Chapter 15
Testing

Version History

Version #	Date	Notes
0.1	12/18/2023	First Draft submitted to CPR team
0.2	2/9/2024	Final Draft revised per review by CPR Team
0.3	4/23/2024	Final Draft revised per Expert SME review
0.4	6/6/2024	Final Draft revised per CPR Leadership review
0.5	6/19/2024	Final Draft revised per CPR Leadership re-review and Expert SME review
1.0	7/22/2024	Final revised per CDPH Directorate review
1.1	1/13/2025	Final rebranded

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15. Testing

Public Health Emergency Preparedness and Response Capabilities: Public Health Laboratory Testing.

Related CDPH AAR Chapters: Data and Reporting; Epidemiology and Surveillance; Enterprise Technology.

In this chapter, some abbreviations may be used interchangeably with their respective full spellings for ease of reading.

Chapter Summary

Overview

This section provides a high-level overview of milestones and activities related to this chapter.

SARS-CoV-2 first emerged in late 2019, and in the next several months it quickly became clear that California's testing infrastructure was unprepared to meet the coming demand for mass testing. The Governor's Office subsequently formed the Testing Task Force (TTF) in late March and early April 2020, a public-private partnership with representatives from the California Health and Human Services Agency (CalHHS), the California Governor's Office of Emergency Services (Cal OES), and CDPH.

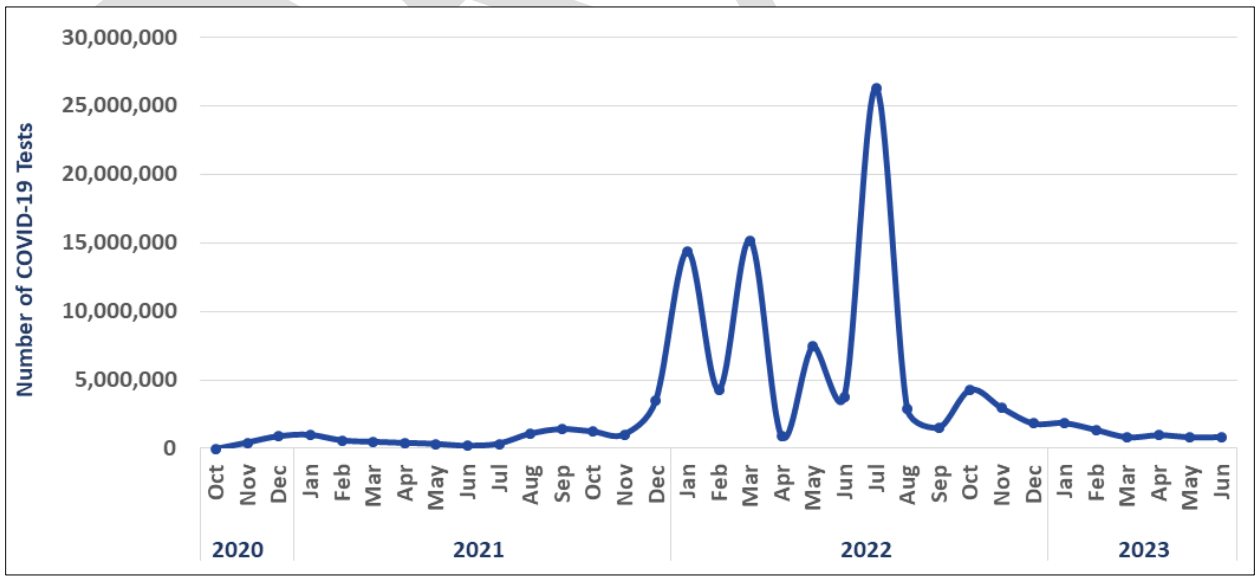
The TTF was formed to support California's response to COVID-19 by increasing access to testing for all Californians, particularly communities at higher risk. Testing equity emerged as a primary focus in summer 2020 and was incorporated in all testing programs. Early in the pandemic response, the only testing modality (type) available was polymerase chain reaction (PCR) testing, a sensitive molecular test. PCR test samples are collected from individuals, transported to a lab for processing, with results typically available in 24-72 hours. The TTF focused on creating community-based testing sites and a State-run lab to expand PCR testing.

Initially, the TTF was organized into so-called "cohorts" by organization type (e.g., schools, the California Department of Social Services [CDSS] and Community-Based Organizations [CBOs]). Each cohort oversaw testing

programs and/or managed the vendor(s) who provided the testing or testing support services. However, this changed with the introduction of professional Clinical Laboratory Improvement Amendments (CLIA)-waived rapid antigen testing in Fall 2020. Antigen tests could be performed by anyone with a CLIA waiver, and results were available within 15-30 minutes. Although antigen tests were less sensitive than PCR tests, they were less expensive and more convenient. New vendors soon emerged to offer antigen-related testing services.

It became clear that the infrastructure that had been built for PCR programs (e.g., logistics, distribution, workflows, and technology systems) could be quickly pivoted to support a different modality. Consequently, the TTF leveraged its PCR testing infrastructure to develop multiple antigen testing programs, eventually including Over-the-Counter (OTC) antigen tests, which became available in late 2021. At its height, the TTF managed seven cohorts, consisting of over 6,700 testing sites. Over the course of the pandemic, the TTF supported administering over 14 million COVID-19 PCR tests, distributed 107 million OTC tests, and 25 million professional antigen tests in California. At its height in 2021-2022, the TTF managed State and federal budgets exceeding $2 billion. **Figure 1** depicts the tests administered and delivered by the TTF in California by month from October 2020 to June 2023.

Figure 1: COVID-19 Tests Administered and Delivered by Month (October 2020 – June 2023)



Source: Testing Task Force

The TTF continued to evolve throughout the pandemic response and develop new program offerings to meet California's needs. The TTF went through three distinct phases—TTF 1.0, TTF 2.0, and TTF 3.0.

TTF 1.0: March 2020 – June 2020

TTF 1.0 was co-chaired by leaders from CDPH and Blue Shield California. During this first incarnation, the TTF focused on identifying and expanding the State's lab capacity, projecting demand for testing, and procuring testing supplies that were in extremely short supply. At this point in time, only PCR testing was available and the State contracted with two vendors to establish State-run specimen collection sites across California. Establishing these PCR testing sites expanded capacity; however, problems arose during the rushed implementation. After the initial roll-out of these sites in summer 2020, the TTF began to troubleshoot issues, especially addressing the unanticipated equity challenges. Most of the testing sites were accessed by making an appointment on-line and then driving or walking through a lane at a designated location to provide a test sample. This presented barriers to Californians who lacked transportation or digital access. The emergence of these initial equity challenges highlighted the importance of testing equity, which became a subsequent focus of all TTF programs. To address inequities at the PCR sites, the TTF contracted with vendors to offer mobile and walk-up testing services. The TTF also established an Equity Lead, developed equity metrics based on the Healthy Places Index (HPI) and other variables, and instituted weekly monitoring and reporting on testing equity for all programs.

At the end of June 2020, the TTF's co-chairs stepped down, marking the end of TTF 1.0

TTF 2.0: July 2020 – June 2021

Clinical leadership supported TTF in early July 2020 until new co-chairs could be brought onboard in late July 2020. During the initial weeks of July 2020, despite the expansion of State-run test collection sites, testing volumes could not keep up with demand during the July 2020 surge in part due to international testing supply shortages and laboratory staffing challenges. This contributed to long testing turnaround times, which averaged 7-10 days. This was a significant problem, as results were needed much sooner for testing to be an effective mitigation tool. As one leader noted, "if you can't get results back in 24-48 hours, then the test isn't that useful." Upon investigation, leaders realized that a

shortage of critical testing supplies (including pipettes, reagents, and plastics) were preventing labs from increasing testing volumes. The State began meeting with supply companies and successfully contracted with vendors to provide additional testing supplies and equipment.

New TTF co-chairs came onboard August 1, 2020 and were drawn from Kaiser and CDPH. The Kaiser co-chair remained onboard through December 2020 and following his departure at the end of December 2020, TTF was then co-chaired by two CDPH leaders beginning January 1, 2021. At this time, TTF 2.0 was formed to further increase testing capacity, address inequities, and reduce turnaround time. One of the biggest initiatives associated with this phase was the decision to launch the State-run Valencia Branch Laboratory (VBL) in Southern California, which the Governor announced in August 2020. The State contracted with additional vendors to provide the lab's operations as well as reporting and registration software. Testing capacity was still lower than State officials desired, and consequently the construction of VBL was expedited. The TTF set up a network of testing sites across the State (the "wheel"), which would provide the specimens via a courier service (the "spokes") to be processed at VBL (the "hub").

The TTF transitioned its existing PCR sites to the new "hub, spoke, and wheel" model and also began conducting intensive outreach to community-based organizations (CBOs) to establish more testing sites. For these new, State-supported sites, the TTF provided set-up assistance, resources, and supplies, with the sites ultimately intended to be run by CBOs and community members. The TTF used its equity metrics to help determine site locations and focused on reaching out to organizations who served communities in the lower HPI quartiles. As the TTF worked around the clock to stand up these sites, they soon realized that there was not a quick, consistent, and reliable way for the sites to transport their specimens to the VBL for processing. Consequently, the State contracted with a vendor to establish the California COVID-19 Courier Network (CCN), a Statewide network of drop-boxes designed specifically for test collection sites to deposit their test samples where they would be transported (the spokes) to the VBL (hub) free of charge.

Following expedited construction, the VBL launched in November 2020 and immediately encountered challenges. Staffing shortages and the Winter surge of 2020-2021 contributed to lengthy turnaround times. Additionally, the VBL experienced quality control issues, complaints, and reports of inaccurate testing

results, which triggered inspections and public scrutiny. Ultimately, PCR testing proved to be a difficult modality to scale quickly, due to its expense, processing time, and complexity.

Around the same time, the TTF began to pilot antigen testing programs following the federal approval and subsequent manufacturing of the first antigen test kits in Fall 2020. Unlike PCR tests, which were processed in a lab, antigen tests could be performed on site. As a CLIA-waived point-of-care test, they were subject to stricter regulations, which initially impeded mass implementation of this quick and easy testing method. As the TTF established pilot antigen programs at skilled nursing facilities (SNFs), California Department of State Hospitals (DSH) facilities, and schools, over the winter and into Spring 2021, it also developed a solution to the regulatory barrier. Ultimately, CDPH issued Statewide CLIA waivers (first for schools and then to other locations) that would allow testing sites to offer antigen testing ultimately under three CDPH lab directors to oversee three cohorts (schools, CDSS, and CBOS) licenses' and Statewide ordering physicians. The last few months of TTF 2.0 was focused on developing the infrastructure to support these cohorts. Although the cohorts possessed similar infrastructure, there was more work than a single vendor could manage and the clientele from each cohort had uniquely different needs.

TTF 3.0: July 2021 – June 2023

TTF 3.0 was led by a single CDPH chair, instead of co-chairs or a public-private partnership. Under the third incarnation of the TTF, CDPH officially launched its Statewide free professional antigen testing program (which had been under development during the final few months of TTF 2.0). The antigen program built upon the infrastructure developed for PCR testing. It was challenging for some CBOs and SNFs to understand the program's unique reporting requirements, which were unusual due to CDPH's licensing waiver. The TTF provided extra support and guidance for these struggling sites.

The TTF schools team implemented on-site antigen and PCR testing at California's K-12 schools. Some schools had already established PCR testing through the VBL. The TTF antigen program had a State CDPH medical officer lead and two contracted medical officers to support it throughout the 2021-2022 academic year. PCR testing, with its lengthy turnaround times, proved ill-suited to schools since students had to stay home while waiting for test results. Ultimately, antigen testing was the most popular option for schools, with PCR testing being most often used as a confirmatory test.

There was strong medical officer leadership supporting the TTF's testing programs in schools. While different individuals served in this position over the course of the pandemic, the TTF maintained a medical officer schools lead who reported directly to TTF leadership.

Simultaneously, the TTF launched additional community based on-site antigen testing programs (for CDSS and for CBOs) using the same framework created for VBL and enhanced for schools. At this time the TTF only had one additional medical officer who provided clinical support to these non-schools programs.

In Spring and early Summer 2021, the TTF began enrolling schools, CDSS, and CBOs in its antigen testing programs. Initially, demand was low. However, in late Summer and early Fall 2021, the Delta surge coincided with back-to-school and the release of State health officer orders requiring testing of some school staff, as well as other government employees. This led to a demand for testing, and, ultimately, a spike in over 4,200 sites registering for TTF programs in less than one week. This number included thousands of government employees in 100 departments spread across 1,000 offices, over 2,000 schools sites, 700 CDSS sites, and 1,500 CBOs who wanted to enroll in the antigen program.

In response, TTF staff established new cohorts to serve different unique groups and to help manage overwhelming demand. The TTF also expanded existing cohorts to help onboard more organizations into the programs. Some sites also enrolled in confirmatory PCR testing to offer both testing modalities. As the TTF leadership and staff from all cohorts worked around the clock to enroll thousands of sites and process millions of orders, they were also challenged by an international shortage of professional antigen test kits. TTF leadership had pre-emptively ordered 11 million antigen tests in preparation for return to in-person school and work, but the test companies failed to deliver 9 million of these tests.

