California COVID-19 Testing Task Force Update

April 22, 2020
Agenda

- Introductions and logistics
- Objectives
- Approach
- Progress
- Next steps
- Questions
Logistics

- **Participation by invitation only** – please send participation requests to testing.taskforce@state.ca.gov

- All of this is to facilitate a **trusted, open dialogue** in a highly fluid situation

- **A newsletter** will follow this meeting and can be used to share with/update others in your community
Introductions

Today’s speakers

• **Dr. Charity Dean**, Assistant Director, California Department of Public Health

• **Paul Markovich**, President and CEO, Blue Shield of California

• **Dr. Christina Kong**, Vice Chair and Medical Director of Pathology & Clinical Lab, Stanford University

List of Task Force leaders provided on Task Force website at testing.covid19.ca.gov
Roles in this public-private partnership

• Appropriate state officials *always* make decisions

• Individuals from the private sector are providing important support at a critical juncture and *do not* make decisions
Two types of COVID-19 tests mentioned in these materials

<table>
<thead>
<tr>
<th>Detection of...</th>
<th>PCR (molecular diagnostic)</th>
<th>Serological tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virus</td>
<td>Antigens or antibodies</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Common sample type</th>
<th>PCR (molecular diagnostic)</th>
<th>Serological tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deep nasal or throat swab</td>
<td>Blood/plasma</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Key considerations</th>
<th>PCR (molecular diagnostic)</th>
<th>Serological tests</th>
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<tbody>
<tr>
<td>Gold standard for diagnostic testing</td>
<td>Do not diagnose infection, but can be useful for antibody detection</td>
<td></td>
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Task Force goals and approach

Our goals
- Increase total number of tests
- 24-hour turnaround
- 90% accuracy
- Equitable and convenient access

Our approach

Access: Establish statewide collection sites for equitable access

Test processing: Maximize throughput and turnaround time of labs

Statewide distribution: Establish a smart distribution of scarce supplies

Facilitate innovation: Provide recommendations on new, promising tests

Data and analytics: Track and report results

Community-driven workforce needs: Maximize using members of the community for the work
Reaching our goals will require taking a range of actions

Current and expected number of COVID-19 tests in California
Tests/day (PCR & Serology Tests)

<table>
<thead>
<tr>
<th>Date</th>
<th>Tests/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>End of March (actual)</td>
<td>2,000</td>
</tr>
<tr>
<td>Goal by 4/17</td>
<td>10,000</td>
</tr>
<tr>
<td>Goal by 4/30</td>
<td>25,000</td>
</tr>
</tbody>
</table>

Average actuals for April 16-20: 16,900

Actions to increase test volumes:

- Increase capacity for existing labs to process tests
- Increase number of specimens collected for processing
- Assess and deploy new tests (e.g., point of care, serology)

1 Including serology tests; actual testing numbers will depend on need, goal is to have the capacity to do this number of tests

Current as of 04/20
Task Force is optimizing end-to-end testing workflows

**Providers**
Patient Referred for Testing

**Sample Collection sites**
Collection Site Collects Samples
- Work to set up a statewide network of new collection sites
- Secure sufficient supplies for sample collection

**Sample Processing sites**
Network of Organizations Processing Tests
- Optimize supply distribution for existing tests
- Identify and scale promising new tests

**Test results captured and reported**
Track results and make them available in aggregate to the public.

**CA Task Force Team**
The Task Force has identified ~270 existing collection sites across the state.

<table>
<thead>
<tr>
<th>Type of site for sample collection</th>
<th>Number of sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drive through collection sites</td>
<td>30+</td>
</tr>
<tr>
<td>Clinics (including VA), physician offices, urgent care centers</td>
<td>40+</td>
</tr>
<tr>
<td>Hospitals (with or without own labs)</td>
<td>200+</td>
</tr>
</tbody>
</table>
We are developing recommendations on where to establish additional sites for equitable access.

**Criteria for recommendation of additional sites:**

- Ensure a collection site within approx. **30 min** driving time in urban areas and within approx. **60 min** in rural areas.
- Ensure there is sufficient capacity at each site to handle projected volume.
- Minimize backlog, turnaround time by guiding sites where to send specimens.

**Existing COVID-19 collection sites in CA**

<table>
<thead>
<tr>
<th>Population density</th>
<th>People/sq. mile</th>
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<tbody>
<tr>
<td>&lt; 50</td>
<td></td>
</tr>
<tr>
<td>51 - 100</td>
<td></td>
</tr>
<tr>
<td>101 - 200</td>
<td></td>
</tr>
<tr>
<td>201 - 500</td>
<td></td>
</tr>
<tr>
<td>501 - 1000</td>
<td></td>
</tr>
<tr>
<td>1001 - 2000</td>
<td></td>
</tr>
<tr>
<td>&gt; 2000</td>
<td></td>
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</tbody>
</table>

Drive-time coverage:
- **30 minutes**
- **60 minutes**
The Task Force is developing a playbook to stand up new collection sites

Goals for the playbook:

• Enable launch of new collection sites rapidly
• Maintain standard workflows, data sharing
• Meet community-driven needs

TABLE OF CONTENTS

• **Section One**: State-wide network of specimen collection sites

• **Section Two**: “Playbook” for establishing a specimen collection site

• **Section Three**: How to implement network

SAMPLE CONTENTS

Section Two: Playbook for Establishing a Specimen collection site

We have developed a playbook that provides guidance on the key elements described with setting up and running a test site. They are provided below.

**Staffing & Leadership**

The following teams, roles, and leaders are recommended. Staffing needs are dependent upon location, capacity, number of lanes, etc.

