

# ELC ENHANCING DETECTION: CALIFORNIA TESTING PLAN

## 2020 Overarching Jurisdictional SARS-CoV-2 Testing Strategy

|                  |               |
|------------------|---------------|
| Jurisdiction:    | California    |
| Population Size: | 39.51 Million |

### 1. Describe the overarching testing strategy in your state or jurisdiction.

California (CA) has multiple approaches to increase availability and access for SARS-CoV-2 testing. Since late March, daily volumes of PCR testing in CA have increased from 2,000 tests/day to a current peak of ~88,000 tests/day with capacity to test 4-5% of the overall population monthly.

CA's fully-integrated testing plan to optimize end-to-end testing workflows by: 1) Expanded access to testing, with regularly updated and broadening testing guidelines and tailored testing solutions for populations based on need (e.g., testing for high-risk/vulnerable populations); 2) Expand a network of sample collection sites for equitable access to testing across populations and geographies; 3) Optimize capacity for sample processing and improve turnaround time for testing by maximizing use of available high-throughput testing platforms at labs and an adequate workforce to meet current/future testing needs; and 4) Support timely and accurate reporting of test results and integrating testing with contact tracing.

Given high testing needs, CA is considering potential strategies to make costs of testing sustainable, including new, cost efficient testing options, facilitating connections between local testing sites and labs, and piloting new approaches to test processing (e.g., sample pooling). To execute this plan, the Testing Task Force (TTF) was established with multi-stakeholder collaboration comprised of public/private sector and academic partners to take a comprehensive view on testing and actively collaborate with all involved stakeholders (e.g., elected officials, local public health officers, industry associations, manufacturers, health systems).

A: Actions for access to reliable, timely, and accurate specimen processing: 1) Gathered full capacity information for COVID-19 testing in CA, including all types of lab equipment and testing platforms potentially available for testing; 2) Identified labs that meet criteria for testing readiness, including CLIA licensure, registration with CA Laboratory Field Services (LFS), ability to process FDA EUA RT-PCR tests and ability to report test processing outputs through CalREDIE, the statewide system for electronic disease reporting and surveillance. All SARS-CoV-2 test results are required to be reported to public health via electronic laboratory reporting (ELR) or via flat file (CSV), or manual laboratory reporting module for laboratories that are transitioning to ELR or are very low volume submitters. Daily, the data reported to public health are compared to the aggregate counts laboratories self-report through the Lab Testing Metrics application to identify gaps in laboratory reporting for follow-up. Positive test results received by CalREDIE sent to the state's contact tracing application (CalCONNECT) used by LHJs for contact tracing.

Total capacity of labs that meet all readiness criteria exceeds 120k PCR tests/day allowing for flexibility to further scale testing in case of outbreaks or to meet anticipated increase in testing in the summer/fall. To expand current capacity and meet surges in demand, identifying additional labs that meet testing readiness criteria, exploring high-throughput and novel testing options and methodologies (e.g., antigen testing, pooling of PCR tests); 3) Identified high-throughput labs across public health,

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academic, and commercial sectors, widely share “lab list” with partners, lab director and partner communication to optimize utilization of available resources and identify opportunities to expand testing; 4) For testing platforms that account for majority of available capacity (e.g., Roche 6800/8800 Cobas machines, Hologic Panther, Abbott m2000, Thermo Fisher, BD platforms), reached out to manufacturers to understand availability of supplies and connect labs that are facing supply shortages to manufacturers; 5) Gathered information about lab operations (e.g., working hours, workforce, potential opportunities) to redirect equipment capacity to COVID-19 testing as needed; 6) Launched a Lab Testing Metrics App (an application that interacts with all COVID-19 testing labs) for reporting and identify supply shortages, staffing needs and other bottlenecks that can limit capacity for testing. The app allows labs to provide daily testing data and report supply shortages. Testing data is being reconciled with CalREDIE daily; 7) Launched sample pooling pilot with Stanford Hospital and Clinics, aiming to utilize scarce resources for test processing more efficiently and potentially to lower testing costs. Once sample pooling protocols are validated, CA will issue guidelines to support broader utilization in labs; and 8) Launched sequencing pilot with CZ Biohub Laboratory, recruited PHLs and university hospital participants, modeled “right-size” sequencing statistics to generate information on SARS-CoV-2 spread, mutation and introduction of new strains to inform real time disease control and contact tracing.

Information from these efforts allowed CA to identify testing platforms critical for scaling capacity statewide (e.g., Hologic Panther), establish infrastructure and create transparency to manage risks (e.g., workforce and supply shortages), and prepare to scale testing volumes across various types of needs. To maximize use of testing platforms, CA actively orchestrates how test processing capacity is used across testing needs/use cases, including fixed capacity for community-based testing, mobile testing for rural areas, end-to-end testing solutions for congregate settings and surge capacity for outbreak response and contact tracing.

