



Center for Laboratory Sciences

The Laboratories at CDPH

Jeff Schapiro, MD, D(ABMM)
Assistant Deputy Director,
Center for Laboratory Sciences
California Department of Public Health

October 15, 2025

Laboratory Sciences

- Highly specialized
- Highly regulated
- High Quality
- Preparedness and response
- Subject Matter Experts
- Advocacy
- Workforce planning
- Foundational...not ancillary

CDPH Strategic Plan (2025-2030)



6 Strategic Priority Areas



Develop Our People



Improve Our Emergency Preparedness and Response



Embrace Data Modernization



Communicate to Empower Our People to Promote Public Health



Advance Healing, Equity, and Health Equity



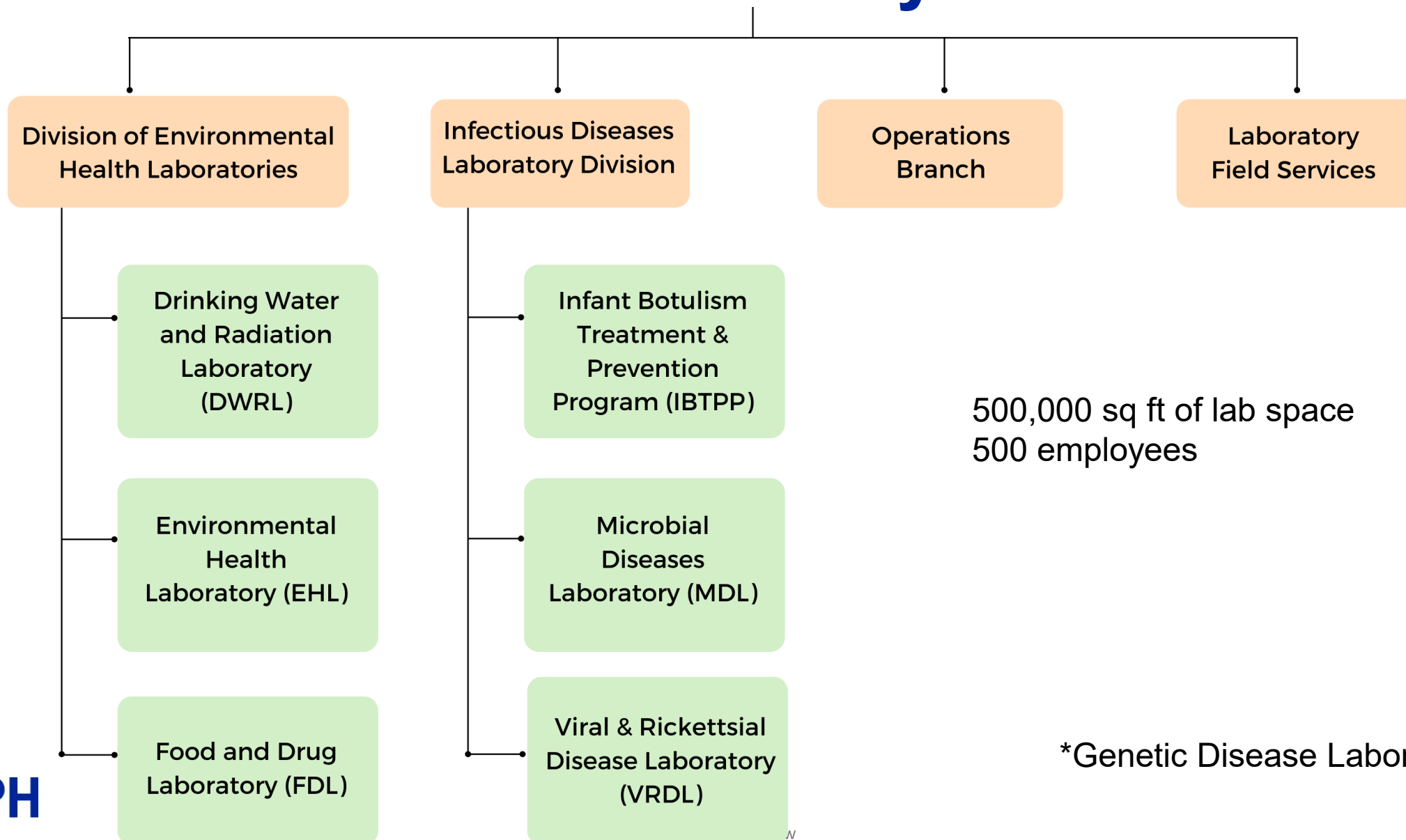
Promote Healthy Communities

HISTORY OF CLS

The Reorganization

Fall 2022/Winter 2023 brought together several laboratories on the CDPH Richmond Campus

Center for Laboratory Sciences



500,000 sq ft of lab space
500 employees

*Genetic Disease Laboratory

Center for Laboratory Sciences Vision and Mission Statements

Vision Statement:

The worldwide leader for advancing health through laboratory sciences.

Mission Statement:

To provide innovative and reliable laboratory science, quality and evidence-based data to save lives and promote health.