During Summer 2021, the TTF also developed a number of Outbreak Response Teams, which was staffed by vendors who could be deployed to conduct rapid testing and vaccinations in the community.

The rapid growth of the TTF's testing programs sometimes resulted in confusion, unintended competition, and silos between the schools program and the six other TTF cohorts. Although antigen testing continued to grow in popularity, some organizations still continued to use the TTF's PCR testing programs, which often filled a gap during surges or antigen test kit shortages.

For some schools in disadvantaged communities, the administrative burdens of running the antigen program proved overwhelming. To address this the TTF developed equity programs to provide additional operational support, either through end-to-end vendors who would run all testing operations or direct funding through grants that schools could use to hire testing personnel.

In late Fall 2021 the first At-Home/OTC COVID-19 tests became available. Consequently, the TTF developed its At-Home/OTC testing program, which was modeled on the initial infrastructure created for VBL, modified for the on-site antigen programs and ultimately used for OTC tests. The OTC program distributed test kits for individual use without the requirement to report results. The TTF began to offer OTC test kits to schools and CBOs to further expand testing capacity across the State. Around the same time, the TTF also piloted the first international airport testing program in the country at SFO; the program used both professional on-site testing and OTC testing for post-travel infection and to identify variants. In Winter 2021-2022, the Omicron surge presented California with an unprecedented COVID-19 surge and sudden demand for tests skyrocketed again. The TTF had pre-ordered approximately 15 million test kits several months before the Omicron surge, but this order was not fulfilled due to international test kit supply shortages, shipping delays, and winter storms. With no test kits available, CDPH had to carefully ration test kits to prevent morbidity, keep the economy open, and keep children in schools. During the Omicron surge the TTF also expanded its airport program to two other international airports in California (LAX and Orange County) as well as the Tijuana Cross Border Bridge.

In early Spring 2022, after the Omicron surge, test kits again became readily available throughout the US. The TTF ordered 5 million test OTC test kits to be delivered monthly to CDPH/CalOES warehouses through December 2022 to ensure a stockpile for California to withstand future surges. Once supplies stabilized, the OTC program again focused on equity and prioritized distributing test kits to California's low-income, uninsured, and under-insured populations.

Simultaneously, in Spring 2022 oral therapeutics became available, but barriers existed in accessing the medications. The TTF worked closely with the testing vendor Optum Serve to implement the first Statewide "Test-to-Treat" program in the country. This Test to Treat program offered expedited access to therapeutics right in the field as soon as someone tested positive for COVID-19. This model was then expanded in Fall 2022 when the Test-to-Treat program was linked to

positive test results associated with both the on-site antigen program as well as the OTC program.

The VBL operated until May 2022, at which point the State transitioned to a single vendor facilitating PCR testing at a network of commercial labs in order to have the capacity for rapid expansion during surges.

During the 2022-23 budget and academic year, the TTF managed the contraction of the TTF's testing programs. While the PCR testing utilization continued to decline, the TTF focused on its antigen testing programs, especially distributing OTC test kits. The TTF streamlined its vendors and integrated its antigen testing cohorts and also its various data streams.

In January 2023, TTF demobilized the vendor providing Test-to-Treat across the State and limited the program to a few buses that were available on standby for rapid dispatch. In March 2023, following the end of California's declared state of emergency for COVID-19, the State demobilized its PCR lab network and PCR testing programs. The TTF also demobilized vendors who had been providing operational support to schools and community sites. As CDPH prepared to deactivate from the emergency response, plans were made to continue some testing activities beyond June 2023. CDPH created a new Office of Infectious Disease Preparedness and Response (OIDPR) within the Center for Infectious Disease (CID), and the OTC program was moved to this office to continue distribution of OTC test kits. Additionally, a scaled-down version of the TTF's professional antigen testing program in the community was maintained within CDPH's Center for Laboratory Sciences (CLS).

Ultimately, over 14 million COVID-19 PCR tests were administered, 25 million professional antigen tests were performed or allocated through the TTF professional antigen TTF programs, and over 107 million OTC tests were allocated and distributed by TTF in collaboration with the State's warehouse team. The TTF leaders and subject matter experts (SMEs) stressed the importance of maintaining the TTF testing infrastructure built throughout the pandemic response. This infrastructure includes a few thousand community and partners and their staff that are trained volunteers, technology systems, vendor partnerships, operational and logistical processes, data and reporting processes, and other components. "This is the answer to the next pandemic," one TTF leader noted, emphasizing that "we have all the mechanisms to get tests out there quickly" and that it was critically important to maintain it for future testing

and treatment needs in the community, either for other emergencies or for other diseases.

Timeline and Key Milestones

2020	
Winter 2019/2020	• **January – February**: COVID-19 testing very limited and controlled by the CDC
Spring 2020	• **March 4**: Governor declared State of Emergency in California • **March 9**: California Code of Regulations Title 17 updated to add COVID-19 to list of reportable conditions • **March 18**: CDPH issued requirement for labs to report both negative and positive COVID-19 test results • **Late March – early April**: Testing Task Force (TTF)1.0 formed
Summer 2020	• **April – May**: State contracted with two vendors to establish PCR test collection across California, and laboratory support services • **May – June**: Commercial PCR testing became more widely available • **July**: TTF 2.0 launched • **August 26**: Governor announced contract with PerkinElmer to build a State laboratory • **Late August**: FDA issued Emergency Use Authorization (EUA) for first rapid antigen test kit, BinaxNOW
Fall 2020	• **October 30**: Governor announced creation of Valencia Branch Lab (VBL) • **October**: TTF began establishing additional PCR community-based testing sites • **November**: State contracted with vendor to establish the COVID-19 Courier Network (CCN) • **November**: VBL launched and began processing samples • **November**: TTF piloted high frequency antigen testing in >30 SNFs and 6 State department hospitals
2021	
Winter 2020/2021	• **December**: TTF piloted antigen testing programs in K-12 schools • **Late December**: First COVID-19 vaccines arrived in California

	• **January**: PCR testing piloted and then launched to 900 sites including clinics, hospitals, schools, and other organizations • **February:** TTF allocated $176 million in ELC funds
Spring 2021	• **April:** TTF allocated $882 million in ELC schools funds • **April**: TTF launched first statewide CLIA waiver professional antigen program in schools under one lab director • **March – June**: TTF recruited two additional Statewide lab directors to establish cohorts for CDSS and CBOs • **March – June**: TTF developed and refined infrastructure for antigen programs • **March – June:** TTF began recruiting schools, CDSS, and CBOs for three Statewide antigen cohorts
Summer 2021	• **July**: TTF 3.0 launched • **August – September**: Delta Surge • **August**: Over 4,200 sites registered to onboard for TTF professional antigen programs in less than a week • **September:** International test shortage results in ~11 million tests not delivered to CDPH • **September**: TTF launched and implemented additional operational support to schools (via end-to-end vendors or direct funding)
Fall 2021	• **October**: Outbreak Response Team program formed • **October**: TTF piloted first testing program in international airport • **November**: TTF piloted antigen At-Home / OTC program • **November – December**: TTF launched OTC program

	2022
Winter 2021/2022	• **December:** TTF expanded international airport testing to three additional locations • **December – January**: During Omicron surge TTF opened professional antigen sites to the local community and helped deploy the National Guard to increase testing access • **December – January**: International test shortage resulted in 15 million OTC tests not delivered to CDPH
Spring 2022	• **March – April:** TTF secured General Funding to purchase five million OTC kits per month (through December 20222) to ensure available stockpile for surges • **May**: TTF transitioned from the single VBL to a lab network, **May – June**: TTF implemented first Statewide Test-to-Treat program in the country at over 140 testing sites
Summer 2022	• **June**: Direct funding for schools program discontinued and end-to-end vendor support for schools scaled down • **July – December:** Antigen cohorts consolidated to one cohort under a single lab director
Fall 2022	• **October**: Professional antigen and OTC antigen programs integrated with Therapeutics Task Force's telehealth program • **October**: Outbreak Response Team program largely demobilized
	2023
Winter 2022/2023	• **January – March:** Optum Serve Test-to-Treat sites demobilized leaving five buses on standby • **February 28**: California's State of Emergency for COVID-19 ended
Spring 2023	• **March**: PCR Lab Network demobilized and PCR programs discontinued • **March – April**: End-to-end school vendors demobilized • **April**: Vendor testing buses for community events decreased to three buses • **May 11**: End of federal state of emergency
Summer 2023	• **June 30**: CDPH's Medical Health and Coordination Center (MHCC) deactivated from COVID-19 response • **June 30**: TTF shut down • **June 30**: OTC program and professional antigen program relocated to other centers within CDPH

Primary Testing Vendors

The TTF relied on many vendors to offer its testing services. **Figure 2** summarizes the TTF's primary testing vendors discussed in this chapter. This list does not include all the TTF vendors.

Figure 2: Primary Testing Vendors

Vendor	Description
Optum Serve	Optum Serve was one of the earliest and longest-running TTF vendors. The State contracted with Optum Serve to establish drive-up PCR testing sites in 2020. Additional services were added as the pandemic evolved, and Optum Serve began to offer both antigen and PCR testing and expanded to offer the first Test-to-Treat program in the country. The State contracted with Optum Serve to offer mobile testing teams, walk-up testing sites, traveling testing buses, Test-to-Treat, and end-to-end operational testing support for schools.
PerkinElmer	The State contracted with PerkinElmer in Summer 2020 to expand testing capacity within local public health labs by offering equipment and supplies to test. In Fall 2020 the State contracted with Perkin Elmer to establish the Valencia Branch Lab, the State's PCR testing lab. PerkinElmer was responsible for all VBL operations, including specimen accessioning, processing, lab operations, and lab logistics.
Color	The State contracted with Color in 2020 to manufacture and provide PCR test kits as well as the patient registration and reporting system for the VBL. In 2022, Color also took over PerkinElmer's responsibilities when the State transitioned away from a single lab to a network of multiple labs (run by Color). The State also contracted with Color to rapidly develop a professional antigen testing program to help the state meet overwhelming demand for professional antigen testing in fall 2021. The state also contracted with Color to provide end-to-end testing services for both PCR and antigen for schools, state employees and community organizations.
Verily	The State contracted with Verily to operate PCR testing sites in rural locations in spring 2020, since Optum Serve was not initially able to serve these areas. Later, the State contracted with Optum Serve to take over sites that had been run by Verily.

Vendor	Description
Primary	The State contracted with Primary in 2021 for a reporting and registration software platform for its professional antigen testing programs.
Mobile Med	The State first contracted with Mobile Med in 2020 to establish a courier network to transport PCR specimens from various testing sites across California to the Valencia Branch Lab. Later, the State also contracted with Mobile Med to provide end-to-end testing services in schools and for outbreak response teams.
Vestra	The State contracted with Vestra to offer end to end antigen with confirmatory PCR testing services for K-12 schools.
Bay Area Phlebotomy Lab	The State contracted with Bay Area Phlebotomy to offer end to end antigen with confirmatory PCR testing services for K-12 schools.
Snap Nurse	The State contracted with Snap Nurse to offer end to end antigen with confirmatory PCR testing services for K-12 schools.
Mobile Health	The State contracted with Mobile Health to offer end to end antigen with confirmatory PCR testing services for K-12 schools.
Gingko Biologics	The state contracted with Gingko Biologics to offer end to end PCR pooling with confirmatory professional antigen and PCR testing services for K-12 schools.

Main Strengths and Successes

This section describes the Main Strengths and Successes, including findings and corrective actions, related to this chapter. Further elaboration and a more detailed discussion of these strengths and successes can be found in the Analysis of Activities section.

1. The Testing Task Force built an extensive Statewide testing network, which resulted in administration of over 14 million PCR COVID-19 tests. This infrastructure was leveraged to develop subsequent antigen testing programs and Test-to-Treat programs.

The Governor's Office formed the TTF in Spring 2020 as a public-private partnership to expand California's testing capacity. Over the course of the pandemic, the TTF evolved through three different phases in response to changing pandemic needs. The TTF was led initially by CDPH and private leadership until January 2021, after which it was led first by two CDPH experts until June 2021 and thereafter by a single CDPH experts. Initially, the TTF focused on building capacity for PCR tests and solving testing supply shortages. When it became clear that more capacity was needed, the State partnered with vendors to build its own lab and establish an extensive network of community-based PCR testing sites. As the TTF was expanding its PCR network, it also piloted antigen testing programs, which became available in Fall 2020. Implementing antigen testing at scale required the TTF to come up with an innovative solution to a difficult regulatory barrier—letting organizations offer testing under CDPH's licensing waiver. Leveraging the infrastructure it had built for PCR programs, the TTF pivoted to enroll thousands of participants in its antigen programs for schools, CDSS, CBOs, and other entities. The TTF evolved and grew in size to seven different cohorts, each managing different clientele with unique needs. When the At-Home/OTC program became available in Fall 2021 each cohort incorporated OTC tests into their program offerings. The TTF's many innovations included developing a courier network for sample transportation, equity-based operational support for schools, airport testing for returning international travelers, and the implementation of Test-to-Treat sites that offered testing and therapeutics dispensing at vendor and community sites across

California. Ultimately, over 14 million PCR COVID-19 tests were administered through TTF community sites. Additionally, the TTF's professional antigen programs performed and distributed over 25 million 107 million OTC tests.