B: To meet future testing needs and provide equitable access, CA has multiple initiatives to expand specimen collection capacity beyond traditional sites (e.g., hospitals, federally qualified health centers, urgent care centers) and expand capacity beyond traditional public health laboratories (PHLs) (e.g., expand to new commercial/clinical labs, ensure these new labs are linked to CalREDIE and the Lab Testing Metrics App, and authorized under LFS to conduct diagnostic testing).

Approach to expanding the network of collection sites is informed by: 1) Proximity. The testing network needs to ensure that every CA resident can reach a collection site within 30 minutes in urban areas and within 60 minutes in rural areas; 2) Equity. Populations in various living situations (e.g., long-term care facilities, nursing homes, correctional facilities, rural CA, primary language non-English) should have equitable access to collection sites; 3) Strategically place collection sites to serve underserved communities; and 4) Prioritization. Prioritizing expansion of sample collection capacity to address the frequent testing needs of high-priority populations, according to CA testing guidance. Expanding testing capacity informed by guiding principles: 1) Cost efficiency. Testing capacity should be expanded via the most cost-efficient option where possible (e.g., prioritize increasing existing site capacity over establishing new sites); 2) Technology. Developing partnerships with academic institutions to provide high-throughput laboratory testing and connections to research and development; and, 3) Prioritization. Public health and clinical laboratories with rapid turn-around times to test the highest-priority, urgent specimens for faster disease control decisions while high-throughput labs provide regular testing for routine specimens.

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Based on these guiding principles and identified testing needs, CA is planning to actively support the following types of collection sites: 1) Community-based collection sites in non-rural areas, including 78 OptumServe sites and 14 Verily sites that are already available and have capacity to collect up to 17k specimens daily. This network utilizes public spaces (e.g., schools, theaters, county fairs), focusing primarily on underserved communities across CA. The network will be further expanded based on utilization and unmet demand for testing that are being monitored at a county level. CA launched a publicly available map and directory of all community-based sites that supports search by location and includes links to schedule appointments; 2) Shared fixed sites and mobile solutions for rural areas, including 4 sites confirmed for launch in rural areas (in partnership with OptumServe) and mobile solutions to be deployed with Verily in 12 additional rural counties; 3) Rapid and mobile point of care solutions for outbreak response, including pop-up collection sites, emergency departments and collaborations with PHLs to ensure appropriate outbreak investigation and response; 4) Collection sites for exposed populations identified through contact tracing, including potential options to make specimen collection easily accessible in pharmacies (with rapid processing in local high-throughput labs) and home-based collection (to reduce healthcare worker exposure).

To rapidly scale sample collection, CA is centrally procuring swabs, viral transport media, and sample collections kits (including approved alternatives) and made available through the existing Medical and Health Operational Area Coordinators who understand local needs and are best positioned to allocate limited supplies. CA is leveraging local workforces to scale sample collection, by: 1) Engaging local workforce at new collection sites (e.g., OptumServe and Verily) to operate at maximum capacity; 2) Allowing pharmacists to order and collect specimens for authorized tests; 3) Exploring engagement of providers in adjacent professions (e.g., EMT/EMS) to support specimen collection at congregate settings; and 4) Redirecting state workforce toward testing and contact tracing priority needs.

C. Understanding the need for speedy, cost-efficient, and readily accessible testing, CA is: 1) Evaluating alternative testing options and options for serological testing. To expand capacity for PCR testing, CA completed an in-depth assessment of serologic testing. The TTF have released guidelines for specific, appropriate indications for serologic test utilization by clinical providers and laboratories. Based on current information about serology tests, CA is pursuing use of these tests in the following situations: A) Determine prevalence: Surveillance studies to determine population-level estimates of exposure to SARS-CoV-2 (i.e., prevalence) in a community, typically through a serologic survey; B) Identify convalescent plasma donors: Identification of individuals who have recovered from SARS-CoV-2 infection (viral RNA negative), are SARS-CoV-2 serology positive, and can potentially donate plasma; and C) Identify a false negative PCR result: In cases with high clinical suspicion for COVID-19 and negative SARS CoV-2 viral RNA test, a positive serology test would provide support for recent or prior SARS-CoV-2 infection. 2) Making serologic testing available for providers and labs. In April 2020, CA procured and made available to local labs and providers 1.5 million serology testing kits for Abbott Architect and Alinity platforms.

CA will continue assessment of new testing options (e.g., point of care and serology tests). Given limited opportunities to replace PCR with serology testing in the near-term, CA is evaluating alternate PCR processing methodologies to conserve PCR tests (e.g., specimen pooling). Academic labs are validating a methodology and may be able to apply the techniques to broader testing of asymptomatic populations in the future.

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D. With rapidly changing circumstances, CA has openly communicated with all relevant stakeholders, including the general public, elected officials, LHJs health officers and emergency response teams, provider community, industry and state associations, and others.

