DUTY STATEMENT

Employee Name: **XXX**	Position Number: **580-700-5612-909**
Classification: Research Scientist IV (Microbiological Sciences)	Tenure/Time Base : Permanent/Full-Time
Working Title: Quality Systems Lead Scientist	Work Location: 850 Marina Bay Parkway Richmond, CA 94804
Collective Bargaining Unit: R 10	Position Eligible for Telework (Yes/No): Yes
Center/Office/Division: Center for Laboratory Sciences	Branch/Section/Unit: Operations Branch / Lab Operations 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 ensuring that scientists and microbiologists adhere to regulatory guidance and perform high quality laboratory testing for highly complex research methods and technologies .

The Research Scientist IV will be responsible for providing leadership and guidance to ensure quality policies, processes, and procedures are established across multiple laboratory programs in the Center for laboratory Sciences (CLS). Conceives, plans, and conducts scientific research work with the goal of enhancing and expanding the capacity and capability of CLS testing procedures through

quality, safety and effective methods. Develops Quality Management Systems in compliance with regulatory standards, reviews records and SOPs for effectiveness and efficiency, coordinates with SOP authors, records comments, and complaints, initiates corrective action process and provides guidance on conducting root cause analyses to implement regulatory changes/improvements and reports findings and resolutions to laboratory systems to meet quality standards and documentation. Maintain records, coordinate assessments, oversee document control. Establish and maintain a strong leadership role with recruitment and retention strategies. Represents department at external laboratory quality meetings and participates in legislative and regulatory package work.

The incumbent works under the guidance of the Research Scientist Supervisor II, Chief of Laboratory Operations Section within the Operations Branch.

Special Requirements

- ☐ Conflict of Interest (COI)
- ☐ Background Check and/or Fingerprinting Clearance
- ☐ Medical Clearance
- ☒ Travel: up to 10%
- ☐ Bilingual: Pass a State written and/or verbal proficiency exam in
- ☐ License/Certification:
- ☐ Other:

Essential Functions (including percentage of time)

35% Serves as a subject matter expert on regulatory guidance (CLIA and ISO17025) pertaining to laboratory testing certification and accreditation of high complexity microbiological research methods and instrumentation. To direct, organize, plan and support the direction of major scientific research studies, in collaboration with programs through the Center, to improve detection and identification of infectious disease-causing microorganisms; define mechanisms and modes of infectious disease transmission; identify mechanisms of tissue injury; support improved investigation of infectious disease outbreaks; and improve methods to prevent infectious disease transmission. Uses scientific expertise and available resources such as high-complexity instrumentation platforms for molecular, chemical and genomic sequence analyses, and newly developed testing platforms within the laboratory to respond to internal and external questions or requests related to laboratory testing associated with State regulations. Design experimental approaches to meet quality standard for meeting regulatory compliance criteria, and oversees implementation and optimization studies for improvement and streamlining testing and data reporting to federal state programs (e.g. CDC, US EPA, US FDA, CA DTSC and others). Reviews Clinical Laboratory Improvement Amendment (CLIA) applications for completeness and to ensure authenticity of the documents. Verifies that any laboratories applying for the certificate of accreditation provide supporting documents from the accreditation organization. Collaborates with the program requestors to identify the needs and concerns of the site projects regarding microbiological testing and communicates these needs to the Research Scientist (Supervisory) and appropriate laboratory staff. Reviews documents associated with sample analysis requests,

receipts, and testing for infectious agents and toxic substances, including illicit high-risk substance and submits final reports on the evaluations and recommendations for improvements. Monitors the progress of samples submitted for laboratory analysis and testing and submits the final reports to the requestors. Ensure that thorough and organized records, written notes of investigations and analyses, and data and information are routinely prepared and kept in a retrievable condition and in a manner which is accessible to the laboratory members and supervisors. Reviews technical and scientific documents such as sampling plans, Quality Assurance Project Plans (QAPPs), waste analysis plans, and risk assessments that are submitted by national accreditation programs for meeting quality control and quality assurance (QA/QC) parameters to maintain accreditation status as a certified public health testing laboratories .. Provides consultative advice to Center for laboratory sciences (CLS) programs, as well as state public health labs (PHL) regarding laboratory testing and data interpretation in various forms from emails and phone conversations to formal memorandums and reports. Provides data interpretation, validation regarding project needs, and pursues the corrective action process to all CLS programs, state PHL and other laboratory partners to ensure highest level of testing quality.