CLS Values

Leading



Excelling



**Creating
Communities**



Leading

- We lead the world in public health **laboratory practice, preparedness, research and expertise.**
- We inspire others by modeling excellence through **collaboration and collegiality.**

Excelling

- We **lead with integrity and innovation** by honoring our distinguished history, embracing emerging technologies, and setting the standard for scientific rigor and operational excellence.
- **Excellence and reliability** are the hallmarks of our work—from research and test development to data quality—driving continuous improvement and earning trust through transparent, impactful results.
- By consistently applying **integrity, innovation, and scientific precision**, we build trust, improve health outcomes, and establish the benchmark for excellence.

Creating Communities

We cultivate the world's strongest network of public health laboratories through **partnerships**, ensuring equitable access to scientific advancements and improving health outcomes.

Fostering a thriving and **inclusive workforce, through trust, engagement, communication, and collaboration**, bringing passion and joy to our shared mission.

Building **community through compassion** by embracing empathy, collegiality, and collective efforts to save lives and improve well-being.

Microbial Diseases Laboratory

Infectious Diseases Laboratory
Division

- Tier 1 Select Agent and Advanced Regional Laboratory Response Network (LRN-B) laboratory
- Tuberculosis National Drug Susceptibility Testing (DST) Reference Center
- Bacterial, mycobacterial, fungal, and parasitic disease detection and epidemiologic investigations
- **CELEBRATING 120 years!**

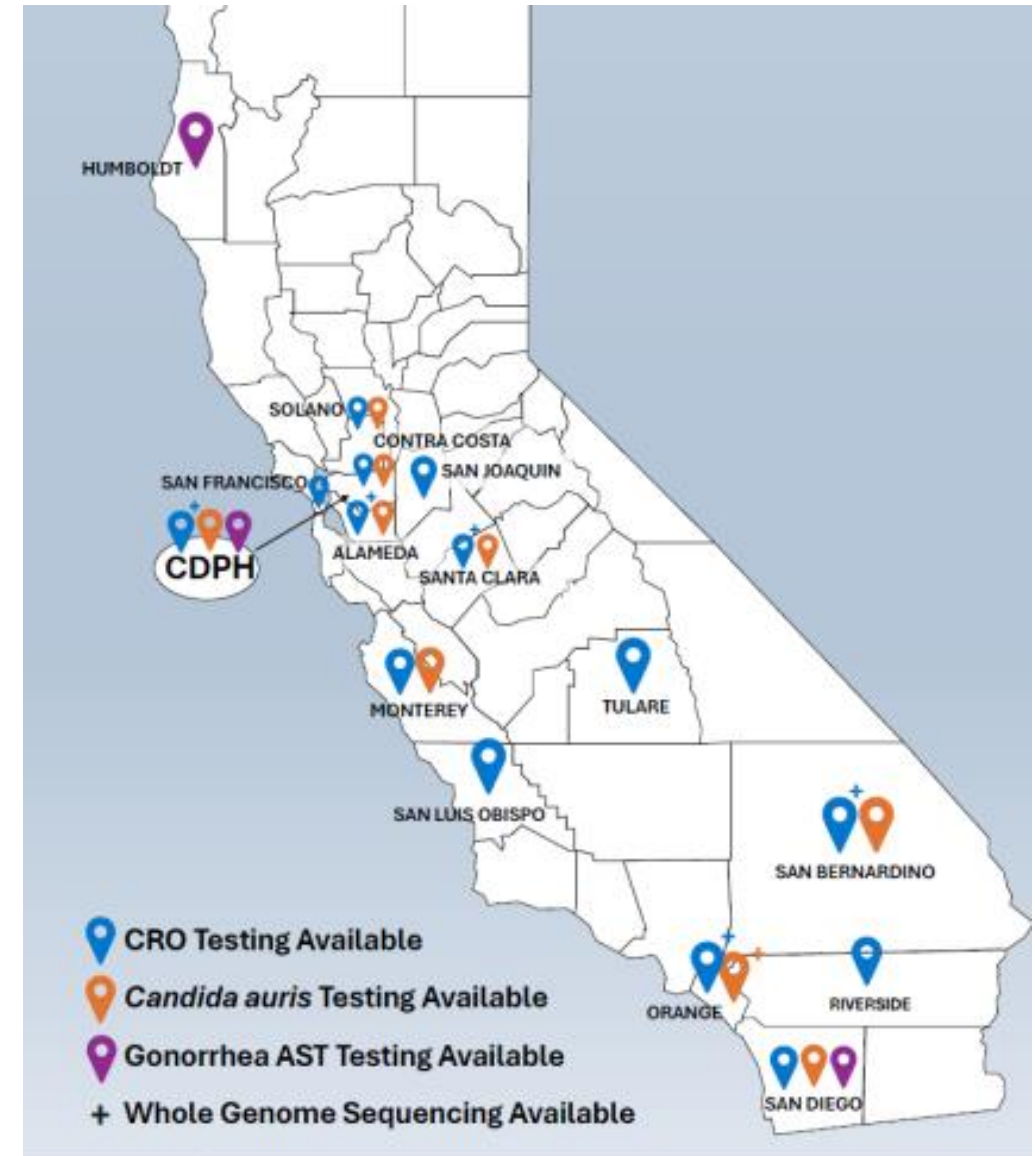
MICROBIAL DISEASE LABORATORY

- Bacterial Diseases Section (BDS)
- Foodborne & Waterborne Diseases Section (FWDS)
 - enteric disease surveillance, PSP testing, foodborne pathogen detection
- High Risk Pathogens Section (HRPS)
 - LRN-B coordination; Tier 1 Select Agent testing, botulism testing
- Immunodiagnostics & Molecular Characterization Section (IMCS)
 - genomic sequencing for antimicrobial resistance & surveillance of healthcare-associated infections
- Mycobacterial, Mycotic & Parasitic Disease Section (MMPDS)
 - providing PZA WGS mDST for 26 state PHLs