Communication efforts include: 1) TTF website: repository of all communication and public materials (e.g., CDPH guidelines, TTF newsletters) about SARS-CoV-2 testing; 2) Regular webinars for local/state/federal elected officials to update on efforts underway and answer questions; 3) Regular webinars for county health officers to update on centrally-driven distribution of supplies and collection efforts and tracking of county testing metrics; 4) Strategic planning sessions with county public health officers, emergency response teams, and testing site coordinators; 5) Weekly sessions/briefings with lab directors and health system leaders; 6) Coordination of statewide network of 30 PHLs to provide guidance and assess critical needs; and 7) Test matching to link requests from local health jurisdictions to testing resources in commercial, clinical, academic and PHLs.

To manage statewide communication efforts, the TTF supports communication at a local level with community outreach guides for local stakeholders and communication toolkits to promote appropriate utilization of testing sites. In addition to regular communications, CA is making investments in enhanced reporting and data transparency, including: 1) New Lab Testing Metrics App that supports daily information exchange with labs and gathers accurate information about testing volumes and supply shortages; 2) State- and county-level testing dashboards as a single source of truth about testing volumes; and 3) Additional dashboards available to selected stakeholders (e.g., testing site utilization dashboards with aggregated profiles of tested populations, supply distribution updates).

Regular reporting informs outreach efforts and state/local decision-making. Example, decisions to expand collection sites' capacity are based on regular utilization monitoring and feedback from counties. Decisions to engage non-traditional testing labs are based on needs to rapidly scale testing to accommodate increased demand. CA counties have significant autonomy to define/implement solutions to address local needs with effective state-level oversight to ensure appropriate utilization of resources, equitable access, and cost-effective solutions.

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**Table #1a: Number of individuals planned to be tested, by month**

| BY MONTH:    | May-20    | Jun-20    | Jul-20    | Aug-20    | Sep-20    | Oct-20    | Nov-20    | Dec-20    | TOTAL      |
|--------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| Diagnostics* | 1,350,000 | 1,800,000 | 2,620,000 | 3,060,000 | 3,500,000 | 3,640,000 | 3,790,000 | 3,950,000 | 23,710,000 |
| Serology     | 250,000   | 575,000   | 604,000   | 634,000   | 666,000   | 699,000   | 734,000   | 771,000   | 4,933,000  |
| TOTAL        | 1,600,000 | 2,375,000 | 3,224,000 | 3,694,000 | 4,166,000 | 4,339,000 | 4,524,000 | 4,721,000 |            |

\*Each jurisdiction is expected to expand testing to reach a minimum of 2% of the jurisdictional population.

**Table #1b: Planned expansion of testing jurisdiction-wide**

| Name of testing entity    | Testing venue (select from drop down) | Performing Lab (if different from testing entity) | Daily diagnostic through-put | Daily serologic through-put | Specific at-risk populations targeted (list all)   |
|---------------------------|---------------------------------------|---|------------------------------|-----------------------------|--|
| OptumServe                | Community-based                       | Quest   | 12,500                       | 0                           | Healthcare and safety workers, racial and ethnic minorities, other populations   |
| Verily (Physical, Mobile) | Drive-thru testing site               | Quest   | 8,000                        |                             | Healthcare and safety workers, racial and ethnic minorities, other populations<br><br>Healthcare and safety workers, racial and ethnic minorities, other populations |
| Adventist                 | Hospitals or clinical facility        |   | 500                          | 40                          | Patients   |

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| Name of testing entity               | Testing venue (select from drop down) | Performing Lab (if different from testing entity) | Daily diagnostic through-put | Daily serologic through-put | Specific at-risk populations targeted (list all)                               |
|--------------------------------------|---------------------------------------|---|------------------------------|-----------------------------|--|
| Cedars-Sinai Hospital Lab            | Hospitals or clinical facility        |   | 350                          | 1,100                       | Patients   |
| Dignity                              | hospitals or clinical facility        |   | 550                          |                             | Patients   |
| KorvaLabs                            | Community-based                       |   | 12,000                       |                             | Healthcare and safety workers, other essential workers, SNF, other populations |
| Labcorp                              | [Select One]                          |   | 5,300                        | 3,500                       |  |
| Providence                           | Hospitals or clinical facility        |   | 1,250                        |                             | Patients   |
| Quest                                | [Select One]                          |   | 19,000                       | 3,900                       |  |
| Southern CA Permanente Medical Group | Hospitals or clinical facility        |   | 2,750                        |                             | Patients   |
| Scripps                              | hospitals or clinical facility        |   | 500                          |                             | Patients   |
| Sharp Memorial Hospital              | Hospitals or clinical facility        |   | 750                          |                             | Patients   |
| Stanford                             | Hospitals or clinical facility        |   | 980                          |                             | Patients   |