Finding/Corrective Action: The TTF's innovative testing programs built on initial infrastructure created for a State lab and successfully helped expand capacity that can be leveraged in future pandemics. (*ID: Testing 1*)

2. The TTF successfully operationalized equity into its testing programs and cohorts through a multi-pronged, data-driven approach.

The TTF embedded testing equity in all its programs and cohorts beginning in summer 2020. After early inequities were discovered, the TTF appointed an Equity Lead to oversee and track equity metrics, and improve how testing resources were distributed. The TTF's approach to equity was multi-pronged and innovative. The TTF collaborated with Local Health Jurisdictions (LHJs) and community-based organizations to ultimately establish over 6,700 thousand free State-supported PCR and professional antigen testing sites in lower Healthy Places Index (HPI) quartiles, serving primarily to vulnerable and underserved populations. When it became clear that some sites had no way to get their PCR samples to the lab for processing, the TTF established a courier network to provide free sample transportation and FedEx shipping for remote locations. For antigen testing programs, which faced greater regulatory challenges, the TTF provided comprehensive support, including grants and operational assistance, especially to schools and community organizations in need. Additionally, the At-Home/OTC program focused on distributing antigen kits to the uninsured and under-insured without reporting requirements. TTF team members continually worked with vendors to operationalize and improve equity, and the TTF's progress towards its equity goals were monitored through weekly assessments of testing volumes, turnaround times, and testing locations, particularly in the lowest HPI quartiles. This data, combined with race, ethnicity, case, and death rate metrics, enabled the TTF to identify equity concerns and develop solutions. TTF SMEs and leadership emphasized the innovative,

dedicated commitment to testing equity, and recommended that CDPH create an equity playbook for future emergency responses.

Finding/Corrective Action: CDPH should consider creating an equity playbook for future emergency responses, drawing on the equity work accomplished by the TTF and other response teams. (*ID: Testing 2*)

3. To expand PCR testing capacity, California built and operationalized its own State-run laboratory.

In Summer 2020, it became clear that testing capacity was not expanding as quickly as needed. Labs were hampered by testing supply shortages and overwhelmed by increasing testing volumes, which negatively impact testing turnaround times. In response, CalHHS and State leadership formed a public-private partnership with two vendors (PerkinElmer and Color) to establish a State-run laboratory called the Valencia Branch Lab. The VBL was based on a new "hub and spoke" testing model, in which testing sites across the State (the spokes) would send their specimens to the centralized State-run lab (the hub). This new model was designed to increase testing capacity, reduce turnaround times, and ensure a more stable supply of testing materials. In just two months, the State contracted with vendors to construct and operationalize the lab, which included building and outfitting the lab itself, as well as the hiring, training, and validation testing when necessary. Through this significant effort the VBL launched in November 2020.

Finding/Corrective Action: Future efforts to establish a State-run lab can leverage the lessons learned from VBL. (*ID: Testing 3*)

4. The Testing Task Force established over 200 Vendor-run and 3,400 State-supported PCR community testing sites.

While CalHHS and its vendor partners worked on building VBL, the TTF expanded its staff to create a network of testing sites. These included expanding existing State-run fixed sites, mobile buses, and traveling teams, as well as collaborating with CBOs to establish a new type of testing site ("collection site"). For new State-supported PCR community sites, the TTF helped with site set-up and provided free test kits, test processing, training on how to swab and process specimens for transportation to the lab, and a registration and reporting platform. The

sites were subsequently run by community members and utilized public spaces such as schools, faith-based organizations, and fairs. This new model, in which the State partnered with communities to help them become self-sufficient and conduct ongoing testing, was highly innovative and changed the model of care delivery for infectious disease testing. As the TTF worked with CBOs, the team developed hundreds of community health workers to expand testing access to uninsured or under-insured populations. In addition to CBOs, many non-profit organizations, faith-based organizations, and employers enrolled in the community PCR program.

Finding/Corrective Action: The State-supported PCR testing sites introduced a new model for infectious disease testing that can be leveraged in future pandemic responses. (*ID: Testing 4*)

5. The TTF established the innovative California COVID-19 Courier Network, which added over 110 drop-box locations across California to help community-based testing sites transport their PCR samples quickly and free of charge.

In the latter part of 2020, as the TTF focused on integrating new community-based collection sites into the State's PCR testing initiative, the TTF identified a critical need to efficiently transport samples to the lab. Many community sites were hundreds of miles from the lab and lacked the resources to pay for shipping costs. Expanded transportation options had to be equitable, cost-efficient, and provide easy ways for remote community-based testing sites to get their samples to VBL. The TTF's solution was to implement the innovative California COVID-19 Courier Network (CCN). This Statewide network utilized strategically placed drop-boxes, which allowed sites to drop off their samples to be transported to the lab by a courier vendor. Collaborating with CBOs, schools, and other entities on drop-box locations, the TTF facilitated placing over 110 drop-boxes across California, including rural and high-volume testing areas. The CCN not only bridged a significant gap in the testing process but also solidified the TTF's commitment to equitable healthcare logistics, proving to be a unique and successful solution at a critical time. When some rural schools turned out to be too far from a drop box, the TTF added another transportation option by partnering with FedEX to offer prepaid shipping labels to schools. Some SMEs felt

that the FedEx option was even more successful than the original CCN for lower volumes of testing in remote locations.

Finding/Corrective Action: The California COVID-19 Courier Network was a successful pandemic innovation and can be used as a model in future responses to address similar transportation challenges. (*ID: Testing 5*)

Finding/Corrective Action: In the future, SMEs recommended that the State consider also focusing on providing pre-paid shipping labels, especially for rural community organizations and school districts. (*ID: Testing 6*)

6. To rollout antigen testing the TTF developed innovative community-based solutions to testing including addressing regulatory barriers and linking testing directly to treatment.

When the first COVID-19 antigen tests became available in early fall 2020, California initially faced challenges integrating them into its existing PCR testing strategy. Antigen tests were quicker and cheaper but less sensitive than PCR tests, necessitating a paradigm shift for broader acceptance. Early shipments of antigen tests from the federal government directly to California facilities revealed significant regulatory hurdles. Since antigen test results were interpreted on-site, they were considered point-of-care tests, and were subject to specific CLIA requirements. In order to remove barriers to using the professional antigen tests, TTF established high-frequency antigen testing pilots in SNFS, DHS facilities, and schools. The SNF and DSH immediately saw benefits of decreased infections and reduced outbreaks in these congregate setting. The TTF shared these findings broadly at the regular monthly stakeholder meetings to help the professional antigen tests gain acceptance. However, the CLIA-waived prerequisites proved to be significant obstacles for broad roll out. Many potential community-based testing sites did not have CLIA waivers and CLIA waived-lab directors became very hard to find. To address these hurdles, CDPH and the TTF schools team collaborated to issue the first Statewide CLIA waiver to streamline the authorization process for sites to administer antigen tests without individual CLIA certifications. Instead, community site volunteer testing personnel were trained and, after passing a skills assessment and knowledge competency test, could perform tests under the State's CLIA waiver. The State developed three statewide CLIA waivers to address

schools, DSH facilities, and CBOs. Concurrently, TTF leveraged its existing infrastructure for PCR testing, refined the process and training programs for widespread professional antigen test implementation. These efforts laid the groundwork for a no-cost Statewide professional antigen testing program, thus expanding the State's testing capabilities while navigating new regulatory landscapes.

Finding/Corrective Action: CDPH's Statewide professional antigen program was an extensive public-private partnership (of over 6,700 sites) that met an important community-based testing need and can be leveraged for other CLIA point-of-care tests and outbreaks in the future. (*ID: Testing 7*)

Finding/Corrective Action: CDPH's Statewide CLIA waivers for antigen testing were an innovative solution to a regulatory barrier and can be leveraged for other point-of-care tests in the future. (*ID: Testing 8*)

7. The TTF established a robust Statewide professional antigen program, which offered free antigen testing to community-based organizations, CDSS, SNFs, state and other employers, and other community-based entities.

In April 2021, the TTF initiated the "professional antigen program" for Statewide CLIA-waived antigen testing, which involved meticulously enrolling sites and providing comprehensive resources including a website and playbook. The process entailed assessing testing demand, choosing reporting technology, application review by the TTF, logistical preparations, and training. In addition to managing the onboarding and training and compliance process, the TTF managed antigen test supplies, processed test orders, enrolled sites in confirmatory PCR testing, and monitored testing usage. Organized into three cohorts, the professional antigen program catered to diverse clientele, with three separate cohorts devoted to schools, DSS, and CBOS (which served homeless shelters, agriculture and food processing facilities, migrant housing, community centers, and others). Many SMEs emphasized that the program's ongoing engagement with local partners helped it evolve as needs changed. In particular, the community-based cohort appreciated the TTF's commitment to continuous improvement and the regulatory compliance support provided by CDPH's Lab Field Services Division. Feedback mechanisms and a culture of adaptability within the

TTF led to incremental enhancements, which were deemed essential for the program's success.

Later in 2022, TTF supported the professional antigen program to integrate with California's Test-to-Treat initiative, which expedited access to COVID-19 therapeutics following a positive test result. This involved including links to telehealth resources on positive electronic test results.

Finding/Corrective Action: CDPH should consider leveraging the infrastructure and relationships built for the professional antigen program for other infectious disease and outbreak response testing needs. (*ID: Testing 9*)

8. The TTF's At-Home/Over-the-Counter antigen testing program distributed over 107 million test kits.

In Fall 2021, the TTF began to develop a new At-Home/OTC antigen testing program, which was separate from the professional antigen program. Access to the OTC tests was also offered through the community network that had been developed for both the professional antigen and PCR programs in addition to other pathways. Initially, the OTC program was focused on meeting test demand in the midst of a second international test kit shortage during the Omicron surge in Winter 2021-2022. As the Omicron surge subsided and OTC test kits became readily available, the TTF secured an ongoing supply chain of 5 million OTC tests kits a month and began focusing its OTC efforts on providing test kits to California's uninsured, under-insured, and populations with limited access to testing. The OTC program provided free online ordering and direct distribution of test kits to community organizations serving uninsured or underinsured individuals (or directly to participants) with as few barriers as possible. The program did not require test results to be reported. As the program's popularity grew, the TTF refined eligibility criteria to maintain focus on those most in need. Later in 2022, TTF supported the OTC program to successfully integrate with California's Test-to-Treat initiative. For the OTC program, this integration involved educating participants about Test-to-Treat and making sure they knew how to access COVID-19 therapeutics. Overall, the OTC program maintained a dynamic approach to emerging pandemic needs and trends, and successfully distributed over 107 million test kits.

Finding/Corrective Action: The OTC program operationalized an online test ordering and distribution model focused on uninsured and underinsured individuals that could be leveraged for other point-of-care tests. (*ID: Testing 10*)

9. The TTF's dedicated schools cohort offered free antigen and PCR testing to K-12 schools as well as operational support.

Due to the unique environment and sheer number of California's K-12 schools the TTF developed a separate schools cohort. This cohort administered a variety of testing programs, which offered different testing modalities and levels of support. Initially, the TTF offered free PCR testing (of individual students or of groups) to schools. After professional antigen testing became available and the TTF had piloted professional antigen testing in schools, the TTF implemented a separate schools professional antigen program. Schools in the professional antigen program could also opt to enroll in confirmatory PCR testing. During the pilot the TTF received feedback that a lack of personnel to administer the program was the biggest barrier schools faced when implementing testing. In response, the TTF devised two equity-based options to provide additional operational support for eligible schools. Eligible schools could opt to receive either no cost "end-to-end" (E2E) vendors, who would run all testing operations, or they could receive direct funding to hire testing personnel. Ultimately, these additional operational services helped schools implement testing programs that would not have been possible otherwise. For all of its testing programs, the TTF schools cohort built a comprehensive infrastructure that included establishing playbooks, developing and tracking trainings, creating and managing MOUs, onboarding schools and managing enrollment, overseeing reporting and compliance, conducting outreach and education, and managing vendors. Ultimately, over 1 million COVID-19 tests were administered at over 4,700 testing sites at K-12 schools.

Finding/Corrective Action: The TTF successfully provided California's K-12 schools with many testing options to support testing in schools, and built extensive infrastructure and relationships that can be leveraged in the future. (*ID: Testing 11*)

Finding/Corrective Action: The E2E program and the direct funding program were innovative solutions to promote testing equity and reduce

barriers to access, and can be leveraged for school-based outbreaks for COVID-19 and other diseases in the future. (*ID: Testing 12*)

10. The TTF established and managed an Outbreak Response Team to offer testing and vaccination services during the outbreaks.