CA SHARP Network

15 Network Labs

- Strengthening **HAI/AR** Program capacity
 - Healthcare-Associated Infections/Antimicrobial Resistance
 - Epidemiology and Laboratory Capacity (ELC) Cooperative Agreement.
- *Candida auris*
- Carbapenemase producing organisms
- Gonorrhea antibiotic resistance
- HAI/AR whole genome sequencing



Laboratory Response Network (LRN)-B

- Response Network for biological threats
 - National Laboratories
 - Reference Laboratories (~100 State and Local PHL)
 - Testing of environmental and clinical samples
 - Training and guidance for Sentinel laboratories
 - Sentinel Laboratories (>25,000 clinical labs)
 - Early detection
 - Rule out or refer

California LRN-B Network

14 LRN-B Reference PHLs

Humboldt, Orange, Shasta, Sacramento, Sonoma, San Joaquin, CDPH, Fresno, Santa Clara, Tulare, SLO, LA, San Bernardino, San Diego

2 Advanced Reference LRN-B

CDPH, Los Angeles

1 Tier 1 Select Agents-registered

CDPH

Viral and Rickettsial Disease Laboratory

Infectious Diseases Laboratory
Division

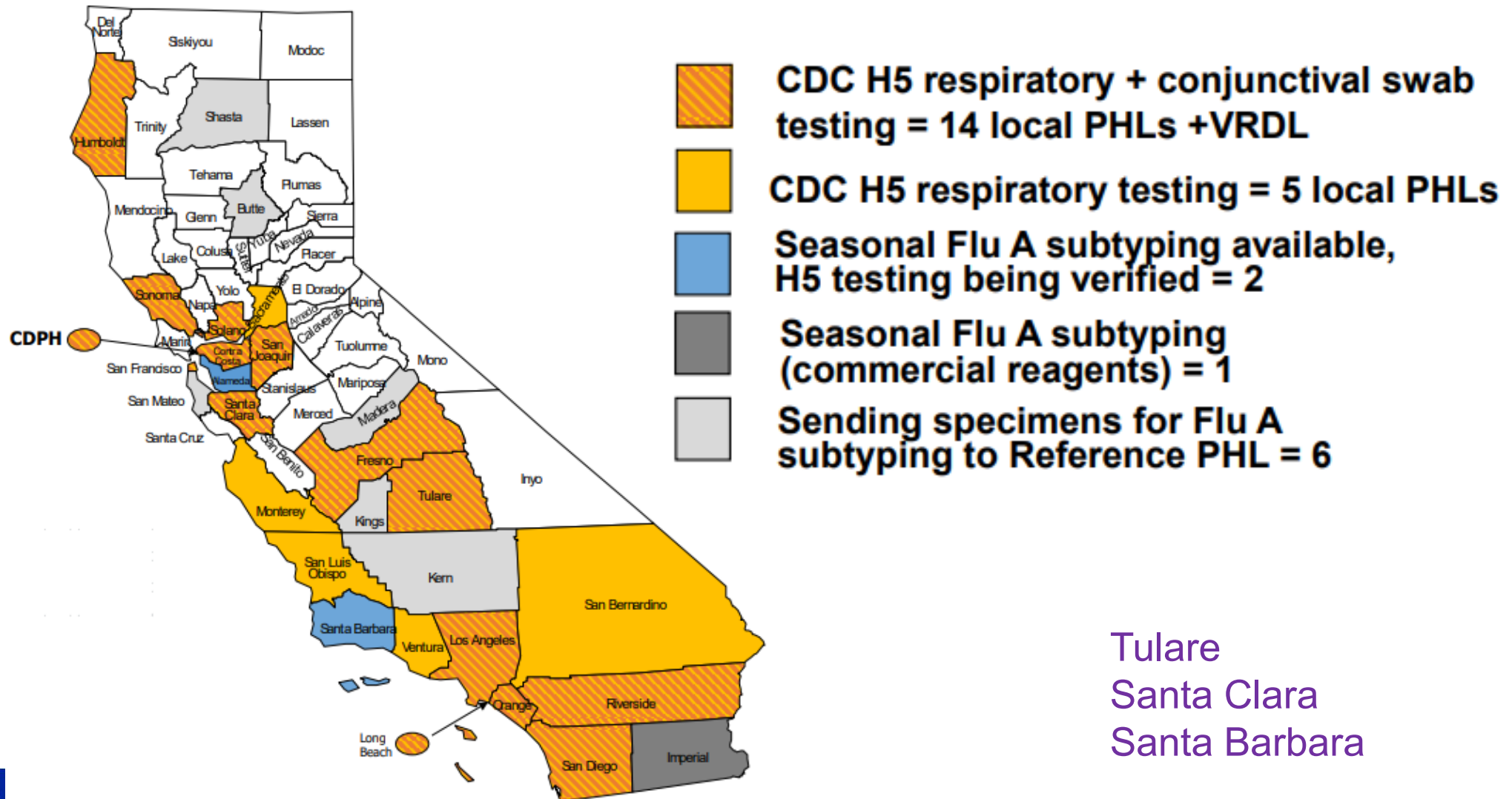
- 1 of 3 National Influenza Reference Centers
- 1 of 4 federally funded national Vaccine Preventable Diseases (VPD) Reference Centers