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|--|---------------------------------------|---|------------------------------|-----------------------------|--|
| Sutter   | Hospitals or clinical facility        |   | 980                          |                             | Patients   |
| Kaiser Permanente Berkeley (Regional Laboratory) | Hospitals or clinical facility        |   | 2,200                        |                             | Patients   |
| UC Davis   | Hospitals or clinical facility        |   | 280                          | 50                          | Patients   |
| UC Irvine  | Hospitals or clinical facility        |   | 320                          | 70                          | Patients   |
| UCLA   | Hospitals or clinical facility        |   | 350                          | 230                         | Patients   |
| UCSD   | Hospitals or clinical facility        |   | 1,000                        | 380                         | Patients   |
| UCSF   | Hospitals or clinical facility        |   | 1,100                        | 35                          | Patients   |
| USC  | Hospitals or clinical facility        |   | 400                          | 190                         | Patients   |

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|--------------------------|---------------------------------------|---|------------------------------|-----------------------------|---|
| Westpac Labs             | Commercial or private lab             |   | 2,600                        | 400                         |   |
| Los Angeles County PHL   | Public health lab                     |   | 577                          |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| San Diego County PHL     | Public health lab                     |   | 550                          |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| Orange County PHL        | Public health lab                     |   | 398                          |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| San Francisco County PHL | Public health lab                     |   | 375                          |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| Sonoma County PHL        | Public health lab                     |   | 282                          |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |



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|--|---------------------------------------|---|------------------------------|-----------------------------|---|
| Ventura County PHL                                   | Public health lab                     |   | 282                          |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| CDPH Viral and Rickettsial Disease Laboratory (VRDL) | Public health lab                     |   | 229                          |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| Napa-Solano-Yolo-Marin County PHL                    | Public health lab                     |   | 223                          |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| Santa Clara County PHL                               | Public health lab                     |   | 208                          |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| Sacramento County PHL                                | Public health lab                     |   | 190                          |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |

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|----------------------------|---------------------------------------|---|------------------------------|-----------------------------|---|
| Alameda County PHL         | Public health lab                     |   | 188                          |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| Monterey County PHL        | Public health lab                     |   | 182                          |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| San Joaquin County PHL     | Public health lab                     |   | 159                          |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| San Bernardino County PHL  | Public health lab                     |   | 148                          |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| Contra Costa County PHL    | Public health lab                     |   | 133                          |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| San Luis Obispo County PHL | Public health lab                     |   | 112                          |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and  |

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|------------------------|---------------------------------------|---|------------------------------|-----------------------------|---|
|                        |                                       |   |                              |                             | ethnic minorities, other populations, surveillance  |
| Riverside County PHL   | Public health lab                     |   | 108                          |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| Tulare County PHL      | Public health lab                     |   | 107                          |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| Humboldt County PHL    | Public health lab                     |   | 91                           |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| Long Beach City PHL    | Public health lab                     |   | 85                           |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| Shasta County PHL      | Public health lab                     |   | 78                           |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |

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| Name of testing entity   | Testing venue (select from drop down) | Performing Lab (if different from testing entity) | Daily diagnostic through-put | Daily serologic through-put | Specific at-risk populations targeted (list all)  |
|--------------------------|---------------------------------------|---|------------------------------|-----------------------------|---|
| Fresno County PHL        | Public health lab                     |   | 66                           |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| San Mateo County PHL     | Public health lab                     |   | 58                           |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| Imperial County PHL      | Public health lab                     |   | 57                           |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| Butte County PHL         | Public health lab                     |   | 25                           |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| Kern County PHL          | Public health lab                     |   | 25                           |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| Santa Barbara County PHL | Public health lab                     |   | 25                           |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and  |

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| Name of testing entity | Testing venue (select from drop down) | Performing Lab (if different from testing entity) | Daily diagnostic through-put | Daily serologic through-put | Specific at-risk populations targeted (list all)  |
|------------------------|---------------------------------------|---|------------------------------|-----------------------------|---|
|                        |                                       |   |                              |                             | ethnic minorities, other populations, surveillance  |
| Kings County PHL       | Public health lab                     |   | 10                           |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| Madera County PHL      | Public health lab                     |   | 10                           |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| Merced County PHL      | Public health lab                     |   | 10                           |                             | Patients, outbreaks, contacts, SNFs, healthcare and safety workers, racial and ethnic minorities, other populations, surveillance |
| Other                  |                                       |   | 7,829                        | 1,971                       | Other labs  |

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## 2020 Direct Expansion of SARS-COV-2 Testing by Health Departments

### **2. Describe your public health department's direct impact on testing expansion in your jurisdiction.**

The CA Department of Public Health (CDPH) is leading statewide efforts to scale capacity for testing, address testing needs, collaborate with other state departments, private/public stakeholders, and the Governor's Office, launching testing efforts to support state reopening and cautiously easing social distancing measures.