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30% Conceives, plans, and conducts scientific research work with the goal of enhancing and expanding the capacity and capability of CLS testing procedures through quality, safety and effective methods. Researches new methods on continuous quality improvement activities to implement within the Center's Divisions, Branches, and programs. Develops a Quality Management Systems (QMS) that is in full compliance with regulatory standards for high complexity scientific methods. Reviews, records, and revises the Laboratory Standard Operating Procedures (SOPs) for effectiveness and efficiency and makes recommendations for improvements. Coordinates with the SOP authors in updating and implementing the improvements to all CLS programs, state PHL and other laboratory partners.. Records comments and complaints from requesters, clients, stakeholders, as well as federal and state partners and initiates the corrective action processes and data analyses for mitigation steps. Acts as part of a team in the root cause analysis investigation and provides oversite of the corrective actions implemented. Reviews regulatory or compliance documents related to Laboratory Quality Management Systems and compares them to the laboratory current management system practices. Implements regulatory changes or improvements. Reports findings to Senior Research Scientist (Supervisory) and Research Scientist Manager.

20% Document necessary information on laboratory requests and control logs. Maintain a record of all tests performed, including results by data entry into computerized system, maintain a record of all tests reported on and results returned, and prepare and maintain statistical reports to use for further specialized research in quality and safety testing for submission to administrators for CLS laboratory consideration. Coordinates external assessments. Oversees and maintains document control systems and processes and inventory program. Collaborates with national partners and federal agencies including the Association of Public Health Laboratories, Centers for Medicare and Medicaid Services (CMS), United States Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA) and United States Department of

Agriculture (USDA) for scientific research projects. Prepares research progress reports and submits research studies for publication.

10% Represents the department and external laboratory quality meetings, and serves as Lead of the CDPH Laboratory Practices and as quality manger on committees. Participates in legislative analysis and regulatory package work. Drafts laboratory guidance and best practices documents for publication.

Marginal Functions (including percentage of time)

5% Other work-related duties as assigned.

☐ 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: AR
Date: 5/17/24

DUTY STATEMENT

Employee Name: **XXX**	Position Number: **580-700-5608-909**
Classification: Research Scientist IV (Chemical Sciences)	Tenure/Time Base : Permanent/Full-time
Working Title: Quality Systems Lead Scientist	Work Location: 805 Marina Bay Parkway Richmond, CA 94804
Collective Bargaining Unit: R10	Position Eligible for Telework (Yes/No): Yes
Center/Office/Division: Center for Laboratory Sciences	Branch/Section/Unit: Operations Branch/Lab Operations Section

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Job Summary

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The incumbent works under the guidance of Research Scientist Supervisor II, Chief of Laboratory Operations Section within the Operations Branch.

Special Requirements

- ☐ Conflict of Interest (COI)
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- ☐ Medical Clearance
- ☒ Travel: up to 10%
- ☐ Bilingual: Pass a State written and/or verbal proficiency exam in
- ☐ License/Certification:
- ☐ Other:

Essential Functions (including percentage of time)

35% Serves as a subject matter expert on regulatory guidance (CLIA and ISO 17025) pertaining to laboratory certification and accreditation of high complexity chemical research methods and instrumentation. To direct, organize, plan and support the direction of major scientific research studies, in collaboration with programs through the Center, to improve the quality of detection and identification of environmental hazards and adulterants to human health. Uses scientific expertise and available resources, such as high-complexity instrumentation platforms for molecular, chemical and genomic sequence analyses, and newly developed testing platforms within the laboratory to respond to internal and external questions or requests related to laboratory testing associated with State regulations. Design experimental approaches to meet quality standard for meeting regulatory compliance criteria, and oversees implementation and optimization studies for improvement and streamlining testing and data reporting to federal state programs (e.g. CDC, US EPA, US FDA, CA DTSC and others). Collaborates with the program requestors to identify the needs and concerns of the site projects regarding standardized testing and communicates these needs to the appropriate laboratory staff. Performs inspections on operators and maintainers of the GC-MS, GC-MS/MS, HPLC-MS/MS, UPLC-MS/MS, ICP-MS, and other high-complexity scientific instrumentation, to make sure all are adhering to all the regulatory requirements. Conducts root cause analyses of testing operations and data reporting platforms for improving data integrity and reporting efficiency to stakeholder and partners. Reviews documents associated with sample analysis requests, receipts, and testing for infectious agents and toxic substances, including illicit high-risk substance and submits final reports on the evaluations and recommendations for improvements. Monitors the progress of samples submitted for laboratory analysis and testing and submits the final reports to the requestors. Ensure that thorough and organized records, written notes of investigations and analyses, and

data and information are routinely prepared and kept in a retrievable condition and in a manner which is accessible to the laboratory members and supervisors. Reviews technical and scientific documents such as sampling plans, Quality Assurance Project Plans (QAPPs), waste analysis plans, and risk assessments that are submitted by national accreditation programs for meeting quality control and quality assurance (QA/QC) parameters to maintain accreditation status as a certified public health testing laboratories . Provides consultative advice to Center for laboratory sciences (CLS) programs, as well as state public health labs (PHL) regarding laboratory testing and data interpretation in various forms from emails and phone conversations to formal memorandums and reports. Provides data interpretation, validation regarding project needs, and pursues the corrective action process to all CLS programs, state PHL and other laboratory partners to ensure highest level of testing quality.

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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: AR
Date: 5/17/24