Viral and Rickettsial Disease Laboratory

- Respiratory and Gastroenteric Diseases Section (RGDS)
 - National Influenza Reference Center (NIRC), COVIDNet
- Vaccine Preventable Diseases Section (VPDS)
 - National Vaccine Preventable Diseases Reference Center
- Zoonotic and Vector-Borne Diseases Section (ZVBDS)
 - National Reference Center for Arbovirus Diagnostics and Rabies
- Molecular Immunoserology Section (MIS)
- Data, Testing, Epidemiology, Quality, and Support (DTEQS) Section

California Respiratory Lab Network

H5N1 HPAI Readiness



Tulare
Santa Clara
Santa Barbara

Vaccine Preventable Diseases

- Measles testing
 - PCR available that can distinguish vaccine strain from wildtype
 - Available at 19 public health labs
- Mpox
 - Clade I and Clade II detection
 - Clade I detection not available commercially

Zoonotic & Vector Borne Diseases

- Rabies
- Hantavirus
- Mosquito & Tick-Borne Viruses
 - West Nile
 - Dengue
 - 18 locally acquired cases in 2024
 - Aedes mosquitoes have been found in over 25 CA counties: Zika, Yellow Fever
 - Anopheles mosquitoes
 - Found throughout the US.
 - Locally acquired malaria cases in Washington and New Jersey

Infant Botulism Treatment and Prevention Program

Infectious Diseases
Laboratory Division

- Consultation for suspected infant botulism cases (<15 months of age)
- Diagnostic services for suspected infant botulism
- After consultation and when appropriate prescribes **BabyBIG**

BABY BIG

- human-derived immune globulin containing antibodies that neutralize botulinum neurotoxins type A and B.
 - It is the only FDA-approved treatment specifically for infant botulism
- Source plasma collection to manufacture BabyBig
 - Partner with Department of Defense to utilize recombinant botulinum vaccine to boost donors for plasma collection.
- In 2024, there were 229 administrations of BabyBig
 - 37 states, 4 countries
 - 188 confirmed cases

Treatment and Consultation

510-231-7600
24/7/365

On-call physician will provide a no-cost clinical consultation



- Releases BabyBIG antitoxin if the patient's clinical findings indicate infant botulism

Testing and Epidemiology

- Operates under California law as an established program of CDPH
- Investigates all California cases of suspected infant botulism and related illnesses with both laboratory and epidemiological techniques
- Provides diagnostic laboratory services for California


Research and Education

- Collaborates with other institutions with capability to improve the study, prevention and treatment of infant botulism
- Provides physician and community education and parent support

<https://www.infantbotulism.org/>

Genomics Center

- Works collaboratively within CLS to support next-generation sequencing (NGS) needs and projects
 - sequencing-based TB-drug susceptibility testing
 - CDC PulseNET sequencing
 - Support for COVIDNet in-house sequencing
 - Supporting for wastewater sequencing
 - Outbreak response
 - Method development



Food and Drug Laboratory Branch

Division of
Environmental Health
Laboratories

- Provides analytical support to screen for, identify, and quantify chemical and microbiological contaminants in
 - Food
 - Drugs
 - Nutritional supplements
 - Cosmetics
- Provides regulatory services for substances of abuse laboratories

FDL ACTIVITIES

- Operates a regulatory program for maintenance of competency for labs that:
 - determining blood alcohol levels
 - providing urine drug screening services to the narcotic treatment programs
- Analyzes food, drugs, cosmetics, and other consumer products for
 - chemical adulterations
 - microbial contamination
 - Includes biotoxins such as botulism, staphylococcal and ricin
 - Generate genomic and geographic data from foodborne pathogens.

FDL ACTIVITIES

- Food Emergency Response Network (FERN)
 - Nationwide collaboration with FDA on food safety and security.
 - Respond to emergencies involving contaminated food.
 - Works with CDPH Food and Drug Branch (CEH)
- Testing of influenza A virus in raw milk and raw milk products
 - February 2025:
<https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/Testing-of-influenza-A-virus-in-raw-milk-and-products.aspx>

Laboratory Flexible Funding Model (LFFM)

- Cooperative agreement, administered by the FDA, supports the Integrated Food Safety System (IFSS).
- It enhances state laboratory capacity for testing human and animal food.
- California participates through the Food and Drug Laboratory Branch (FDLB) and the Drinking Water and Radiation Laboratory Branch (DWRLB), focusing on analytical chemistry and microbiology capabilities aligned with FDA priorities.