A: CA's 58 counties and 61 Local Health Jurisdictions (LHJ) function autonomously to protect public health and partner with other LHJs and CDPH. Each LHJ has a Local Health Officer with broad jurisdictional authority to protect public health by any means necessary under CA statute/regulations. CDPH closely collaborates with LHJs to increase capacity for sample collection, test processing, and reporting at local/regional/state levels.

CA's 30 public health laboratories (PHLs) serve as the front-line testing capacity for emerging diseases and outbreaks. Providing standardized supplies, reagents, and instruments to PHLs significantly improves capacity, throughput, timeliness and consistency of results. Assisting the PHLs to build robust electronic data transmission methods improves state/local understanding of disease prevalence. Support for PHL testing capacity includes: 1) Monitoring daily, real time test numbers and reagent needs; 2) Providing PHLs with supplies to maintain capacity during shortages; 3) Leveraging the PHL network for surge testing with rapid turn-around time for LHJs and facilities with significant increases in COVID-19 transmission.

Establishment of a network of specimen collection sites by the Testing Task Force (TTF) enabled LHJs to expand testing capacity for specific populations, prioritize testing in underserved communities/vulnerable populations, and tailored solutions for essential workers. To expand capacity for sample collection: 1) Partnering with OptumServe and Verily for 100+ new collection sites with additional capacity of ~17K PCR tests/day. Capacity expansion will be considered and approved by CA based on unmet needs and resource utilization across counties, including a) OptumServe and Verily provide end-to-end solutions, from sample collection supplies to contracting with commercial labs for test processing to reporting individual test results; b) Both partners secure workforce for sample collection sites, leveraging local resources and delivering required onboarding/training; c) Vendors are responsible for logistics to transport specimens to partner labs; and d) CA provides ongoing oversight, makes decisions about capacity expansion/resource reallocation based on site performance, facilitates local outreach to ensure appropriate site utilization; 2) Providing access to testing for populations in rural areas, including mobile sites, CDPH has partnered with OptumServe for 6 testing sites in rural counties and identified by geospatial modelling to identify locations so testing is accessible to remote rural areas. CDPH and the Governor's Office of Emergency Services (OES) are partnering with Verily for mobile testing units for 12 rural counties so that people in these areas can access testing without traveling long distances; 3) Procuring and distributing collection supplies via a) Outreach to suppliers/local partners, coordination with FEMA, and exploring alternative supply options helped CDPH secure a significant volume of supplies to cover initial needs post reopening (distributing 1.4/2.0M swabs) and 12M swabs confirmed for delivery. Resources are needed to secure supplies through end of

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2020; and b) Distribution to LHJs by the emergency response infrastructure streamlines ordering and distribution, ensures equality, and tracks ongoing/changing demand for supplies.

To ensure sufficient capacity for testing, CA is validating the overall lab capacity, expanding COVID-19 testing capacity of PHLs, and facilitating connections between labs, testing sites, and populations that need testing. To scale testing: 1) Identify high-throughput labs (e.g., PHLs, academic, commercial) and optimize end-to-end testing workflows on geographic proximity, lab capabilities, and turnaround time. Examples of optimized end-to-end testing: a) Expand existing capacity of PHLs by addressing supply shortages and operational bottlenecks through supply procurement, procurement of new testing equipment/device platforms, supporting ELR via Lab Testing Metrics App, and constructing interfaces for data transmission; b) Partner with academic labs, and supporting processing hubs for the neighboring testing locations; c) Initiate contracts with commercial labs that offer end-to-end testing solutions and have significant available capacity; d) Collaborate with national labs to ensure effective utilization of capacity; and e) Partner advanced capabilities/service labs (e.g., genome sequencing with CZ BioHub).

2) Procure selected testing supplies for high-throughput platforms and collaborate with manufacturers to coordinate supply availability; and 3) Identify opportunities to expand lab capacity and validate testing readiness for commercial/research labs that currently don't perform COVID-19 testing.

B: Given the limited availability of diagnostic tests in March 2020, CDPH set forth guidance for public health officials, health care providers, and labs for determining prioritization of specific groups for PCR molecular testing. As testing capacity rapidly expanded, the guidance was updated to support expanded testing. Based on these guidelines, CDPH has recommended tiers for prioritization: Tier 1-Testing the most vulnerable populations (e.g., hospitalized, chronic disease, congregate settings, essential workers, contact tracing identified, HCW , first responders); Tier 2-Testing lower risk asymptomatic; and b) Surveillance testing of asymptomatic persons as part of community or regional surveillance programs.

