No, they are not exempt. State law requires that POLs be licensed or registered.

Contact Information:

Bea O' Keefe, bea.okeefe@cdph.ca.gov, (510) 620-3837
Karen Nickel, Karen.nickel@cdph.ca.gov, (510) 620-3800
Examiner, Facility Licensing, (510) 620-3800