Environmental Health Laboratory

Division of
Environmental Health
Laboratories

- Technical expertise and new measurement methods for air quality and biochemical speciation to identify emerging environmental pollutants
- Outdoor and indoor air quality (IAQ) investigations of emerging chemicals and pathogens
- Lab support for the California Biomonitoring Program and the Childhood Lead Poisoning Prevention Program

ENVIRONMENTAL HEALTH LABORATORY

BIOMONITORING

- Measure organic and inorganic chemicals and their metabolites in blood, serum or urine samples as
 - part of Biomonitoring California
 - Heavy metals and phenols
 - Volatile organic compounds (VOCs)
 - Polycyclic aromatic hydrocarbons (PAHs)

ENVIRONMENTAL LEAD TESTING

- Support the CDPH Childhood Lead Poisoning Prevention Branch
- Conduct analyses of products, household items to identify sources of lead
- >1600 results reported in 2024

ENVIRONMENTAL HEALTH LABORATORY

INDOOR AIR QUALITY

- Airborne infections
- Emerging product emissions
- Ventilation & filtration
- Mold
- Wildfire smoke
- Metals, Volatile Organic Compounds (VOCs) & Polycyclic Aromatic Hydrocarbons (PAHs) in air
- Flame retardants and asbestos
- School indoor air quality

ENVIRONMENTAL HEALTH LABORATORY

Filtration for Respiratory Exposure to Wildfire Smoke from Swamp Cooler Air (FRESSCA) / FRESSCA-Mujeres

- Summer wildfire events cause smoky air & thermal stress inside CA farmworker homes
- Community-led team to evaluate exposures & solutions for homes with evaporative coolers (EC)

LA WILDFIRE WORK

- determine chemical & particle signatures from samples collected after the fire
 - outdoor ash, indoor dust
 - Goal: inform future recovery efforts, public health planning, and monitoring

Drinking Water and Radiation Laboratory

Division of
Environmental Health
Laboratories

- DWRL provides
 - Environmental radiation and radiochemistry measurements
 - Analytical surveillance in wastewater to detect viral and bacterial diseases
 - Legionella testing in environmental samples
- Tests for
 - Toxic substances and their metabolites in human specimens
 - Organic, inorganic, and emerging contaminants in water
 - Paralytic Shellfish Toxins (PSP)
 - Community Based Drug Checking (CBDC)

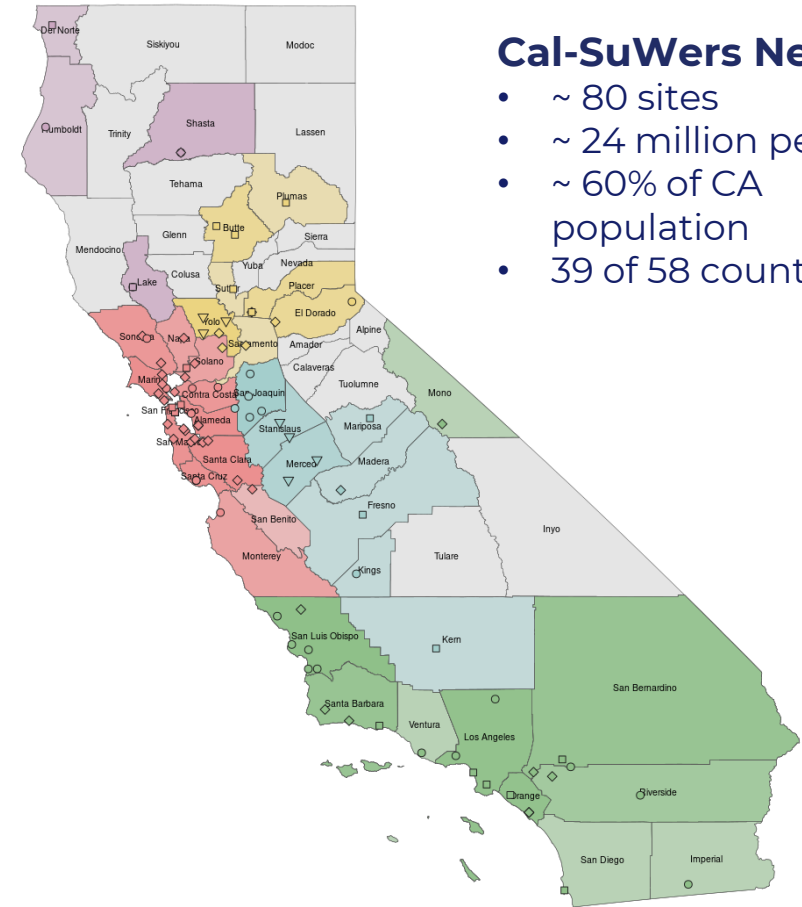
LABORATORY RESPONSE NETWORK

LRN-C (CHEMICAL THREATS)

- Network of local and state public health laboratories
- Test samples in the event of a large-scale chemical emergency
- Response to a wide range of chemical emergencies and threats
- Presence of chemical warfare agents, toxins, and toxic industrial chemicals in human blood and urine samples.
 - Cyanide, mustard agents, nerve agents
- 54 member labs across the US
 - 10 LRN-C level 1 labs including CDPH