In summer 2021, the TTF established the innovative Outbreak Response Team (ORT) program to offer mobile, rapid testing and vaccination services in response to outbreaks. The program, consisting of 10 dual-function teams and four testing-only teams, provided free services through contracted vendors. Deployed strategically across the State, the ORT program deployed teams to over 1,150 sites (including schools, jails, and shelters). Additionally, the program collaborated closely with CDPH's Outbreak Consultation Team (OCT), which provided outbreak consultations and technical assistance, for a comprehensive response to outbreaks. Despite challenges in request processing and underutilization, the ORT program proved flexible and effective, and was able to offer its services to other response teams between surges. The ORT was demobilized in October 2022 due to low usage, yet received positive feedback for its rapid, mobile community resource deployment. According to SMEs, lessons learned highlighted the potential benefits of offering separate testing and vaccination services for future cost efficiency, as well as the need for continuous program promotion and communication. Overall, the ORT program demonstrated a successful, agile response to public health needs, setting a precedent for future outbreak response strategies.

Finding/Corrective Action: The ORT program offers a successful, flexible rapid resource deployment model that can be activated in future emergencies. (*ID: Testing 13*)

Finding/Corrective Action: In the future, the State should reconsider the dual-team (testing and vaccination) model and consider offering separate teams to maximize resources and funds. (*ID: Testing 14*)

Finding/Corrective Action: In the future, the ORT (or similar) program would benefit from having a health educator or communications specialist promote the program on-site to help increase its utilization. (*ID: Testing 15*)

11. The TTF established robust communications with its stakeholders and refined its programs and messaging based on feedback.

The TTF communicated through different channels to its multiple stakeholders and audiences. TTF and CDPH leadership worked closely with the Governor's Office, CalHHS, and CDPH to hold press conferences with officials and meet with the Legislature, local elected officials, professional organizations, LHJs, schools, State partners, CBOS, and others. Early on in the pandemic, the TTF also developed and communicated to a weekly stakeholder group of public and private partners including academics, hospitals and healthcare foundations, long-term care associations, and others. Additionally, the TTF, with support from CalHHS and CDPH leadership, established a regularly-scheduled meeting with California public and private lab directors to better understand challenges faced by labs. Individual TTF programs/cohorts established additional meetings and office hours to communicate with CBOs, DSS, state employees, schools, and other educational partners. The TTF also reported out on other CDPH weekly calls for facilities, SNFs, and LHJs.

The TTF also maintained a robust testing website for the public, the media, and for participants interested in its programs; the website also included information on where to access testing services. In general, the TTF's tailoring of its program communications to different stakeholders and its efforts to improve communications in response to stakeholder needs was successful. Some SMEs recommended that the TTF implement a more systematic process to operationalize best practices, and others noted that CDPH should leverage its partnerships with educational stakeholders (including State- and county-level offices and departments of education) to better reach California's schools.

Finding/Corrective Action: TTF had extensive communications at all levels of government and other public and private stakeholders across the state. CDPH should replicate such stakeholder meetings and communications in future pandemics. (*ID: Testing 16*)

Finding/Corrective Action: In future responses, CDPH can improve its testing (and other) communications by developing a process to incorporate best practices into its response teams. (*ID: Testing 17*)

Finding/Corrective Action: CDPH should explore ways to better leverage its partnerships with additional educational partners to more effectively communicate with schools. (*ID: Testing 18*)

Main Challenges and Lessons Learned

This section describes the Main Challenges and Lessons Learned, including findings and corrective actions, related to this chapter. Further elaboration and a more detailed discussion of these challenges and lessons learned can be found in the Analysis of Activities section.

12. The lack of existing public health laboratory infrastructure prevented the State from rapidly scaling its COVID-19 testing capacity.

According to multiple SMEs, CDPH leadership, and TTF leadership, the State's struggle to rapidly expand testing during the COVID-19 pandemic was largely due to long-standing underfunding of its public health laboratories. Previous coronavirus outbreaks (SARS-CoV in 2003 and MERS-CoV in 2012) were missed opportunities to enhance public health laboratory infrastructure and funding. Due to insufficient facilities, equipment, staffing, and resources, the public health labs, historically functioning as "reference labs," were ill-equipped for the high-volume testing needed during the pandemic. Leaders emphasized the need for a well-resourced public health lab infrastructure that can be quickly scaled up in emergencies. This requires legislative support for additional funding and resources. Leaders expressed concern about the State's ability to scale up testing quickly again without significant resource allocation and infrastructure development. Ultimately, the key lesson learned from early efforts to expand COVID-19 testing is the importance of having rapidly-scalable testing infrastructure in place for future emergencies.

Finding/Corrective Action: CDPH should explore legislative avenues to enhance funding for local public health labs and forge stronger ties with the county-level public health lab network, academics, and commercial labs to enable more quickly scalable testing capacity. (*ID: Testing 19*)

13. Regulatory barriers delayed the State's ability to build testing capacity quickly.

The State's attempt to enhance early PCR testing capabilities highlighted the significant hindrance posed by regulatory barriers.

Regulations, while meant to help guarantee accurate results, were also obstacles that slowed the expansion of testing, according to TTF leaders. Later, during the implementation of the TTF's antigen programs, regulatory hurdles caused internal consternation. Leaders suggested that in emergencies, swift innovation and a willingness to "push the envelope" should take precedence over strict adherence to regulations. Additionally, SMEs expressed the need for the State to establish "off the shelf" expedited regulatory methods in advance, which could be swiftly activated to increase testing through a tiered approach involving State, local, academic, and commercial labs. The University of California (UC) labs exemplified this agility, with UC San Francisco notably setting up diagnostic PCR testing for students in just eight days, indicating the potential speed of capacity building when driven by leadership and institutional support.

Finding/Corrective Action: The State should explore ways to reduce regulatory hurdles and establish expedited regulatory processes that could be activated in future emergency responses to expand testing quickly. (*ID: Testing 20*)

14. The early rush to increase PCR testing capacity frustrated LHJs and led to equity issues and other problems at State-run testing sites.

In the spring of 2020, the State expedited the launch of widespread State-run PCR testing sites in partnership with its vendors Optum Serve and Verily. LHJs were given an aggressive two-week deadline to select locations for these sites. This urgent deployment, described by some SMEs as chaotic, led to several challenges including LHJ resistance and a lack of training and resources (e.g., PPE) for vendors to properly administer the tests. As the State continued to establish these sites, equity issues emerged including digital literacy and transportation. Many of these were drive-up sites and required online appointments, which were barriers for those without cars or with low digital access or literacy. These equity challenges were particularly acute in rural areas. Once equity barriers associated with drive-up testing and appointment scheduling were identified, through a Request for Proposal process, CDPH eventually selected Optum Serve to implement more inclusive

PCR testing models—including testing offered through traveling teams, traveling buses, and walk-up sites.

Finding/Corrective Action: In the future, CDPH should consider LHJ input, transportation access, and digital literacy when expanding public testing capacity. (*ID: Testing 21*)

15. The extremely quick set-up of the Valencia Branch Laboratory led to initial quality control issues and negative publicity.

The accelerated setup of the VBL lab led to early quality control issues and concerns over testing accuracy. As the lab prepared to open, VBL lab directors and CDPH advocated to postpone the launch several weeks over concerns about testing accuracy and reliability. However, due to the pressing need to expand testing the VBL's launch in November 2020 was marred by operational hiccups, public complaints, and reports of inaccurate results, leading to negative media attention. This triggered CDPH to investigate the lab. Ultimately, CDPH did not issue sanctions since the lab addressed its deficiencies and obtained third-party accreditation. Ultimately, the situation highlighted the tension between the need to both move quickly and simultaneously establish adequate quality controls. The key lesson learned, according to SMEs, was the need for State experts to have more oversight and input into the lab's testing operations, via the establishment of contractual safeguards and vendor accountability to ensure testing quality.

Finding/Corrective Action: If the State were to re-establish a State-run laboratory in the future, it should incorporate more robust operational oversight measures in the contractual terms. (*ID: Testing 22*)

16. Staffing shortages, case surges, and technology challenges contributed to long turnaround times at the Valencia Branch Laboratory.

The Winter 2020/2021 surge in COVID-19 cases, combined with industry-wide staffing shortages, significantly increased test turnaround times at VBL. With limited staffing and high test volumes, VBL's turnaround time for tests extended to days—at which point the test results are no longer that useful to control disease spread. The lengthy turnaround times was not unique to VBL, as commercial laboratories across California all faced prolonged test result delays due to high volumes and staffing shortages.

However, the high-throughput design of VBL and its reliance on a complex barcode-based registration system also contributed to delays. Furthermore, misunderstandings around the definition of turnaround time (and the processes that it included) led to credibility issues with LHJs. To mitigate this confusion in the future, SMEs expressed a desire for clearer communication and possible reevaluation of the contractual language related to turnaround time metrics. After the surges, the lab's throughout improved and it was able to process over 90% of tests in under 24 hours. However, its performance dropped during surges when specimens exceeded 300,000 per day. Recognizing the limitation of relying on a single lab, in May 2022, the State transitioned from a single lab model to a lab network run by Color. The Color lab network consisted of five labs, to distribute the testing load and maintain adequate turnaround times, particularly during surges.

Finding/Corrective Action: In the future, CDPH should augment and clarify turnaround time metrics in contracts with testing vendors. (*ID: Testing 23*)

Finding/Corrective Action: Since the complex barcode-based registration system was problematic, in the future CDPH should consider requiring testing vendors to use the simplest testing registration system possible. (*ID: Testing 24*)

Finding/Corrective Action: In future pandemics where the need for high volume testing is needed CDPH should develop a lab network for level loading specimens to maintain turnaround time. (*ID: Testing 25*)

17. Community-based organizations and skilled nursing facilities struggled to comply with the reporting and other requirements of the State's professional antigen testing program.

Participants in the CLIA-waived professional antigen testing program struggled to comply with the program's reporting requirements due to numerous factors. First, the program used a new technology vendor, Primary, for the test registration and reporting process. This was frustrating for facilities and organizations who were already enrolled in the Statewide PCR program, which used reporting software provided by the vendor Color. To participate in the professional antigen program, participants had to learn the Primary software. Many skilled nursing

facilities, who had very limited bandwidth, ultimately found the reporting process too arduous resulting in unused test kits. Community-based organizations also struggled to grasp the program's participation and compliance demands. Many of these organizations served populations in the lowest HPI quartiles and had no medical background. Initially, when these sites received test kit shipments, they would open kits and immediately start using them, unaware of the reporting requirements. This difficulty was exacerbated by the lack of built-in quality control (QC) modules in the COVID-19 antigen testing software. Unlike other point-of-care tests, COVID-19 antigen test kits did not have this feature. According to SMEs, this made it difficult for organizations to comply with regulatory standards and increased the manual workload for TTF staff. TTF experts suggested that the State should work with vendors early on to add QC platforms, which would prevent premature testing without reporting and promote a strategic approach to test reporting, balancing risk, compliance, and usability.

Finding/Corrective Action: In the future, CDPH should explore ways to reduce reporting and administrative requirements for CLIA-waived point-of-care tests. (*ID: Testing 26*)

Finding/Corrective Action: In the future, CDPH should identify and implement a single reporting and registration tool that can be used for all testing modalities and programs. (*ID: Testing 27*)

Finding/Corrective Action: In the future, CDPH should encourage or require vendors to include QC platforms in point-of-care tests. (*ID: Testing 28*)

18. The TTF's Personnel Grant Funding Program for schools was difficult to administer, resulting in backlogs and funding delays.

The TTF's Personnel Grant Funding Program, designed to provide direct funding for schools to hire testing personnel, proved to be one of its most challenging initiatives to administer. Initially conceptualized by early TTF schools leadership, the concept was significantly difficult to implement. The program involved a complex, multi-step funding process, which included creating and sending invoices, awaiting their return, and obtaining necessary leadership signatures. This process led to substantial

backlogs and confusion due to unclear fiscal processes, necessary deadlines, and reliance on the TTF leadership already working around the clock to sign off on all letters and invoices. Consequently, schools often received funds late, leaving them with only one to two months to determine expenditures against them. This inefficiency led some leaders to believe that it would have been more effective to solely offer operational support through end-to-end vendors, as the Personnel Grants Funding Program not only caused administrative burdens but also delayed financial support.

Finding/Corrective Action: CDPH should reconsider whether or not it should offer direct funding for the Personnel Grant Funding Program in future emergency responses. (*ID: Testing 29*)

19. TTF programs and cohorts experienced challenges to obtain, train, and manage redirected staff.

The TTF's programs and cohorts faced numerous challenges with redirected staff, most of which were drawn from other CDPH programs. According to SMEs, the process of obtaining redirected staff was lengthy and complicated. The TTF also encountered resistance from CDPH programs, who were often unwilling to release staff for extended periods of time. When the TTF successfully obtained redirected staff, some SMEs felt it was not worth the effort to train and manage them, since they often only performed basic tasks and were frequently recalled to their original programs in short order. The SMEs made a variety of recommendations to improve the redirection process, including making it mandatory instead of voluntary, aligning staff interests with program needs, and recruiting redirected staff with more technical skills (such as data, reporting, and epidemiology), as well as require State staff from other State departments outside of CDPH to be redirected when dealing with a large-scale pandemic such as COVID-19.