- **Site Manager**: Responsible for the oversight of all specimen collection sites and staff.
- **Staffing Coordinator**: Responsible for oversight of staff scheduling.
- **Image Lead**: Responsible for overseeing the operation of the screening tool used for triage of potential patients to be tested. If triage is administered via a hotline, call center staff will also be needed.
- **Registration Lead & Team**: Responsible for conducting patient check-in, and directing patients to lanes, based on lane traffic.
- **Medical Lead & Staff**: Responsible for collecting, labeling, and storing samples. The medical staffing needs should be derived from the number of lanes of your site.
- **Logistics Lead**: Responsible for transporting samples to the contracted lab.
- **Lab Point of Contact**: An assigned point of contact who can answer results regarding test processing.
- **Communication Lead & Team**: Responsible for receiving testing results from the lab, and communicating the results to patients via phone or email.
- **Security Lead**: Responsible for securing the specimen collection site.

The following site elements are recommended. Site needs may be adjusted for site location, capacity, number of lanes, etc.

- **Centrally located site**: Before selecting a site, the approximate demand and throughput of your site should be established. See the “Calculating Throughput” section of this playbook for more information. Ensure the site will allow lanes to be configured without accumulating traffic on public streets.
- **Sizing**: Protect specimen collection site staff and materials in inclement weather.
- **Aggregation**: Properly store samples until lab transport.
- **Biobank disposal service**: To pick up and dispose of labeled PPE.
- **Signage and Cues**: To provide visual cues to patients on how to proceed through the site, limiting the need for verbal contact.
The Task Force is making progress to secure scarce collection supplies

Supplies needed for specimen collection and transportation

- Swabs
- Transport medium
- Collection tubes
- Biohazardous bags
- Personal protective equipment (e.g., N95 masks, gowns, gloves)
California has sufficient lab capacity to meet the task force’s daily testing goal.

**Capacity for PCR COVID-19 test processing in California**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Capacity</th>
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<tbody>
<tr>
<td>Roche</td>
<td></td>
</tr>
<tr>
<td>Hologic(^2)</td>
<td></td>
</tr>
<tr>
<td>Abbott</td>
<td></td>
</tr>
<tr>
<td>Thermo Fisher</td>
<td></td>
</tr>
<tr>
<td>BD</td>
<td></td>
</tr>
<tr>
<td>Other manufacturers</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>60k+</td>
</tr>
</tbody>
</table>

\(^1\) Relative capacity takes into account availability of supplies for test processing and lab operating hours.

\(^2\) Calculation based on lab reported install base, assume same throughput as Panther Fusion once test kit is approved.

SOURCE: Install base aggregates data reported by labs; information is being refined through targeted outreach.
We are tracking tests/day daily

Total testing volume in California, tests/day

Current as of 04/20
We will use this information to provide recommendations as to where collected specimens should be sent.

Specimen collection by hospitals (inpatient and outpatient)

Specimen collection in congregate setting

Drive-through centers, clinics, physician offices, urgent care centers

Hospital-owned labs

High-throughput labs

Public health labs

Role of the Task Force:
- Guide people toward staffed and supplied collection sites
- Match collection sites to labs that have capacity for faster test processing turnaround
The Task Force is developing a dynamic model to inform where supplies should ideally be distributed

- **Maximum capacity for COVID-19 testing in California**
- **Testing volume by lab**
- **Supply inventory in labs and collection sites**
- **Expected supply shipments for distribution**

**Model engine:**
Identification of bottlenecks and opportunities to increase throughput

**Allocation decisions (made by appropriate state authorities)**
Allocation based on criteria approved and prioritized by state decision-makers

**Projected changes in testing volumes**
We are also examining new tests and alternative methods

**Assessment approach**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Serology tests</strong></td>
<td>Technical assessment that includes a comprehensive set of performance metrics and follows a systematic multi-step approach</td>
</tr>
<tr>
<td><strong>Rapid point of care tests</strong></td>
<td>Focus on congregate settings, vulnerable populations, and first responders</td>
</tr>
<tr>
<td><strong>Specimen pooling</strong></td>
<td>Assessment focused on feasibility and identification of low prevalence areas where pooling may be beneficial</td>
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</table>
The Task Force has developed recommended minimum performance levels for serology tests

<table>
<thead>
<tr>
<th>Assessment scheme</th>
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<tr>
<td><strong>Step 1</strong></td>
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<tr>
<td>Does the testing method have performance data derived from clinically and</td>
</tr>
<tr>
<td>scientifically valid methods?</td>
</tr>
<tr>
<td><strong>Step 2</strong></td>
</tr>
<tr>
<td>Does the testing method have adequate clinical sensitivity (min 90%) and</td>
</tr>
<tr>
<td>specificity (97%)?</td>
</tr>
<tr>
<td><strong>Step 3</strong></td>
</tr>
<tr>
<td>What is the relationship of sensitivity/specificity and predictive values for</td>
</tr>
<tr>
<td>each test method?</td>
</tr>
<tr>
<td><strong>Step 4</strong></td>
</tr>
<tr>
<td>What are additional available performance metrics (e.g., turnaround time,</td>
</tr>
<tr>
<td>specimen type, reagent stability and availability)?</td>
</tr>
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</table>
What we hope you take away from this session

• We have developed a comprehensive but highly manual picture of testing in CA
• Picture is dynamic, changing every day
• Task Force is working hard to help:
  • Optimize distribution of testing supplies and equipment where needed
  • Recommend when new tests should be put into widespread use
  • Propose resources needed to expand testing capacity
  • Ensure equitable and appropriate statewide access to testing
• Efforts gaining traction as we have moved from ~2,000 tests per day when we started to averaging ~16,000 per day
• We have a path to goal of 25,000 tests per day and plenty of work left to do to achieve it
Next Steps

• Newsletter with updates about our work

• Please reach out to testing.taskforce@state.ca.gov if you have any questions about the Task Force efforts