DWRL Microbiology Unit

- CDPH Drinking Water & Radiation Lab (DWRL)
 - Digital Droplet PCR for COVID, Flu A (+H5), RSV, Mpox (Clade II)
 - Utility plants collect samples 3X/week
 - Data supplied to CDPH and CDC
 - Targets in progress
 - Mpox Clade I
 - Measles
 - Provides training to other PHLs



Cal-SuWers Network

- ~ 80 sites
- ~ 24 million people
- ~ 60% of CA population
- 39 of 58 counties

Radiochemistry Unit (RCU)

- The only state - level laboratory capable of measuring radiological contamination in environmental samples
 - Performs testing of air, water, soil, marine life, vegetation, food, consumer products and other environmental samples
 - 38 public health radiological laboratories in the US
- US EPA certified
- Part of Food Emergency Response Network (FERN)
- FDA Cooperative Agreement (LFFM)

Radiochemistry Unit (RCU)

- Alpha emitters
 - mostly naturally occurring isotopes (Uranium, Thorium, Plutonium)
 - Severe acute DNA damage
- Beta emitters
 - mostly fission products (Iodine-131, Strontium-90, Cesium-137)
 - Dangerous due to accumulation
- Gamma emitters
 - secondary radiation, lowest energy but highest penetration power
 - Chronic DNA damage

Radiochemistry Unit (RCU)

- Identify where contamination is from and support preventing future exposures
- Developing nation-wide radiological testing capacity
- Development of radiological testing in wastewater
- Part of state radiological emergency response team
 - maintains semi-hot facility where emergency samples are processed and prepared for testing.
- Invitation to join CDC LRN-R pilot study
 - Measurements of gross alpha radioactivity in urine.

Radiochemistry Unit (RCU)

Support for the Radiologic Health Branch of CEH

- Monitoring of Nuclear Power Plants environment
 - Diablo Canyon NPP
 - San Onofre NPP
- Monitoring of airborne radiation
- Other environmental monitoring
- Testing for compliance of licensed facilities with environmental regulations
- Superfund sites

LABORATORY FIELD SERVICES (LFS)

- Regulation
- Tissue Banking, Blood Banking, and Biologics
- Clinical and Public Health Laboratories

OVERVIEW OF LFS

LABORATORIES

- licensing and registration
- On site inspections
- Complaint investigations

ADMINISTRATION

- Customer call center

POLICY

- Regulations
- Legislative affairs
- Clinical Laboratory Technology Advisory Committee (CLTAC)

CLIA SURVEY

- Laboratory CLIA and state inspections
- Laboratory CLIA certification

LABORATORY PERSONNEL

- Personnel licensing and certification
- Training programs
- Certification examinations
- Continuing education programs

WHAT IS CLIA?

Clinical Laboratory Improvement Amendments of 1988

- Overseen by CMS in partnership with CDC and FDA
- Federal regulatory program that sets quality standards for all laboratory testing performed on human specimens
 - Personnel qualifications
 - Quality control
 - Proficiency testing
 - Recordkeeping and reporting
- CLIA certification is mandatory for labs that want to legally perform diagnostic testing

OVERVIEW OF LFS

REGULATION AND ENFORCEMENT

- Promotes regulations to clarify and implement governing statutes that set laboratory, tissue and blood bank standards and
- Provides analysis of proposed legislation and policies.
- Enforces laws for laboratories, laboratory personnel, blood banks, tissue banks, and biologics facilities.
- Ensures compliance by investigating complaints, and imposing penalties.

OVERVIEW OF LFS

TISSUE BANKING, BLOOD BANKING, AND BIOLOGICS

- Protects donors and recipients of human blood and tissue by ensuring safe and reliable sources of human blood and tissue for transplantation and transfusion
- Ensures the production of safe and effective biologics from human blood and tissue.

CLINICAL AND PUBLIC HEALTH LABORATORIES

- Ensures accurate and reliable laboratory testing
- Ensures laboratory testing personnel meet high standards for education and training.

CONTACT LFS

Complaints: lfslabcomplaints@cdph.ca.gov

- LFS Call Center: lfsc@cdph.ca.gov or call (510) 620-3800
- Tissue bank questions: LFSSTissue@cdph.ca.gov
- Biologics and blood bank questions: LFSBiologics@cdph.ca.gov
- CLIA related inquiries: LFSCLIA@cdph.ca.gov

Personnel

- New applications: LFSnewapplications@cdph.ca.gov
- Renewals: LFSrenewals@cdph.ca.gov
- Director level applicants: LFSdirectors@cdph.ca.gov

CLS PARTNERSHIPS

California Association of Public Health Laboratory Directors (CAPHLD)

Association of Public Health Laboratories (APHL)

Center for Disease Control (CDC)

CAPHLD

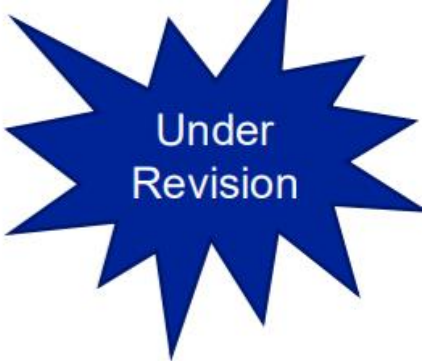
- 28 Public Health Laboratories
- 6 CDPH labs
- California established regulations for Public Health Laboratories (PHLs) in the 1940s.
- California PHLs are required to meet mandated California and Clinical Laboratory Improvement Amendment (CLIA) regulations and requirements.

