

## DUTY STATEMENT

Employee Name:	Position Number: <b>580-751-7946-909</b>
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	Branch/Section/Unit: Laboratory Field Services (LFS)/ Clinical Laboratory Improvement Amendment (CLIA) Survey Section

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 reviewing reports compiled for 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. The Examiner II, Laboratory Field Services provides complex technical expertise and consult with staff and laboratories on compliance with State and Federal laws and regulations, as well as conducts complaint investigations.

The incumbent works under the direction of the Examiner III.

### Special Requirements

- Conflict of Interest (COI)
- Background Check and/or Fingerprinting Clearance
- Medical Clearance
- Travel: 50%
- Bilingual: Pass a State written and/or verbal proficiency exam in
- License/Certification:
- Other:

### Essential Functions (including percentage of time)

- 35% Performs onsite inspections of clinical laboratories and physician office laboratories to determine compliance with California Business and Professions Code, Chapter 3 and Federal 42CFR Part 493 requirements for clinical laboratories and Clinical Laboratory Improvement Amendments of 1988 (CLIA) 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 Federal and State laws and regulations based on findings and observations. Communicates with the State 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 diagnostic hospital and non-hospital clinical laboratories for Examiner I staff. Coordinates Examiner I field survey schedules to meet State and Federal standards.

Coordinates the inspection schedules for Examiner Is, in accordance with state and federal survey standards. Consults with Examiner Is 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. Prepares Inspection findings on the 2567 Statement of Deficiency report using 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 CLIA program and

state licensure. 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. Provides 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 facility licensing 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.

Assists the Examiner III in the preparation of sanction referral packages for the Center for Medicare and Medicaid Services (CMS) CLIA program. Collaborates with the Examiner III to determine if laboratories cited for deficiencies should be processed for termination. When appropriate, coordinates adverse action cases against laboratories cited for deficiencies, and monitors the corresponding termination process.

- 20% Provides excellent customer service and expert technical assistance through all methods of communication responding to complainants, the regulated community, the legislature, the Governor's office, 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 the public.

- 10% Participates with legal counsel in preparation of possible court hearings related to laboratory sanctions for non-compliance and testifies at hearings on behalf of the CDPH. Attends and completes all mandatory Federal and State training and meetings. Prepares and gives presentations and researches and writes reports as needed. 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.

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### **Marginal Functions (including percentage of time)**

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- 5% Performs other, Examiner II, LFS work-related duties as required.

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
Supervisor's Signature	Date	Employee's Signature	Date

**HRD Use Only:**

Approved By: AC

Date: 1/3/25

## DUTY STATEMENT

Employee Name:	Position Number: <b>580-751-7949-909</b>
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### Special Requirements

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Consults with Examiner III 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.

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Supervisor’s Name:	Date	Employee’s Name:	Date
Supervisor’s Signature	Date	Employee’s Signature	Date

**HRD Use Only:**  
Approved By: AC  
Date: 12/2024