Measures taken to support testing guidelines: 1) Prioritize testing sites for underserved communities and equitable access, in partnership with OptumServe and Verily; 2) Arrange for healthcare workers, essential employees, and high-priority populations to be tested at new collection sites; 3) Tailor solutions for testing of vulnerable populations in congregate settings (e.g., offering a testing model for SNF workers, options for onsite sample collection, rapid point-of-care processing in case of outbreaks). Recognizing that SNFs are severely impacted with high morbidity and mortality, CDPH developed guidance/plan for baseline, surveillance, and response-driven testing of SNF residents/healthcare workers to limit exposure and prevent the spread. CDPH issued a requirement for all SNFs to complete baseline testing for residents and healthcare workers by June 30, 2020 with regular testing for staff at 25% weekly: 1) Use small sample surveillance testing and increase testing if a positive individual is identified; 2) Employ multiple testing strategies to identify positive individuals, then routinely test negative individuals; 3) Repeat testing of all staff and residents 1-2 times/wk; 4) When urgent needs exceed existing capacity, unique staff (e.g., strike teams) will be used to assist with outbreaks; 5) National Guard, State Military, Local Home Health Agencies, contracted EMS used to augment testing and tracking results; 6) Use NHSN data for long term care. 7) utilize genomic sequencing.

CDPH provided a comprehensive list of testing labs/vendors to provide scalable testing for employers (e.g., SNFs, correctional facilities) facilitating onsite access to testing. Recommendations were made to identify and contract with a lab that will provide testing services, including ongoing surveillance and surge contracts. The Healthcare Associated Infection (HAI) team is working with LHJs to enhance

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Infection Prevention (IP) capacity. Facility level, recommendations for full time IP to train in tracking test results and communicate to LHJs, and IP training for the medical directors of facilities and all staff to review and interpret the testing data and work on investigations to interrupt transmission. HAI conducts phone consultations and virtual tours and when appropriate onsite visits to assess status, needs and provide training.

Special collection sites for homeless populations with culturally competent trained staff, walk-in availability, and additional support resources. Weekly, CDPH shares demographics with LHJs about who is being tested and LHJs can compare this to their known population distribution and use the information to ensure equitable distribution of testing. Offer financial assistance to selected populations where insurance coverage is not feasible at state sites and explore ways to partner with existing community groups that serve vulnerable populations to design and operationalize accessible testing solutions.

C: TTF identified gaps/improvements in the end-to-end logistics of testing and CA is: 1) Matching labs to collection sites with a match-making model aimed to reduce underutilization of capacity in some high throughput labs and access to testing for healthcare facilities with low throughput or supply-constrained labs; 2) Procuring supplies centrally using a robust distribution model so areas of high demand have sufficient supplies and inventory is in low demand areas; and 3) Tracking and reporting testing, supply distribution, site utilization, and other performance metrics frequently/transparently via published dashboards and reports at the state/county level. CA enhanced data collection efforts and launched a “Lab Metrics App” that is collecting lab level data on processing and planned upgrades to CalREDIE.

D: CDPH released guidelines that limit the use of serologic testing and surveillance studies to determine COVID-19 prevalence, identification of convalescent plasma donors, identification of false negative PCR test results when clinical suspicion is high and indicating prior infection. A working group with scientific and commercial understanding of serology informs CDPH of developments and refresh guidelines as new information/tests are available.

PHLs must conduct serologic testing for epidemiological studies and plasma donation screening. Platforms include the Abbott Architect and Alinity, Diasorin Liasion, Bio-Rad EVOLIS, Dynex DS2, and semi-automated instruments. Serology testing for diagnostic purposes or to support return-to-work decisions is not recommended by the guidelines.

CDPH issued guidance on antigen testing highlighting the tradeoff in lower sensitivity despite faster speed compared to PCR testing. While antigen testing may be used for diagnostic purposes, follow-up PCR testing may be required to confirm negatives prior to treatment decisions. CDPH does not recommend use of antigen tests that are not authorized under EUA.

E: CA is taking a direct role in critical areas that will be the focus for resource utilization: 1) Invest in a reporting infrastructure, establishing new tools and augmenting existing systems to measure testing volumes daily at a granular level (e.g., dashboards). Insights inform decisions to redeploy resources and focus efforts to de-bottleneck testing in important geographies and vulnerable populations; 2) Engage LHJs to ensure sufficient testing capacity to meet the current target of 1.5 tests per day per 1000 people, one of the metrics for reopening; 3) Serve vulnerable populations with guidance on testing frequency and working with relevant departments and local authorities to ensure availability/access to testing; 4) Conduct population-based surveillance to understand population level trends in prevalence in



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partnership with Emory University as a national prevalence monitoring effort; and 5) Lead efforts to integrate testing, genomic sequencing and contact tracing, availability of “fast track” testing options for individuals identified through contact tracing and appropriate care/social support and follow-up, as available. TTF is collaborating with labs to understand capability to provide samples for genome sequencing and existing capacity to perform genome sequencing. TTF is evaluating a plan to launch an end-to-end solution for genome sequencing to leverage existing partnership with CZ Biohub, commercial and academic labs, aim to create sustainable and affordable capacity for sequencing (total sequencing volume estimated ~5 -10,000 samples/month), for statewide phylogenetic tree and outbreak investigations.