CAPHLD

Workforce Development

- Public Health Microbiologist (PHM) training
- Training of future public health lab directors
 - LabAspire Program
 - Leadership skills
 - Administrative skills
 - Succession planning
 - Grant supported.
 - Funding ends 2027. HERO funding through State Budget Acts
 - Looking for permanent funding

CCLHO Policy Platform

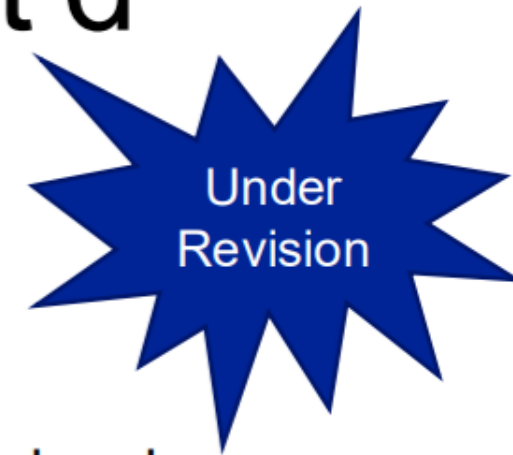


Under
Revision

Foundational Capabilities: Assessment

- Laboratory Capacity
 1. Preserve public health laboratory capabilities and functions to support all local jurisdictions.
 2. Support multi-jurisdictional agreements for service sharing or regionalization of public health laboratory services as needed.
 3. Support and encourage data sharing among local health jurisdictions for improved communicable disease outbreak and public health response.
 4. Analyze and improve the efficiency of public health laboratories by optimizing the balance of state, regional, and local laboratory capabilities.
 5. Support PH laboratory capacity to rapidly add testing for novel or emerging diseases.
 6. Support measures that ensure an adequate and skilled workforce and resources necessary to provide timely services.
 7. Maintain and expand the ability of PH laboratories to aid in outbreak investigations and PH response such as optimizing culture dependent methods and whole genome sequencing.

CCLHO Policy Platform, cont'd



- Foundational Areas: Communicable Disease
 - Public Health Labs
 1. Ensure adequate support, funding and resources for state and local public health laboratories to assist in the diagnosis, control, and prevention of illnesses of public health concern, including routine communicable disease control, emerging infectious diseases, health care associated, drug resistant infections and bioterrorism.

CAPHLD

Northern California

Alameda County
Butte County
Contra Costa County
Humboldt County
Sacramento County
San Francisco City & County
San Joaquin County
San Mateo County
Santa Clara County
Shasta County
Napa Solano Yolo Marin County
Sonoma County

Central California

Fresno County
Kern County
Kings County
Madera County
Monterey County
San Luis Obispo County
Santa Barbara County
Tulare County

Southern California

Imperial County
Long Beach City
Los Angeles County
Orange County
Riverside County
San Bernardino County
San Diego County
Ventura County

APHL

- 135 member laboratories – 30 within California
- 14 countries with APHL staff
- Collaboration, Education, Workforce Development, Subject Matter Experts
- Infectious Diseases and Environmental Health
- Global Health
- Newborn Screening and Genetics
- Preparedness and Response
- Informatics
- Quality Systems

- Food Safety Projects
 - Council to Improve Foodborne Outbreak Response: Education
 - PulseNet and Metagenomics: Advanced Analytics
 - Pathogen Specific Work: Diagnostic Development
 - Culture Independent Diagnostic Test Subcommittee: New Technologies

Pacific Rim Consortium

- Alaska
- California
- Guam
- Hawaii
- Nevada
- Oregon
- Washington

CDC

- **Federal Shutdown:**
 - CDC laboratory services are accepting all specimens but only conducting critical testing
- Laboratory Response Network
- PulseNet – foodborne disease surveillance
- AR Lab Network – antibiotic resistance
- Influenza Surveillance Network
 - National Influenza Reference Center
- National TB Drug Susceptibility Testing Reference Laboratory
- Infant Botulism Treatment and Prevention Program