Finding/Corrective Action: In preparation for future emergencies, CDPH should reevaluate the staff redirection process and consider making adjustments to better align staff skillsets with the needs of testing response teams. (*ID: Testing 30*)

20. Internal communication and coordination challenges within the TTF contributed to silos and inefficiencies.

Internal communication challenges increased as the TTF rapidly expanded and added programs, consultants, vendors, and redirected staff to meet ever-increasing demands. Initially, the TTF conducted a recurring All Hands meeting. In mid-2022, faced with the decreasing staff levels, TTF implemented a consultant recommendation to discontinue the All Hands meeting and replace it with three separate meetings (dedicated to schools, non-schools, and all other programs) to better manage workloads and support programs that were losing staff. Team members felt the loss of the All Hands meeting further contributed to silos that had already developed during the rapid stand-up of multiple programs and cohorts simultaneously. These silos and inefficiencies became more evident during the final year of TTF, when cohorts were consolidated and there was a lack of standardized processes and procedures across cohorts doing similar work. The absence of a single centralized communication in the final year of TTF hindered collaboration, which was especially pronounced between the antigen and PCR programs. Additionally, the internal communication silos within the TTF made it challenging for program teams to manage multiple email inboxes. Without a clear organizational structure, team members fielding the inbox questions often found it difficult to route questions to the proper TTF contact, which resulted in delayed responses and confusion. Team members also struggled to address incoming questions due to a lack of awareness of communications that other cohorts had sent out. Ultimately, these challenges highlighted the need for improved internal TTF communications in the final year, including a regular All Hands meeting.

Finding/Corrective Action: In future emergency responses, CDPH should maintain an All Hands meeting throughout the response and an up-to-date organizational chart for testing response teams. (*ID: Testing 31*)

21. The TTF program teams had varying levels of access to resources, tools, and leadership, which created internal competition and frustrations.

In order to manage testing volumes and the unique needs of different clientele, the TTF was composed of seven cohorts, some of which managed more than one testing program. Because programs and cohorts were stood up simultaneously during surges, there were

insufficient resources and tools available to meet demand. Consequently, different cohorts ended up using different technology systems and tools, which were provided by various contractors or vendors. This resulted in frustration and at times a sense of competition between cohorts since some vendors were better than others at various tasks.

For instance, the schools antigen program lacked CDPH epidemiological support and technological resources that were available to the professional antigen program. Meanwhile, the OTC program, offered the same antigen test kits used by schools but with fewer administrative requirements. This prompted CDPH SMEs and the program participants to question the school program's rigorous procedures. The PCR schools testing program, which was not subject to CLIA licensing, lacked ownership on the schools side when the medical officer supporting this program resigned from their position in spring 2022. Hence, TTF relied on existing PCR leads and support staff to cover the schools PCR program. According to SMEs, without clear schools PCR leadership and an assigned CDPH medical officer, the team struggled with operational delays and sponsorship. Overall, SMEs in the cohorts emphasized the need for consistent sponsorship, resourcing, decision-making, and support for the testing programs across all cohorts, regardless of modality.

Finding/Corrective Action: Finding/Corrective Action: In future emergency responses, CDPH should strive (if possible) to have sufficient number of experts and resources to equally assign leadership, resources, and support across all testing programs throughout an emergency response. (*ID: Testing 32*)

22. Many contractors on the TTF did not have public health experience and some were perceived to be driving important policy decisions.

Because large scale disease testing is not a core function within CDPH, the TTF relied primarily on consultants and contractors to staff and run the testing programs. While the TTF SMEs acknowledged the effectiveness to obtain these resources, CDPH could not readily contract for public health, clinical, and scientific expertise due to shortages in these fields. With limited in-house CDPH testing leadership and expertise

available, some SMEs perceived several consultants particularly during the 2022-2023 academic year having too much influence on TTF policy. Several TTF SMEs felt the "one size fits all" for the professional antigen testing program approach driven by some contractors needed more refinement, and that contractors "were not listening to the experts." SMEs suggested that future responses incorporate better information-sharing and communication regarding the parameters of contractors' roles and authorities.

Finding/Corrective Action: CDPH should develop more detailed contracts explaining the roles and responsibilities of contractors. (*ID: Testing 33*)

23. The TTF lacked expertise to select testing vendors.

The TTF heavily relied on a variety of vendors to operationalize its testing programs; vendors manufactured and distributed test kits, provided reporting and registration software, operated labs and lab networks, and ran testing sites. After receiving significant federal and State funding for its testing programs, the TTF needed to scale up at an unprecedented pace. However, it was difficult to hire vendors because there were few vendors available, and most vendors were new to COVID-19 testing and were also scaling up their own services. Additionally, the TTF team had limited expertise in vendor selection and contracting development. Only State employees can select and contract with vendors, which was challenging because many of the TTF programs were led by consultants.

SMEs indicated that some of the vendors selected overpromised and underdelivered, leading to quality control issues and risking the program's integrity. To overcome these challenges, the cohorts refined their vetting process and instituted more structured evaluations. The experience highlighted the necessity of having enough qualified State personnel for vetting and contracting processes.

Finding/Corrective Action: During a similar pandemic, CDPH should redirect, hire, and/or train more employees in contracting and vendor selection processes, develop more detailed contracts, and utilize the documented vendor selection criteria and processes developed by the TTF. (*ID: Testing 34*)

24. The TTF devoted considerable effort to reviewing and monitoring vendors programs to improve equity.

Improving testing equity was a primary goal of the TTF's programs throughout the pandemic response. However, the TTF SMEs observed vendors had different understandings of what equity meant and how to operationalize it. As a result, TTF SMEs devoted significant time working with vendors to improve program equity outcomes (for instance, adding more bilingual staff to reach Spanish-speaking populations). The experience underscored the necessity of explicitly including equity-related stipulations in contracts such as language access and translation requirements. Additionally, the TTF monitored vendors' performance by reviewing their mandatory detailed equity reports—a requirement that proved to be crucial. This approach helped measure testing access across different demographics and highlighted the critical need for comprehensive data from vendors to assess their effectiveness in reaching equity-targeted populations.

Finding/Corrective Action: In the future, CDPH should include more robust equity considerations in vendor contracts, including the requirement to report equity-related data, in its contracts with testing vendors. (*ID: Testing 35*)

25. TTF's budgetary and fiscal functions lacked consistent ownership and clarity.

According to SMEs, the TTF initially had no dedicated fiscal team and thus experienced significant challenges in its fiscal management due to a general lack of fiscal staff and ownership. Confusion arose on who was responsible for program budgets. The TTF waited for six months for a State fiscal lead; once this lead joined in June 2021, obtaining sufficient fiscal support staff proved challenging. TTF program managers, reliant on a frequently-changing fiscal administration team, sometimes found themselves unexpectedly involved in financial matters despite this not being their expertise. SMEs stated an entire testing program was nearly shut down due to a misunderstanding over funding accidentally being credited to the wrong budget, as the program managers were reliant on a team who did not have in depth understanding of the TTF programs and budget. While this error was rectified in time, it highlighted the need for the budget team to have a deep

programmatic understanding of a rapidly changing landscape of contractors, invoices, third-party billers, and reimbursement rules. Due to these complexities, TTF leadership took on a lead budgets role in collaboration with the TTF fiscal lead and CDPH's Center for Preparedness and Response (CPR). Due to limited fiscal staff, TTF leadership and team members, including contractors, developed a vendor invoice review processes to assist the financial team. In the future, SMEs suggested that a qualified State-staffed fiscal administration team handle all financial processes on response teams. The early involvement of State fiscal staff was deemed essential for the effective functioning of emergency response teams. Lastly, fiscal roles and responsibilities should be clearly established to avoid any conflict of interests with contractors on the team.

Finding/Corrective Action: In future responses, CDPH should ensure that all task forces include a dedicated State fiscal administration team formed as early as possible. (*ID: Testing 36*)

Finding/Corrective Action: CDPH should establish and clearly communicate roles, responsibilities, and ownership for fiscal administration teams. (*ID: Testing 37*)

26. A lack of data and reporting infrastructure led the TTF to rely on contractors for these functions, which proved challenging.

During the COVID-19 pandemic, California's TTF played a crucial role in collecting, monitoring, and distributing data regarding its extensive testing programs. In addition to monitoring COVID-19 case rates and test positivity rates based on PCR test results, which were tracked in the State's disease surveillance system (CalREDIE), the TTF also tracked operational metrics, including test turnaround times, site utilization rates, race, ethnicity, and equity data, and antigen testing volumes and positivity rates not reported to CalREDIE. However, the lack of a pre-existing system(s) for tracking this data led the TTF to rely on disparate vendor dashboards and tools that had to be built from scratch by vendors, which presented challenges.

Additionally, the TTF lacked CDPH epidemiological support. While the TTF attempted multiple times to request redirected CDPH technology, epidemiological, and data staff, these individuals were already working

in other response teams and were not available. The TTF also attempted to hire epidemiological data and analytics experts, and repeatedly posted a position for nine months. No applicants were received, and the TTF therefore solely depended on its consultant (McKinsey) for data integration and reporting needs and skills. McKinsey created useful tracking tools to consolidate and standardize disparate vendor data. However, when McKinsey's departed in Spring 2022 the TTF SMEs were unable to use the complex infrastructure built by McKinsey and had to rebuild it in another system. SMEs emphasized that there were many lessons learned from TTF's data reporting challenges. These included the need for standardizing vendor data, the importance of using sustainable tools and systems that can be easily transitioned to the State, and the importance of involving CDPH experts when establishing testing data streams.

Finding/Corrective Action: In the future, CDPH epidemiology and data experts should be included in Statewide testing programs to help with data and reporting. (*ID: Testing 38*)

Finding/Corrective Action: In the future, CDPH should require its testing vendors to report data in consistent, standardized ways. (*ID: Testing 39*)

Finding/Corrective Action: In the future, CDPH should require its data and reporting contracts to build infrastructure that can be easily transitioned to the State. (*ID: Testing 40*)

Analysis of Activities

This section elaborates and provides more detail on the findings, corrective actions, and lessons learned that are presented in the Main Strengths and Successes and the Main Challenges and Lessons Learned sections.

Early PCR Testing

Early Testing was Extremely Limited and Overseen by the CDC

- When SARS-CoV-2 first emerged in late 2019, there was no existing test for the virus. California's testing infrastructure was lacking and unprepared to meet the coming demand for mass testing. In January and early February 2020 the CDC developed an early PCR test, but this test was not always accurate due to challenges with the test assays and reagents. By the end of February 2020, there were improvements in testing assays, and enhanced reagents before the CDC test became available.
- However, access to these PCR tests was still limited. The CDC's testing criteria allowed only those individuals who displayed symptoms and had recently traveled to China to be tested. This approach proved to be inadequate, as the virus was found to spread between both symptomatic and asymptomatic individuals. As California's public health officials realized this, the demand for testing soared, and, according to one SME, "it became painfully obvious that we didn't have the capacity to meet the demand."
- CDPH maintains a state public health laboratory in Richmond and there are 28 local public health labs at the county level, each with varying testing capabilities. Public health labs are usually considered "reference labs" and are focused on disease control. As reference labs, they use their advanced technical capabilities to perform specialized tests, provide confirmatory testing, validate new testing methods, and track emerging strains of infectious diseases. Prior to the pandemic, the testing capacity of California's public health laboratory system was approximately 17,000 tests per day. While the State's public health labs worked with the CDC to perform early COVID-19 testing, it was clear to officials that the volume of testing needs exceeded the capabilities of the public health laboratory system. According to one leader, "prior to the pandemic, no one thought

we'd be wanting to test the entire [State] population" at such high volumes and frequency.

- Discussions began at various levels of California government about how to expand testing capacity. At CDPH, leadership from the California Public Health Laboratory and the Laboratory Field Services (LFS) branch began discussions with federal, state, and academic partners about the possibility of using lab-developed tests (LDTs). LDTs are designed, manufactured, and used within a single clinical laboratory; only the lab that develops the LDT can use it, and the test cannot be marketed or expanded to other labs. LDTs were historically used for labs to provide testing for rare conditions that were not addressed by commercially available tests. Usually, the Food and Drug Administration (FDA) approves and authorizes tests, including LDTs. But according to SMEs, the FDA indicated that it would consider granting individual states the authority to approve LDTs for COVID-19.
- CDPH consequently began holding meetings and discussions about whether it had the capability to approve LDTs as a State agency. However, there was no precedent and expertise for the State to do this. At the same time, CDPH also began exploring the possibility of partnering with the University of California (UC) clinical and research labs to offer COVID-19 testing. Discussions about how to expand testing went on for several months, as CDPH explored the various options that were available to it within the regulatory framework. As one leader noted, "there was a lot of uncertainty and confusion in the beginning about who could do what, and who had the authority to do it."

Testing Task Force Formed by the Governor's Office, CalHHS, and Cal OES

- On March 18, 2020 CDPH issued a letter to laboratories requiring them to report both negative and positive COVID-19 test results. This was unprecedented, as labs before had never reported negative results for any disease condition. However, CDPH needed this information to assess how many tests were being performed as well as the test positivity rate, which indicated case trends and spread. As one SME explained, monitoring positive and negative test results "gives you more surveillance information," including information on what populations are getting tested and where. Ultimately, with this information "you can make sure that you are testing the right populations," the SME added.

