

DUTY STATEMENT

Employee Name:	Position Number: 580-751-7946-005
Classification: Examiner II, Laboratory Field Services	Tenure/Time Base: Permanent / Full-time
Working Title: Clinical Laboratory Inspector	Work Location: 320 West Fourth Street Los Angeles, CA 90013
Collective Bargaining Unit: R10	Position Eligible for Telework (Yes/No): Yes
Center/Office/Division: Center for Laboratory Sciences / Laboratory Field Services	Branch/Section/Unit: Laboratory Field Services/ On-Site Licensing

All employees shall possess the general qualifications, as described in California Code of Regulations Title 2, Section 172, which include, but are not limited to integrity, honesty, dependability, thoroughness, accuracy, good judgment, initiative, resourcefulness, and the ability to work cooperatively with others.

This position requires the incumbent to maintain consistent and regular attendance; communicate effectively (orally and in writing) in dealing with the public and/or other employees; develop and maintain knowledge and skill related to specific tasks, methodologies, materials, tools, and equipment; complete assignments in a timely and efficient manner; and, adhere to departmental policies and procedures.

All California Department of Public Health (CDPH) employees perform work that is of the utmost importance, where each employee is important in supporting and promoting an environment of equity, diversity, and inclusivity, essential to the delivery of the department's mission. All employees are valued and should understand that their contributions and the contributions of their team members derive from different cultures, backgrounds, and life experiences, supporting innovations in public health services and programs for California.

Competencies

The competencies required for this position are found on the classification specification for the classification noted above. Classification specifications are located on the [California Department of Human Resource's Job Descriptions webpage](#).

Job Summary

This position supports the California Department of Public Health's (CDPH) mission and strategic plan by conducting onsite surveys, inspections, and investigations of in-state and out-of-state laboratory facilities and testing personnel for conformity with licensing and certification requirements of the California Department of Public Health (CDPH) and for compliance with state and federal laws, rules, and regulations. Provides complex technical expertise and consults with laboratories on compliance with state and federal laws and regulations, as well as conduct complaint investigations. Travel both in and out of state required up to 40% of the time.

The incumbent works under the general direction of the Examiner III.

Special Requirements

- Conflict of Interest (COI)
- Background Check and/or Fingerprinting Clearance
- Medical Clearance
- Travel: Up to 40%, may be required
- Bilingual: Pass a State written and/or verbal proficiency exam in
- License/Certification: License/Certification: Clinical Laboratory Scientist license or Public Health Microbiologist certification
- Other:

Essential Functions (including percentage of time)

- 35% Performs onsite inspections of clinical laboratories and physician office laboratories to determine compliance with state and federal laws, rules, and regulations, with standards related to all aspects of pre-analytical, analytical and post-analytical performance.
- Conducts inspections using the Outcome Oriented Survey Process (OOSP), documenting fully for legal actions all evidence relating to non-compliance, while ensuring patient confidentiality. Conducts and documents interviews of facilities' staff, complainants, and others, as needed. Observes, requests, and reviews facilities' policies and procedures, employee records testing documentation, and other information as necessary. Requests and reviews applicable files for relevant information. Independently, or as part of a team, makes a determination of compliance with state and federal laws and regulations based on findings and observations. Communicates with the CLIA licensing team as needed.
- Reviews Examiner I survey reports and makes recommendations regarding the issuance of laboratory licenses and approvals for accuracy, appropriateness and clarity; consults with field surveyors regarding survey reports in order to determine whether the laboratory is in acceptable compliance with appropriate state and federal laws and regulations. Interprets state and federal laws and regulations pertaining to clinical laboratories for Examiner I staff.
- Coordinates the inspection schedules for Examiner I's, in accordance with state and federal survey standards. Consults with Examiner I's regarding their survey reports to determine compliance of inspected clinical laboratories with both state and federal laws and regulations. Interprets and provides subject matter expertise on state and federal clinical laboratory laws and regulations.
- Communicates survey findings verbally with laboratory directors or designee during exit interviews. Prepare inspection findings on the required state documents, or the 2567 Statement of Deficiency report, uses the Principles of Documentation (POD). Reviews Plan of Correction (POC) and Allegation of Compliance (AOC) to ensure correction of deficiency. Makes recommendations regarding initial certification and recertification of laboratories for participation in the state licensure and CLIA program. Evaluates clinical laboratory performance in proficiency testing and make recommendations as needed.

Maintains and updates information in state and federal databases. Travel is required for day and overnight trips both within California and out-of-state.

30% Performs follow-up inspections as necessary to ensure correction of deficiencies. Conducts complaint investigations, as assigned, to determine possible violations of state and federal law, documenting fully for legal actions all evidence relating to non-compliance, while ensuring patient confidentiality. Conducts and documents interviews of facilities’ staff, complainants, and others, as needed.

Assists Examiner III with documentation of information needed for enforcement actions against a laboratory. Evaluates qualifications of testing personnel to determine compliance with appropriate licensing or certification requirements while conducting onsite inspections. Cross-trained to perform CLIA Survey duties including, but not limited to, onsite licensing surveys and complaint investigations, validation surveys, proficiency testing surveys, and Medi-Cal inspections. Serves as a back-up to other Examiner IIs.

20% Provides customer service and expert technical assistance through all methods of communication responding to complainants, the regulated community, the public, the media, and others. Responds to written and telephone inquiries regarding interpretation of laws, regulations and policies (state and federal) to the laboratory community and general public.

10% Participates with legal counsel in preparation of possible court hearings related to laboratory sanctions for non-compliance and will testify at hearings on behalf of the CDPH. Researches and prepares for presentations and reports as needed. Writes, reviews, and updates work procedures.

Attends and completes all mandatory state and federal training and meetings. Assures accurate completion of timesheets. Completes timely travel reservations as required, and submits timely travel claims reimbursements using the California Automated Travel Expense Reimbursement System (CalATERS). Writes, reviews, and updates work procedures.

Marginal Functions (including percentage of time)

5% Performs other work-related duties.

I certify this duty statement represents an accurate description of the essential functions of this position. I have discussed the duties and have provided a copy of this duty statement to the employee named above.

I have read and understand the duties and requirements listed above and am able to perform these duties with or without reasonable accommodation. (If you believe reasonable accommodation may be necessary, or if unsure of a need for reasonable accommodation, inform the hiring supervisor.)

Supervisor’s Name:	Date	Employee’s Name:	Date
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Supervisor's Signature	Date	Employee's Signature	Date
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HRD Use Only:
Approved By: AR
Date: 7/25/24