CDC

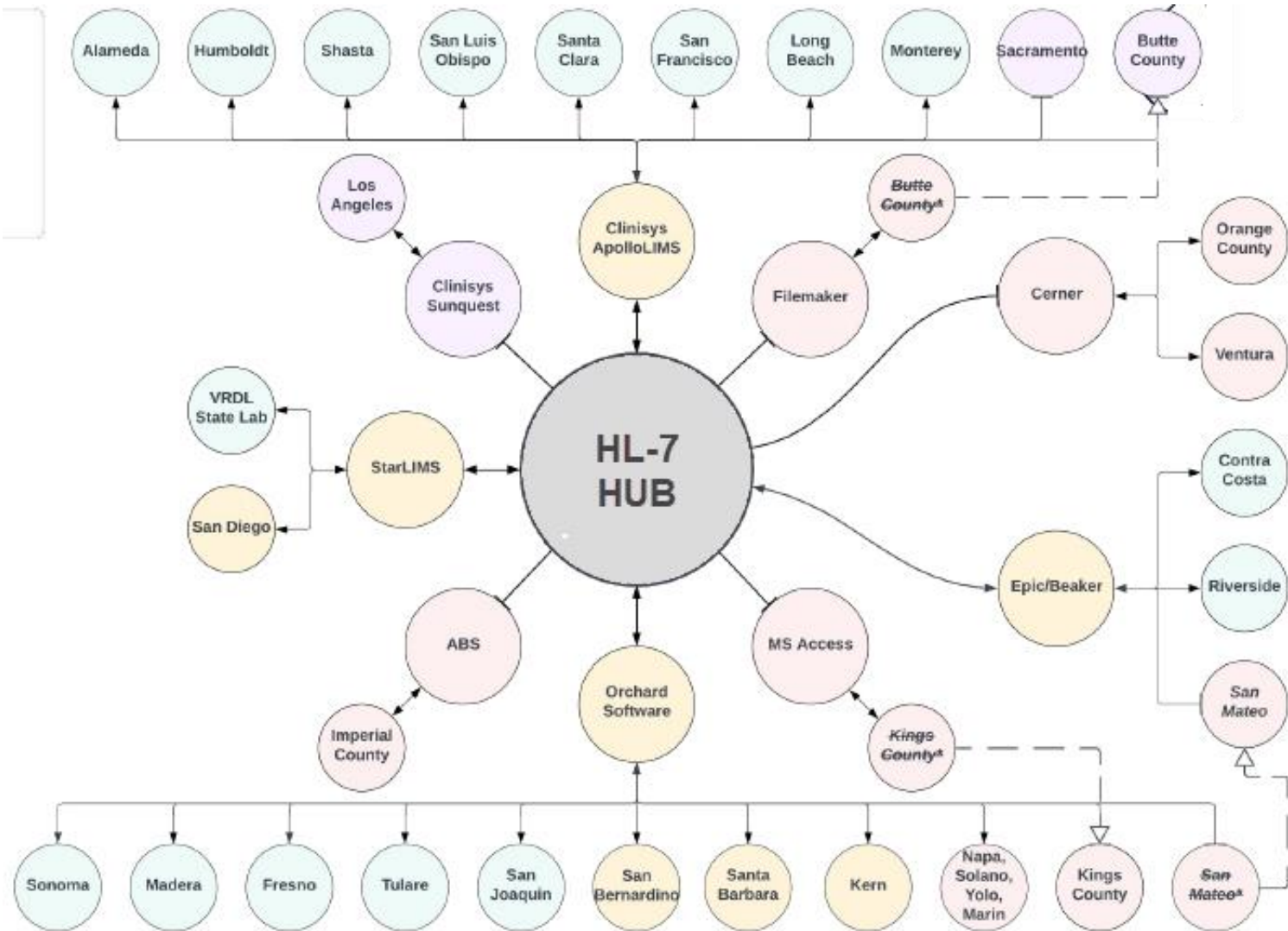
- CDC Test Directory
 - Being updated to distinguish CLIA from non-CLIA test orders
 - 120 CLIA tests, 145 non-CLIA
 - CLIA: clinically reportable and actionable
 - Non-CLIA: research and surveillance
 - 81 tests were taken offline between Dec 2024-Aug 2025
 - 48 permanently removed
 - Some may be modified and brought back
 - 21 brought back
 - 15 more expected back soon

US Public Health Laboratory Networks

Feature	LRN-B (<i>Biological</i>)	LRN-C (<i>Chemical</i>)	FERN (<i>Food Safety</i>)
Lead Agency	CDC	CDC	USDA FSIS & FDA
Focus Area	Bioterrorism, Emerging Infectious Diseases	Chemical Terrorism, Toxic Exposure	Food Contamination (Bio/Chem/Rad)
Lab Tiers	National, Reference, Sentinel	Level 1, 2, 3	Federal, State, Local
Key Capabilities	Confirmatory Testing, Surveillance	Human Exposure Testing, Surge Capacity	Food Testing, Emergency Response
Training & QA	CDC Protocols, Exercises	Method Validation, Proficiency Testing	Method Development, Training
Partners	CDC, APHL, FBI	CDC, FBI, DHS	USDA, FDA, CDC, EPA
Funding	CDC (PHEP)	CDC (PHEP)	USDA, FDA (FERN Grants)
Example Use	Anthrax, COVID-19, Monkeypox	Cyanide, Nerve Agents	Listeria, Staph Toxins

CDC

- Data Modernization Initiative
 - Plan to connect all Public Health Labs
 - Future goal: connections with clinical partners
 - Eliminating paper orders
 - ETOR Portal
 - Electronic Test Ordering and Reporting
 - HL-7 connectivity with Lab Information Systems



Welcome from the CLS Deputy Director!

Anthony.Tran@cdph.ca.gov

Jeffrey.schapiro@cdph.ca.gov

Assistant Deputy Director

[Center for Laboratory Sciences](#)

- <https://www.cdph.ca.gov/Programs/cls/Pages/Center-for-Laboratory-Sciences.aspx>
- CLS.information@cdph.ca.gov