- As labs began reporting positive and negative test results, it became clear that California would need to develop new solutions to expand the State's testing capacity. As mentioned in the Overview, early discussions involving the Governor's Office, CalHHS, and Cal OES resulted in the formation of the Testing Task Force (known as TTF 1.0) in late March and early April 2020. This was one of the 19 Governor's task forces managed by Cal OES, with CDPH playing an integral role on this task force. The TTF was designed as a public-private partnership and was co-chaired by a member of the CDPH Directors Office and the president of Blue Shield California.
- The TTF initially focused on identifying California's existing testing capacity, projecting its needed capacity, and expanding capacity to meet projections. At this stage of the pandemic, there were many unknowns, including how many PCR tests were being performed in the State. To better understand testing volumes, the TTF relied on a consultant (McKinsey) who in May 2020 developed an application for labs to report their testing volumes. This application, known as the Lab Testing Metrics Application (LTM), used estimated volumes rather than actual volumes, which created data and reporting challenges. However, LTM helped provide a baseline that approximately 20,000 to 30,000 PCR were being performed daily Statewide. For further discussion of LTM, see the Data and Reporting chapter in this AAR.
- Representatives from CDPH, CalHHS, and the TTF continued to engage in discussions with the UC system about leveraging UC researchers, labs, and equipment to help expand California's testing capacity. However, the UC labs lacked operational experience and expertise with the strict federal regulations associated with clinical lab testing, which would be a significant hurdle. It was also growing clear that California would need to increase its testing volumes beyond even what the UC system could provide. As a result, a Statewide testing collaboration with UC did not come to fruition.

First Efforts to Expand PCR Testing Capacity by Establishing State-Run Collection Sites

- In April and May 2020, during TTF 1.0, the State expanded testing capacity by funding equipment at State labs and investing in local public health labs to bolster local capacity. Additionally, the State of California swiftly executed a contract with Optum Serve to increase testing across the State

with the goal of launching free PCR testing sites at approximately 90-100 locations around the State within two weeks. To accomplish this, LHJs were asked to determine the specifics of each site, including the type (drive-through or walk-through) and setting (indoor or outdoor). After choosing a suitable location, which ranged from fairgrounds to library parking lots, LHJs were required to finalize a Memorandum of Understanding (MOU) with the chosen site before Optum Serve could begin PCR testing. The State's overarching objective was to have all sites operational within the designated two-week timeframe.

- The initial roll-out of the Optum Serve sites was chaotic and rushed, according to SMEs. Meeting this quick timeline had unintended consequences: many Optum Serve staff were deployed to sites without adequate personal protective equipment (PPE), and many lacked expertise and training to conduct the tests. CDPH leadership and clinical SMEs raised these concerns with TTF and Optum Serve leadership, but the timeline remained unchanged to expand testing capacity as rapidly as possible. After several weeks, many of these initial problems were addressed and Optum Serve site operations improved. However, according to one SME, "there was a lot of residual anger from the LHJs about the way it had happened."

State-Run PCR Testing Sites Experienced Challenges

- The State-run Optum Serve PCR testing sites was generally a success, despite the initial problems associated with the accelerated rollout. SMEs felt that it was beneficial that "we were offering testing at a much higher rate than any other State in the nation," and that the LHJs were involved in determining where to establish sites. To establish State-run testing sites in smaller, rural locations, the State contracted with an additional vendor, Verily, as the Optum Serve testing model did not fit the needs of these smaller locations, according to SMEs.
- In summer 2020, after the initial roll-out of the State-run PCR sites, the TTF began to troubleshoot challenges with the sites. While the site's physical locations had been chosen with equity in mind, unanticipated equity challenges arose. These involved technology issues and the fact that most of these testing sites were drive-up sites. According to one SME, "drive up was a huge issue, because if you didn't have a car, you couldn't get tested." Additionally, the State had not initially set up "geofencing" around

zip codes, which would limit those who were able to make testing appointments to a certain geographic location. As a result, individuals from other zip codes in higher HPI quartiles would "come into the site and snatch up the appointments," according to SMEs.

- The largest unanticipated equity issue proved to be technology-related. Most of the State-run PCR testing sites did not accept walk-ins and required appointments to be made online. However, this proved to be a significant barrier that created inequities. As one SME noted, "a lot of our targeted communities don't have a lot of digital literacy" and lacked the ability to make online appointments.
- This appointment-related challenge was especially pronounced for the rural drive-up sites run by Verily. While Verily had agreed to establish sites in these locations (whereas Optum Serve had not), Verily was reluctant to hire employees to staff its sites, according to SMEs. It was very "tech-based" and preferred to rely instead on volunteers from non-profit organizations, military organizations such as Team Rubicon, and LHJ staff. However, CDPH and the TTF noted that at this time, PCR testing vendors were still very limited, and "we were trying to backfill an area that no one else was willing to take on." The TTF began to receive equity complaints related to Verily's practices. Once the equity barriers associated with drive-up testing and the appointment scheduling became clear, the TTF issued a new Request For Proposal (RFP) through the California Department of General Services (DGS) in October 2020 that required these issues to be addressed. With more robust equity language written into the contract, CDPH eventually contracted with Optum Serve, which took over Verily's work using new PCR testing models—including testing offered through traveling teams, traveling buses, walk-up sites, and drive-up sites.
- Reflecting back on the early PCR sites, SMEs felt that when establishing the early PCR sites, "we just didn't know what we didn't know." After the access-related equity challenges arose, the TTF successfully addressed them and continued to evolve to meet changing needs.

Supply Shortages Contributed to Low Testing Volumes

- By end of June 2020, the State's data indicated that its capacity had expanded to approximately 80,000 to 90,000 tests per day. As one leader noted, "we seemed to have the capacity and things seemed to be going

okay." However, soon thereafter CDPH and CalHHS were surprised to learn that testing capacity was actually much lower, ranging from 10,000 to 40,000 tests per day. Cases were also quickly rising. The State's stay-at-home order had expired on June 15, 2020, leading to a reopening of businesses and the economy. The summer surge of 2020 (also known as the hospital surge) lasted from approximately June through August 2020. During this time, testing turnaround times increased to an average of 7 to 10 days. Lengthy turnaround times undermined the purpose of testing, since individuals who were positive for COVID-19 could potentially continue to expose others while waiting for their test results. Ideally, turnaround times need to be within 24 to 48 hours to make testing an effective tool in slowing the spread of the virus. At the end of June 2020 the co-chairs of the TTF 1.0 stepped down.

- While the State looked for new chairs to assume leadership over what would become TTF 2.0, CDPH and CalHHS convened a meeting with laboratory directors across the State to better understand the challenges that were contributing to low testing volumes and lengthy turnaround times. The State learned that labs were struggling with a shortage of critical testing supplies, including pipettes, plastics, and reagents. This supply shortage was keeping volumes low and turnaround times high. Consequently, CDPH and CalHHS began meeting with supply companies to address these critical shortages, while the State searched for co-chairs to lead the TTF 2.0. The State contracted with Perkin Elmer to provided testing equipment and supplies to approximately 15 to 20 state public health departments.

Importance of Investing in Public Health Laboratory Infrastructure

- The State's early inability to expand PCR testing quickly enough was attributed by many leaders to the decades-long erosion of funding for public health. CDPH and TTF leadership noted that the first novel coronavirus appeared in 2003 (SARS-CoV), followed by MERS-CoV in 2012. Both viruses cause respiratory illnesses. In hindsight, leadership noted that these incidents should have been the trigger to start preparations for a coronavirus pandemic by increasing public health funding streams and investing in infrastructure. Instead, one leader noted that "the previous signs weren't heeded [and] the funding wasn't put in place," and the State was unprepared for the pandemic caused by SARS-CoV-2.

- The lack of prior funding and infrastructure resulted in California's public health lab facilities, equipment, and staffing being insufficient to meet the enormous testing needs associated with COVID-19. The network of public health labs had always functioned primarily as reference labs and had never been designed to conduct mass testing. When the TTF 1.0 was first established some CDPH and TTF leadership felt that expectations were unrealistically high on the State's capability to expand testing capacity. As one leader explained, "everybody wanted testing on street corners by the weekend," but this was "not like flipping on a light switch." Another SME felt that calling on public health labs to "answer this urgent need after 20-30 years of neglect and underfunding was just impossible."
- According to SMEs, a key lesson learned is the importance of maintaining a public health lab infrastructure properly resourced that can be scaled up rapidly. As one leader explained, in the future it may be necessary to stand up testing very quickly, which requires much more than simply performing tests. The State needs to "have the infrastructure already in place so we can just turn it on," one SME noted. This would require providing additional funding and resources to the public health laboratory network through legislation. To get that kind of capacity up quickly requires extensive resources.
- Additionally, one leader recommended that greater collaboration between the State and counties would help enhance the public health lab network. Prior to the pandemic, State funding provided to LHJs often did not reach the local public health lab network, and labs "were just not at the table a lot of times," according to one leader. However, the pandemic revealed the need for the State and county public health labs to work closely together.
- Additionally, another leader suggested creating public-private relationships that are sustained at a low level between pandemics and could be "turned on" when needed during epidemics, pandemics, and surges.

Valencia Branch Lab

Testing Task Force 2.0 Formed to Further Increase Testing Capacity, Address Inequities, and Reduce Turnaround Time

- In late July and early August 2020, TTF 2.0 was established with new co-chairs. In keeping with the previously established public-private partnership model, TTF 2.0 was chaired by a CDPH leader and an executive from Kaiser Permanente until December 2020. Beginning in January 2021, TTF was co-chaired by two CDPH leaders. TTF 2.0 included Cal OES and many other State agencies and departments. It initially held biweekly and later monthly meetings involving around 200 stakeholders from different public and private organizations, such as the California Hospital Association. These meetings kept everyone updated on ongoing activities towards achieving the TTF objectives.
- In summer 2020, TTF 2.0 testing's objectives included continuing to expand testing capacity, reduce supply shortages, and improve testing turnaround time. The formation of TTF 2.0 coincided with the growing awareness that California's testing capacity needed to be increased beyond its initial projections to deal with future surges. Leaders began raising concerns about testing inequities and testing access problems with the TTF, noting that public safety net hospitals were in dire need of testing supplies. TTF leadership emphasized that "if we're choosing, we should choose the public safety net over the private." As a result, improving testing equity became a key focus of TTF 2.0. At the time, PCR testing was still the only modality available, so the TTF focused on making more testing available to vulnerable communities. TTF staff began extensive outreach to communities, hospitals, schools, and other groups to increase access to testing via the Optum Serve sites.

State Leadership Planned a Public-Private Partnership to Further Expand Capacity via the Valencia Branch Laboratory

- Meanwhile, State leadership outside of the TTF contemplated opening a new lab and shifting to a "hub and spoke" testing model—in which testing sites across the State (the spoke) would send their specimens for processing at the centralized State-run lab (the hub). Conceptually this new model would increase testing capacity, reduce turn-around times, and also ensure a more stable supply of reagents and plastics (pipettes, pipette tips, and test trays).
- In late August, CDPH and TTF 2.0 leadership were informed that California had contracted with PerkinElmer, a U.S. based international diagnostic company, to set up the Valencia Branch Lab (VBL). This contract would

allow California to process up to 150,000 COVID-19 PCR diagnostic tests per day and provide turnaround times of under 48 hours from delivery of the sample to the laboratory. Building a new high throughput laboratory of this size and scale allowed California to control its own testing trajectory. The contract was also announced via a Governor's press release in late August 2020. According to SMEs, one of the main reasons for the decision was that it enabled the State to access a stable and robust supply of plastics and reagents, solving the supply shortage problem that had been limited testing capacity.

- According to another press release, the Governor announced the creation of the lab in late October 2020 and that the innovative public-private partnership would help increase testing by 75% and improve the turnaround time to approximately 48 hours. The lab intended to be operational in November and work toward a full capacity of processing 150,000 tests by March 2021. In addition to PerkinElmer, which handled specimen processing and lab operations, CDPH contracted with another vendor, Color, to provide a technology platform that enabled PCR registration and reporting. Color also procured and shipped test collection kits to Optum Serve collection sites and other community-based sites. The State procured and delivered additional supplies including swabs and viral transport media (a solution used to preserve specimens after collection so they can be transported and analyzed in a lab), which could be requested through the existing resource requesting process. For further discussion on resource requesting, see the Resource Requesting and Public Health Ordering System chapter in this AAR.
- Given the urgent need to expand California's testing capacity, the timeline to establish the lab was aggressive. Leadership from CDPH's California Public Health Laboratory, the Center for Laboratory Sciences, and the Laboratory Field Services (LFS) Division participated in meetings with CalHHS, the Governor's Office (GO), and PerkinElmer leadership to begin building the lab. The LFS Branch oversees California's clinical laboratories to ensure the accuracy and reliability of clinical and public health laboratory tests performed in California. As one leader noted, "the industry is very heavily regulated for obvious reasons – the accuracy and reliability of these tests is crucial."

- Since the VBL was being built from the ground up, PerkinElmer needed to hire staff, bring in equipment, modify the site and convert it into a lab space, and do validation testing to ensure the accuracy and reliability of tests. As one SME noted, "all of this takes time, but there was pressure to get testing up and going as soon as possible," as sites were already being set up around the State to collect samples. While PerkinElmer worked on these logistics, CDPH tried to identify a lab director for the VBL. From a regulatory perspective, lab directors are responsible for everything that happens within the lab, which are subject to potential fines and licensing restrictions. According to one leader, it is "very unusual" and "not a standard in the industry" to have one entity providing lab services while another entity provides lab directors. It was difficult to find a lab director willing to fully accept the regulatory risk, and so VBL ended up with several part-time lab directors and an advisory committee of lab directors from within CDPH, one leader noted.