F: Actions taken to create lab capacity, procure supplies, and augment the workforce, include: 1) Explore local workforce options to strengthen and expand sample collection capabilities (OptumServe and Verily preferentially employ local workforces) and link local employers to a lab list on the TTF website; 2) Procure/distribute swabs, viral transport media, and collection kits. A multi-stakeholder group tracks supplies available for distribution and projects future needs to inform potential shortfalls and proactively procure; 3) Work with labs to understand what reagents are short in supply and connect labs to appropriate manufacturers. CA is prepared to recommend the purchase of critical supplies of reagents directly if appropriate; 4) Track test processing needs and availability of equipment throughput to support testing demand. CA is prepared to recommend the purchase of equipment on behalf of labs or contract with national labs to create capacity; 5) Work with state/local authorities to create an initial contact tracing workforce of 10,000 people for identifying potentially exposed populations for rapid testing. CA estimates a need for 20,000 contact tracers; 6) Rapid hiring and on-boarding of new contact tracing staff will be accomplished through contract agencies; and 7) Acquire supplies, reagents, test kits and collection materials required for expanding testing is dependent on federal supply.

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**Table #2: Planned expansion of testing driven by public health departments**

| BY MONTH:   | May-20                         | Jun-20                         | Jul-20  | Aug-20   | Sep-20  | Oct-20  | Nov-20  | Dec-20  | TOTAL |
|---|--------------------------------|--------------------------------|---|--|---|---|---|---|-------|
| Number of additional* staff to meet planned testing levels  | No additional staff needed     | No additional staff needed     | NEED TO EDIT TO INCLUDE REQUESTED STAFF in PPP-HCEA   | NEED TO EDIT TO INCLUDE REQUESTED STAFF in PPP-HCEA                        | NEED TO EDIT TO INCLUDE REQUESTED STAFF in PPP-HCEA                                 | NEED TO EDIT TO INCLUDE REQUESTED STAFF in PPP-HCEA                                 | NEED TO EDIT TO INCLUDE REQUESTED STAFF in PPP-HCEA                                 | NEED TO EDIT TO INCLUDE REQUESTED STAFF in PPP-HCEA                                 | 0     |
| FOR DIAGNOSTIC TESTING  |                                |                                |   |  |   |   |   |   |       |
| How many additional* testing equipment/ devices are needed to meet planned testing levels? (provide an estimated number, and include platform details in narrative above) | No additional equipment needed | No additional equipment needed | For VRDL: 1 high throughput molecular (Hologic Panther or Roche Cobas), 1 Biofire Torch (for sample pooling strategy); For local Public Health Labs (PHLs): 5 Hologic and | For VRDL: 1 miSeq instrument; For local PHLs: 10 miSeq or iSeq instruments | None as of June 15, 2020, provided needs indicated in July and August are fulfilled | None as of June 15, 2020, provided needs indicated in July and August are fulfilled | None as of June 15, 2020, provided needs indicated in July and August are fulfilled | None as of June 15, 2020, provided needs indicated in July and August are fulfilled | 0     |

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| BY MONTH:   | May-20   | Jun-20  | Jul-20   | Aug-20    | Sep-20    | Oct-20    | Nov-20    | Dec-20    | TOTAL      |
|---|--|---------|--|-----------|-----------|-----------|-----------|-----------|------------|
|   |  |         | Panther or Roche Cobas and 10 BioFire Torch or Cepheid modules |           |           |           |           |           |            |
| Volume of additional swabs needed to meet planned testing levels <sup>++</sup>                          | 150000<br>(Note: FEMA Provided 1.2 M swaps in May/ June)   | 600,000 | 2,620,000  | 3,060,000 | 3,500,000 | 3,640,000 | 3,790,000 | 3,950,000 | 21,160,000 |
| Volume of additional media (VTM, MTM, saline, etc.) needed to meet planned testing levels <sup>++</sup> | 450000<br>(Note: FEMA provided 900,000 media in May/ June) | 900,000 | 2,620,000  | 3,060,000 | 3,500,000 | 3,640,000 | 3,790,000 | 3,950,000 | 21,460,000 |

