

**REPORT/RECOMMENDATION TO THE BOARD OF SUPERVISORS
OF SAN BERNARDINO COUNTY
AND RECORD OF ACTION**

April 8, 2025

FROM

JOSHUA DUGAS, Director, Department of Public Health

SUBJECT

Clinical Laboratory Improvement Amendments Application for Certification and Attestation for Clinic Licensing

RECOMMENDATION(S)

1. Approve the following California Department of Public Health Laboratory Services templates, as required for new applications or renewal of existing applications for the Clinical and Public Health Laboratory License to the California Department of Public Health:
 - a. Clinical Laboratory Improvement Amendments Application for Certification
 - b. Laboratory Testing Declaration
 - c. Additional Testing Sites
 - d. Notice of Laboratory Information Change
 - e. Owner's Attestation
 - f. Director's Attestation
2. Authorize the Health Officer as the Laboratory Director of the Department of Public Health, and the Director of the Department of Public Health as the Laboratory Owner and Authorized Representative, to execute and submit the California Department of Public Health Laboratory Services templates, as identified in Recommendation No. 1, for the Clinical and Public Health Laboratory License to the California Department of Public Health, on behalf of the County, subject to review by County Counsel.

(Presenter: Joshua Dugas, Director, 387-9146)

COUNTY AND CHIEF EXECUTIVE OFFICER GOALS & OBJECTIVES

Provide for the Safety, Health and Social Service Needs of County Residents.

Pursue County Goals and Objectives by Working with Other Agencies and Stakeholders.

FINANCIAL IMPACT

This item will not result in the use of Discretionary General Funding (Net County Cost). Application and renewal application fees of approximately \$1000 are paid from the Department of Public Health (DPH) to the California Department of Public Health (CDPH) and are funded through Medi-Cal, private insurance, and private pay patient funds. Adequate appropriation and revenue have been included in DPH 2024-25 budget and will be included in future recommended budgets.

BACKGROUND INFORMATION

Approval of this item will allow DPH to submit a CDPH Laboratory Services Clinical Laboratory Improvement Amendment (CLIA) Application for Certification, the Notice of Laboratory Information Change, an Owner's Attestation, and Director Attestation, which are needed for

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each health center, Public Health Clinic, and mobile clinic performing waived testing to CDPH for any new or renewal applications for the Clinical and Public Health Laboratory License (License).

California requires a License and a CLIA Application for Certification for waiver testing for every facility that performs testing on human specimens for the purpose of providing information for the diagnosis, prevention or treatment of a disease, impairment, or assessment of health.

Waived tests are categorized and defined by CLIA as “simple laboratory examinations and procedures that have an insignificant risk of erroneous result”, such as urinalysis and blood glucose by glucose monitoring devices. The Food and Drug Administration determines which tests meet these criteria when it reviews manufacture applications for test system waiver. Upon the Board of Supervisors’ (Board) approval of this item and execution by the authorized signatories, DPH will submit the required documents to CDPH.

For public clinical health systems/entities, the Board will need to grant authority to an Authorized Representative to sign the Owner’s Attestation. Recommendation No. 2 will authorize the Director of DPH to sign the Owner’s Attestation and the Health Officer to sign the Director’s Attestation on behalf of the department, which are required as part of the CLIA Application for Certification. The Owner’s Attestation and Director’s Attestation are each confirming the information included in the CLIA Application for Certification is accurate. The Laboratory Director, as defined by Title 42, part 493.2, must be a physician, a mid-level practitioner authorized by the State, or a dentist.

Approval of this item will allow DPH to execute and submit the forms listed in the Recommendations in order to complete any new Licenses or Licenses requiring renewal for the clinics to perform waived tests as part of diagnosis, prevention, and treatment of disease. Not renewing the License needed for CLIA waivers would place DPH out of compliance with the state and would directly impact patient care.

PROCUREMENT

Not applicable.

REVIEW BY OTHERS

This item has been reviewed by County Counsel (Adam Ebright, Deputy County Counsel, 387-5455) on March 17, 2025; Finance (Iliana Rodriguez, Administrative Analyst, 387-4204) on March 24, 2025; and County Finance and Administration (Robert Saldana, Deputy Executive Officer, 387-5423) March 24, 2025.

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Record of Action of the Board of Supervisors
San Bernardino County

APPROVED (CONSENT CALENDAR)

Moved: Joe Baca, Jr. Seconded: Curt Hagman

Ayes: Col. Paul Cook (Ret.), Jesse Armendarez, Dawn Rowe, Curt Hagman, Joe Baca, Jr.

Lynna Monell, CLERK OF THE BOARD

BY 
DATED: April 8, 2025



cc: File - Public Health w/attach
CCM 04/11/2025