Valencia Branch Laboratory Experienced Initial Challenges

- In November 2020, the VBL began operating with a "rocky start," one SME noted. "We tried to turn it all on really quickly before we started ironing out the kinks," another noted. While the equipment and supplies were in place, the lab struggled with quality control, complaints, and reports of inaccurate testing results, which triggered inspections and public scrutiny.
- The pressure to get the VBL established quickly compelled some vendors to take "shortcuts," according to SMEs. Quality issues soon emerged that were related to the test's sensitivity and how it was "resulted" based on its cycle threshold (CT) values. The scientific nuances associated with PerkinElmer's presumptive positives are explained in an Issue Brief that CDPH released as part of a one-year retrospective analyses of the lab. One SME summarized the test resulting issue as follows: "they didn't follow their FDA EUA for resulting tests – they couldn't, because they'd modified it, and didn't really validate it." As another explained, the FDA's Emergency Use Authorization covered a certain type of viral transport media, which involved transporting active and potentially infectious strains of the virus. Color developed its own molecular transport media, which was safer since the specimens were inactivated and no longer infectious to those who were handling them. However, since the transport method had been

altered, it was no longer covered by the EUA and was considered to be "non-validated."

- This change contributed to confusion around cut-off values, which are used to determine whether a test is positive or negative. In mid-December 2020, public confusion about test results prompted the laboratory to work with local partners to clarify the language used for results. VBL's challenges were also reported in the news media and several complaints were filed. CDPH's Laboratory Field Services Division began conducting multiple inspections over the next several months, and an external review board was established to investigate the lab. While this resulted in deficiency findings, the lab ultimately addressed all regulatory findings, received third party accreditation, and no sanctions were imposed. During this time, TTF and CDPH leadership were in a challenging situation, according to SMEs, as they had to field questions about the operations of a lab whose inner workings they were not responsible for.

Winter 2020/2021 Surge and Staffing Shortages Led to Delays in Test Turnaround Time at Valencia Branch Lab

- In addition to the quality control issues specific to the VBL, the lab was also challenged by two more industry-wide factors. In late December 2020 and early January 2021 a winter surge caused a sharp rise in testing volume. The increased demand for testing coincided with an industry-wide staffing shortage, and both factors significantly increased VBL's test turnaround time. During the surge, PerkinElmer was not able to hire enough staff to process the growing volume of specimens, which was the result of surging case numbers and increased testing. The rapid winter surge, combined with the inability to swiftly onboard staff to process 100,000 tests daily, created extended turnaround times. This resulted in a "single point of failure," according to one leader, since there was no way to redirect specimens to other labs. The situation underscored the risks of "putting all our eggs in one basket," one leader noted.
- However, VBL was not the only lab to experience staffing shortages and extended testing turnaround times during the Delta and other surges. Experts explained that for PCR testing, the normal turnaround time is 24-48 hours (ideally within 24 hours). But during the surges, it was a "universal experience" for all California labs to have extended turnaround times, one SME noted. All commercial labs experienced prolonged turnaround times

that extended up to 5-7 days, at which point a test result is "not useful for controlling the spread of the infection and getting treatment," one leader noted. Another noted that "tests aren't very useful if people don't get the results in a timely fashion."

- While VBL's staffing constraints were shared across the industry, there are specific lessons learned related to its turnaround time problems. According to SMEs, the vendor's contract based turnaround time metrics on "accessioning time." Accessioning time refers to the time spent receiving and logging a specimen into the laboratory system for analysis. During this process, the specimen is assigned a unique identifier, known as an accession number. The VBL was designed to be a high-throughput lab and PerkinElmer, which was responsible for the lab's operations, relied on a barcode-based registration and reporting system, which was supported by Color. However, the complexity of the barcode system caused delays. "We spent a lot of time early on troubleshooting why a barcode didn't match up to a patient," which was complex and time-consuming, according to a SME. For any future public-private lab partnerships, CDPH should reevaluate the barcode system used at VBL, which proved to be overly complex and delayed throughput.
- LHJs and other sites who submitted their samples for testing thought the 24-48 hour resulting window included transportation time, processing time, and accessioning time. Consequently, SMEs described how CDPH experienced a "real credibility issue" when it communicated the VBL turnaround times (based on accessioning time as opposed to time of test collection) to LHJs, but the LHJs felt that the turnaround times were much longer because they did not know that turnaround time only began at the time of accessioning. Given these difficulties, SMEs noted that a lesson learned is to reevaluate contractual language regarding turnaround time metrics (and reevaluate whether or not turnaround time should only begin at accessioning time), and then manage expectations with stakeholders, including LHJs.
- SMEs also reflected that PCR testing is simply not an easy testing modality to scale, as the process is complex and the tests are costly. As one leader noted, a key lesson learned for the next pandemic is that while "you can have all the pipettes and supply chain you want," there are "other

important pieces that contribute to lab quality, processing, and throughput that were unanticipated."

Evolution from a Single Lab to a Lab Network

- As the testing frequency decreased post-surges, the VBL's turnaround time significantly improved, with over 90% of specimens processed in less than 24 hours. However, the lab's previous struggles during surges highlighted its vulnerability as a single point of failure. This pattern underscored the lab's limitations during surges and periods of heightened demand, which influenced the State's eventual decision to move from the single lab model to a lab network.
- In May 2022, the State transitioned from the single VBL lab run by PerkinElmer to the Color Lab Network (run by Color) for PCR specimen processing. Color's lab network was composed of five individual labs, which enabled "level-loading" of test specimens to keep turnaround times low. In other words, when volumes were high, specimens could be sent to different labs to balance the burden and prevent a single lab from becoming overwhelmed. The shift to the Color Lab Network was designed to facilitate a more flexible approach to testing capacity and more stable turnaround times during surges.
- In April and May 2022, when this shift was underway, SMEs noted that Color switched test types and labs without giving information to TTF leadership, the TTF/Color transition team, or the testing organizations (including schools) that were participating in the PCR testing program. It was a "very dramatic switch" caused by several reasons, SMEs indicated. The sample transportation timeframe required to get specimens to the lab became "truncated," according to one SME, yet this was not communicated by the vendor to the TTF team. "No one knew they were doing different tests, and no one knew we needed to get them there faster," one SME explained. As a result, for a few weeks after this transition, many tests came back inconclusive, because they arrived at the lab too late and were too old to be processed. However, Color worked with the TTF to develop communications quickly about this issue once it was recognized.
- The Color Lab Network continued to operate through 2022 and early 2023. As testing sites transitioned from PCR to antigen testing, the number of sites

using the Color Lab Network dwindled. The Color Lab Network was decommissioned in Spring 2023.

Different Retrospective Opinions Exist about the VBL

- There was a wide range of opinions about the VBL. Many SMEs mentioned the inherent trade-off between rapidly establishing the VBL and its initial quality control issues. As one leader noted, "the inner portions of the lab maybe should have taken more time, but that's the risk when you stand it up so quickly." Another leader questioned the ultimate need to build the State lab but noted that "we were in a really rough place" with few options to expand testing capacity. Others observed that in hindsight, it was difficult to say whether it was best for the State to build its own lab or work with private industry to encourage commercial labs to expand testing capacity. Many of the VBL's challenges, especially staffing and long turnaround times, were not unique and were experienced by other labs during the pandemic as well.
- Another leader pointed out that the main lesson learned was that more State subject matter experts needed to provide input on how PerkinElmer established and conducted its testing operations at VBL. According to one leader, the "only wrong turn" with the VBL was that the State did not include enough contractual stipulations that would safeguard the quality of testing: "there was not enough accountability built in."
- Some SMEs felt that the VBL successfully helped California rapidly expand its PCR testing capacity when it was much needed, and that the State would not have been able to meet the increased demand without the new lab. "Getting the lab up was critical, and I'm proud of the State for stepping up and trying to answer the need," one SME noted.

Tensions Arose Around Regulatory Hurdles, Pointing to the Need for Expedited Regulatory Models

- The State's efforts to quickly expand early PCR testing capacity revealed that regulatory barriers were a major challenge. While testing regulations are in place to ensure reliable and trustworthy results, they proved to be a double-edged sword during the pandemic response. On the one hand, it was critical to ensure that test results were accurate and avoid misdiagnoses. On the other hand, regulatory hurdles contributed to delays

and many regulatory processes could have been streamlined to help expand testing more quickly, SMEs noted.

- According to one leader, the regulatory review process was one of the "biggest shortcomings and bottlenecks in terms of getting more testing." There were many opportunities to streamline the process that could have been implemented, such as relaxing requirements related to the number of samples needed to validate an assay. The State did loosen some restrictions, such as licensure requirements for lab staff, but many bottlenecks remained.
- The trade-off between pushing the envelope and adhering to regulations was also evident in the later roll-out of the TTF's antigen programs (which are discussed in further detail later in this chapter). When establishing the various antigen programs, one leader noted that internal tensions arose between groups who advocated for "pushing on regulations all the time to accomplish things quickly in an unprecedented way," and those who advocated for a more rigid regulatory approach. This resulted in internal delays and conflicts that TTF leadership had to mediate. Ultimately, one leader noted that during a pandemic emphasis should be placed on innovating and pushing against regulations to get programs up and running as quickly as possible. Once programs are established, however, there is more time for regulatory experts to tie up loose ends. As the leader noted, a key lesson learned is the ability to "understand when you need to be visionary, and when you need to pull back and focus on regulatory pieces, because they can't happen simultaneously."
- Given the regulatory challenges, it will be important for the State to develop what another leader termed "off the shelf expedited regulatory methods" before the next pandemic. This would entail having an existing plan, relationships, and contract language in place to quickly implement a tiered response to expand testing capacity consisting of State and local public health labs, UC labs, and commercial labs.
- In such a model, one leader described, the State's public health labs would continue monitoring existing and new diseases. If testing volumes increased quickly, the State could leverage the next tier of UC labs to help expand capacity. Having such a relationship already in place would enable this additional level of testing to be activated quickly. If testing demand continued to climb, the State could have existing contract

language ready for an expediting competitive bid process. If the State were to develop these key relationships and prepare contract language in advance, it would be faster to expand testing capacity using a tiered approach, since the UC labs and large commercial labs have existing infrastructure.

- According to another leader, although the TTF was unable to partner with the UCs at the State level, many UC campuses were able to rapidly pivot and repurpose their academic labs to conduct PCR testing for their student bodies and local communities. One SME noted that UC San Francisco stood up diagnostic lab testing in record speed, within eight days. The speed with which UCs expanded their testing capacity serves as a model for the State.

PCR Testing in Non-Schools

TTF Expanded to Prepare for VBL Implementation

- The Valencia Branch Lab was premised on the new "hub and spoke" approach, which relied on a network of testing sites across the State to send samples to a centralized location for processing and resulting. The new hub and spoke approach required the TTF 2.0 to change its entire Statewide testing approach and network. While CalHHS and CDPH leadership worked on building out the lab, TTF 2.0 leadership focused on building out the testing sites (also referred to as "collection sites") that would provide the specimens for the VBL to process. The TTF expanded, obtained additional redirected State staff, and developed individual teams in an effort to operationalize the new "spokes" that would feed into the central "hub" as quickly as possible.
- This entailed an enormous amount of work in a short period of time. The TTF began preparing to transition the existing Optum Serve sites to the new model, in addition to conducting extensive outreach to recruit new community-based sites. The TTF began to do outreach to hospitals, schools, faith-based organizations, agricultural organizations, CBOs, and other stakeholder groups interested in setting up PCR testing access.
- Additionally, the TTF had to create numerous documents and resources, including playbooks that detailed how to sign up for testing, how to conduct testing, regulations on testing, how specimens would be

transported, how to complete the Memorandums of Understandings (MOUs), and other forms. The TTF also created extensive paperwork for test "resulting" so that results would be standardized. Upon realizing that the State lacked a transportation system to move specimens to the VBL, the TTF contracted with a courier network to provide this service (discussed further below).

- This was all accomplished within four to six weeks. The team, already working extended hours, ramped up their efforts further, regularly working 20 hours a day to build the programmatic infrastructure needed. "I don't think we could have humanly moved any faster than we did," one leader noted. The new redirected staff helped support these new efforts, which were ultimately successful.