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| BY MONTH:  | May-20  | Jun-20   | Jul-20   | Aug-20   | Sep-20  | Oct-20  | Nov-20  | Dec-20  | TOTAL   |
|--|---|--|--|--|---|---|---|---|---|
| Volume of additional reagents needed to meet planned testing levels, by testing unit and platform (i.e. 100K/day - Hologic panther; 100k/day - Thermofisher) | <p>Tests for our 15 installed Roche Cobas (1.5-2M tests/month)</p> <p>New Aptima kits for the 163 Hologic Panthers installed in California (1-1.5M tests/month)</p> <p>Additional Cepheid GeneXpert tests for 41 machines (100K</p> | <p>Tests for our 15 installed Roche Cobas (1.5-2M tests/month)</p> <p>New Aptima kits for the 163 Hologic Panthers installed in California (1-1.5M tests/month)</p> <p>Additional Cepheid GeneXpert tests for 41 machines (100K tests/month)</p> | <p>For VRDL: Kingfisher system/Taq Path Combo PCR extension for 25,000 tests and BioFire respiratory panel and SARS-CoV-2 to test 2,400 specimens; For local PHLs: any platform to conduct 500,000 tests and respiratory panel and SARS-CoV-2 test cartridges to test 24,000 specimens</p> | <p>For VRDL: whole genome sequencing reagents for 10,000 specimens; for local PHLs: whole genome sequencing reagents for 150,000 specimens</p> | None as of June 15, 2020, provided needs indicated in July and August are fulfilled | None as of June 15, 2020, provided needs indicated in July and August are fulfilled | None as of June 15, 2020, provided needs indicated in July and August are fulfilled | None as of June 15, 2020, provided needs indicated in July and August are fulfilled | None as of June 15, 2020, provided needs indicated in July and August are fulfilled |

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| BY MONTH: | May-20   | Jun-20  | Jul-20 | Aug-20 | Sep-20 | Oct-20 | Nov-20 | Dec-20 | TOTAL |
|-----------|--|---|--------|--------|--------|--------|--------|--------|-------|
|           | tests/month)   | Qiagen RNeasy Mini Kits (100K kits/month)<br>Abbot ID Now Kits – 1,800 kits / month<br>(100K tests/month) |        |        |        |        |        |        |       |
|           | Qiagen RNeasy Mini Kits (100K kits/month)<br>Abbot ID Now Kits – 1,800 kits/month<br>Tests for our 15 installed Roche Cobas (1.5-2M tests/month) | Qiagen RNeasy Mini Kits (100K kits/month)<br>Abbot ID Now Kits – 1,800 kits / month                       |        |        |        |        |        |        |       |
|           | New Aptima kits for the 163  |   |        |        |        |        |        |        |       |

# ELC ENHANCING DETECTION: CALIFORNIA TESTING PLAN

| BY MONTH:  | May-20 | Jun-20 | Jul-20 | Aug-20 | Sep-20 | Oct-20 | Nov-20 | Dec-20 | TOTAL |
|--|--------|--------|--------|--------|--------|--------|--------|--------|-------|
| Hologic Panthers installed in California (1-1.5M tests/month)<br><br>Additional Cepheid GeneXpert tests for 41 machines (100K tests/month)<br><br>Qiagen RNeasy Mini Kits (100K kits/month)<br><br>Abbot ID Now Kits – |        |        |        |        |        |        |        |        |       |

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| BY MONTH:  | May-20                         | Jun-20   | Jul-20   | Aug-20   | Sep-20   | Oct-20   | Nov-20   | Dec-20   | TOTAL |
|--|--------------------------------|--|--|--|--|--|--|--|-------|
|  | 1,800 kits / month             |  |  |  |  |  |  |  |       |
| FOR SEROLOGIC TESTING  |                                |  |  |  |  |  |  |  |       |
| Number of additional* equipment and devices to meet planned testing levels | No additional equipment needed | 1 high-throughput serology instrument for CDPH-VRDL (Abbott Architect) | For local public health labs: 5 Abbott Architect, Diasorin Liaison | None as of June 15, 2020, provided needs indicated in July are fulfilled | None as of June 15, 2020, provided needs indicated in July are fulfilled | None as of June 15, 2020, provided needs indicated in July are fulfilled | None as of June 15, 2020, provided needs indicated in July are fulfilled | None as of June 15, 2020, provided needs indicated in July are fulfilled | 0     |

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| BY MONTH:  | May-20                        | Jun-20   | Jul-20  | Aug-20  | Sep-20  | Oct-20  | Nov-20  | Dec-20  | TOTAL |
|--|-------------------------------|--|---|---|---|---|---|---|-------|
|  |                               | 12 serology instruments for public health labs |   |   |   |   |   |   |       |
| Volume of additional reagents needed to meet planned testing levels, by testing unit and platform (i.e. 100K/day - Hologic panther; 100k/day - Thermofisher) | No additional reagents needed | No additional reagents needed                  | No additional reagents needed as of June 15, 2020 | No additional reagents needed as of June 15, 2020 | No additional reagents needed as of June 15, 2020 | No additional reagents needed as of June 15, 2020 | No additional reagents needed as of June 15, 2020 | No additional reagents needed as of June 15, 2020 |       |

\* Report new monthly additions only, not cumulative levels

++ For May and June, only include needs beyond the supplies provided by FEMA. Report new monthly additions only, not cumulative levels.