TTF Expanded and Contracted State-Run Optum Serve Sites As Needed

- The Optum Serve sites were the first testing sites established during the pandemic response. In late 2020, this vendor-provided testing infrastructure changed to accommodate the new hub and spoke testing model using the VBL. This included changing workflows and having the Optum Serve sites send their samples to VBL for processing. In order to accomplish this, the TTF arranged for new test kits to be shipped to Optum Serve sites to facilitate better data integration. These test kits were provided by another vendor, Color, whom the State had contracted with to manage test registration and reporting for VBL. The test reporting included individual, local, State, and federal reporting.
- At the same time, the TTF continued to expand its network of State-run Optum Serve testing sites by identifying and adding more locations. Ultimately, at its height the State-run Optum Serve testing sites included 182 sites in non-rural counties and 45 sites in rural counties. Overall, the State-run PCR testing sites included fixed sites, mobile buses, and traveling teams that could be deployed to different locations. The mobile services could be rapidly mobilized to respond to increased testing needs or outbreaks.
- Over the course of the pandemic, Optum Serve offered different types of testing services, including antigen testing. One of the successes of the Optum Serve sites, according to SMEs, was their ability to expand and contract to accommodate fluctuating demand for testing. For instance,

during the Omicron surge of December 2021 and January 2022, the TTF worked closely with the California National Guard to rapidly expand Optum Serve site capacity. During the surge, over 100 Optum Serve sites were successfully expanded, which allowed the State to perform an additional 100,000 tests per week, due to the deployment of over 250 California National Guard members for four weeks.

- Starting in January 2023, the TTF began decommissioning Optum Serve sites and traveling buses with low utilization rates. The sites were slowly closed over the next two months, leaving only five buses available on stand-by until April 2023. This was then decreased to three buses, which were fully decommissioned in June 2023.

TTF Partnered with CBOs to Establish Community-Based Testing Sites

- In addition to expanding the number of State-run Optum Serve sites, the TTF launched a new type of site, referred to as State-supported PCR collection sites, or community-based sites. These sites were not usually run by a vendor, although they did use supplies and test kits provided by the State and Color. These sites received State support to stand them up, but were subsequently run by community members and (CBOs), and utilized public spaces such as schools, faith-based facilities, agriculture and food processing facilities, migrant housing, homeless shelters, behavioral health and harm reduction services, and elderly care facilities to conduct testing. In this new model, the State provided test kits, test processing and sample processing, and a patient registration system; the collection site was responsible for submitting requests for tests, procuring PPE, providing physical space for testing, conducting community outreach for testing, providing staff and managing on-site logistics, supervising testing, and packaging tests for transportation.
- For this model, the TTF provided sites with support and instructions for running testing sites through a combination of self-serve resources (such as an online registration and MOU), and a playbook that included how to stand up a testing site, how to order kits, how to swab, how to interpret results, and how to transport specimens. Much of this material was available on the TTF's website, including a map of the courier network (CCN) using an ArcGIS web application, to help identify drop-boxes closest to their location. The TTF also provided hands-on support through holding office hours and training.

- The TTF's website provided an onboarding and application process, which included a survey that collected planning information, including the intended site's location(s), intended target populations and demographics, anticipated weekly testing volumes and frequencies, and who would sign the MOU with the State. After the application was completed, a TTF representative would reach out to the applying site to help stand up the site(s).
- Ultimately, the TTF developed over 3,400 State-supported PCR community-based sites. Whereas the State-run sites had been primarily drive-up or walk through sites that required advance appointments, the community PCR sites aimed to expand testing into harder-to-reach areas and eliminate access barriers. These sites were primarily walk-through sites with no advance appointments needed in the communities where individuals lived and/or accessed services. In determining where to expand sites, the TTF used available data to perform proactive outreach to expand testing across zip codes (based on current testing volume, positivity rates, and Healthy Places Index scores). With these sites, the communities served included persons experiencing homelessness, tribal members, agricultural and food processing workers, first responders, faith-based communities, behavioral health centers and their patients, preschool staff, summer camp participants and instructors, and community center populations.
- This new model, in which the State partnered with communities to conduct testing, was highly innovative and "changed the model of care delivery for testing for infectious diseases," according to one leader. Historically, a patient needing disease testing had to go to a doctor's office, have the doctor write an order for a test, and go to a lab to take the test. The doctor would receive the result and inform the patient of the test result. This model is expensive and time consuming. But with the new CBO-based PCR testing sites, the State "changed the model" to have one physician write a "blanket order" for the entire State, according to SMEs. In this new model, "there was no sample collection by a third party," which makes it "simpler," according to SMEs. TTF leadership added that it was also cost effective.
- The TTF cohort who oversaw the PCR community-based program were initially responsible for all community-based PCR sites other than schools. (PCR testing in schools was managed by a different TTF cohort and is

discussed further below). As the cohort worked with CBOs, the team newly developed hundreds of community-based health workers, and was able to expand testing access to populations who were uninsured or under-insured. The team quickly realized that the State lacked the infrastructure to build community health workers, as there was no existing training program, certificate program, or associate degree program that emphasized these skills. Throughout the process, SMEs learned the importance of investing in people skills (and not just resources or technology) to build a strong community health system.

Non-Profits and Employers Also Sponsored PCR Testing

- Non-profit organizations and employers also participated in the PCR community program. Employers were eager to join the program, as it offered a way for their businesses to stay open. During the second half of 2020, when the State's Blueprint for a Safer Economy was in effect, if a county experienced test positivity rates above a certain threshold, businesses could be required to close. Small businesses with few employees were especially motivated to avoid closures associated with high positivity rates and outbreaks. For further discussion of the Blueprint, see the Policy Development and Guidance chapter in this AAR.
- As California went through several surges, including a Summer 2020 surge and a Winter 2020/2021, the TTF emphasized that regular, consistent testing would help catch infections early, reduce the chances of outbreaks, and mitigate the chances that businesses and organizations would have to close. For groups that joined the program, the TTF supplied testing that would enable organizations and employers to test their employees twice per week. This incentive was the driving reason behind employers and non-profit groups participating in the PCR testing program, according to SMEs. As one SME noted, the main motivation for enrollment in the program was that "folks wanted to stay open."
- The program also had a substantial number of faith-based organizations, who wanted to stay open and continue providing services. As one SME noted, "at the beginning, a lot of folks were jumping in because it was the right thing to do." In general, PCR community-based sites were appreciative and embraced the testing technology platform and reporting system supplied by the State's vendor, Color. Most of these organizations did not have an existing technology platform and were

willing to embrace the one provided by the State, and they found the set-up very easy and intuitive, similar to using a new smartphone app, according to SMEs.

- During the Omicron surge of Winter 2021/2022, the TTF cohort continued to work with organizations who were applying for State-supported PCR testing. Many of the CBOs who wanted to begin testing had limited funding, so the TTF helped them establish their testing sites through CBO personnel grants. During this time, the TTF focused on organizations within specific HPI quartiles and serving specific communities in an effort to improve testing equity.
- While the PCR testing programs continued, the TTF piloted professional antigen testing programs late fall 2020 and implemented them starting in early 2021. (Antigen testing is discussed further below.)

Courier Network Created to Transport Samples From Community Sites to the VBL

- In Fall 2020, while PerkinElmer was preparing to launch the VBL and the TTF was working on enrolling new testing sites into its State-run and State-supported PCR program, leadership worked on a plan to transport samples to the VBL. The innovative new testing model, which involved establishing thousands of collection sites across the state, revealed specimen transportation as a gap. As one leader explained, "we suddenly realized that we needed a transport system" to get the sample kits to VBL for processing.
- The TTF recognized that non-profits and small businesses were already allocating staff time to participate in the PCR testing program and did not want these entities to incur specimen shipping costs. "There was a big equity component, and we wanted it to be free," one SME noted. Consequently, the TTF quickly established the California COVID-19 Courier Network (CCN), a Statewide network of drop-boxes that testing collection sites could use to transport test samples to the VBL free of charge.
- The State contracted with a vendor to implement the drop-boxes and a courier system. Once sites completed their testing for the day, they would place them into the drop-boxes and the courier would pick them up and ship them to VBL for processing. As one SME noted, "all of us thought it was the most insane idea but the only pathway we could think of."

- The idea was "really unique" and was a success, according to SMEs. To ensure drop-boxes were placed in useful locations, the TTF partnered with CBOs, faith-based organizations, agriculture and food processing sites, schools, and other groups, who helped identify locations to host the sites. The TTF also added drop-boxes in response to certain testing needs, for instance in rural areas or in areas with high testing volumes. At its height, the CCN had over 110 drop-boxes at a variety of locations across California, including schools, prisons, county offices, and county public health departments.

Infrastructure from PCR Testing Supported the Launch of Whole Genome Sequencing

- In mid 2020 and early 2021, TTF leadership also helped establish CDPH's COVID-19 genomic surveillance initiative, COVIDNet.
- Once the TTF and the State had established the testing site "spokes" to feed into the centralized VBL "hub," it became clear that this infrastructure could be leveraged for genomic surveillance. The positive PCR tests coming from the sites provided an ideal source of samples, a subset of which were selected for whole genome sequencing at VBL and other partner labs. The TTF established the sites equitably across California while considering equity metrics, testing volumes, geographic information, and demographic information. Consequently, the PCR samples provided a comprehensive picture of the virus, and when select genomes were sequenced it helped the State "understand the dynamics of the virus and what variants were in different parts of the State."
- The TTF also used virus samples from its other programs, including the antigen program and airport program (which are discussed further below). As one leader noted, "we have had pretty good success at identifying the first incidents of new variants coming into California with not that much testing." Through the PCR infrastructure the TTF had access to a testing collection network to identify variants across the State and to identify new variants of concern coming into the State.
- For a more detailed discussion of COVIDNet and CDPH's genomic surveillance, see the Epidemiology and Surveillance chapter in this AAR.

Antigen Testing in Non-Schools

Invention of COVID-19 Antigen Tests Prompted TTF to Establish Antigen Pilots and Develop New Regulatory Solutions to Support the Roll-out of Professional Antigen Testing Across California

- In early fall 2020, while California was preparing and launching the VBL and implementing its community-based PCR testing sites, test manufacturers released the first antigen test. Unlike PCR tests, which detect the genetic material of the virus itself, antigen tests detect specific proteins present on the surface of the virus. Compared to PCR tests, antigen tests are generally faster, less expensive, and less sensitive, since they yield results in approximately 15-30 minutes and do not need to be sent to laboratories for processing.
- One of the first rapid CLIA-waived professional antigen tests, BinaxNOW, was released by Abbot Labs and was described by one leader as "basically a do-it-yourself test." Although the FDA issued its Emergency Use Authorization (EUA) for this test in late August 2020, it took time for COVID-19 antigen testing to gain traction and acceptance. With California focused on scaling up its PCR testing, "it took a paradigm shift to accept that those antigen tests could give a reliable answer," one leader noted. The ongoing challenges associated with PCR testing (including supply and staffing limitations and lengthy turnaround times, especially during surges) prompted TTF leaders and public health officials to consider how this new testing modality could fit into the COVID-19 pandemic response.
- During late 2020 and early 2021, TTF established a pilot antigen testing program. The pilots were conducted initially at over 30 SNFs, six Department of State hospitals and ten schools. The success of these pilots in reducing new infections and decreasing outbreaks in these settings was shared at Statewide stakeholder meetings to garner buy in and support for antigen testing. The State's development and implementation of the VBL (including its testing site infrastructure and its registration, onboarding, and operating procedures) informed the development of the pilot antigen programs. After the pilots concluded, the TTF applied the lessons learned to expand its antigen testing programs.
- Questions related to regulatory oversight and regulatory limitations soon arose. Since antigen tests did not need to be run in a lab, they were

considered to be "point of care" (POC) tests, and were thus subject to different regulations. Specifically, they were subject to CLIA, which is administered by the Centers for Medicare and Medicaid Services (CMS) to ensure the accuracy, reliability, and reporting of patient tests and results.

- Initially, California entities who wanted to offer antigen testing needed to have a laboratory director confirmed by CMS, a physician who could order the tests, and an independent CLIA waiver. CLIA waivers are certificates that authorize the site to perform simple POC tests. Other examples of CLIA-waived tests include urine pregnancy tests and blood glucose tests. However, CLIA waivers are costly and time-consuming to obtain. Most sites who wanted to implement antigen testing did not have lab directors or ordering physicians, and they lacked funding to hire these positions, which were in high demand during the pandemic. As the TTF began to explore how to offer low-cost antigen testing more broadly, it became clear that these regulatory requirements were a significant barrier. As one SME noted, "in order to run an antigen test, you had to have a CLIA waiver – but these are very expensive and difficult to get." Another leader added that a lab director and ordering physician were also necessary requirements in addition to the CLIA waiver.
- Concurrently, the U.S. Department of Health and Human Services (HHS) purchased the first batches of the Abbott BinaxNOW tests and began shipping them to SNFs, long-term care facilities (LTCFs), K-12 schools, and underserved communities across the nation. But many of these sites were not prepared to use the tests due to their lack of a CLIA waiver, ordering physicians, or a lab director. "We were running into situations where allocations were being sent out, but sites weren't able to utilize them," one SME noted.
- State laboratory leadership in collaboration with the TTF began working on a solution to this regulatory hurdle. Ultimately, California issued a Statewide CLIA waiver first for the schools professional antigen program and ultimately for developed three Statewide lab directors, CLIA waivers and ordering physicians, thereby providing all sites interested in using professional antigen tests the ability to procure and administer them. Establishing this regulatory solution took time, as CDPH and the TTF determined the various professional antigen "cohorts" that would be needed, which in turn drove the number of lab directors needed. As one

leader noted, "everyone wanted the simple solution, one lab director for the whole State, but there was no one willing to take on that responsibility."

- During the early development of the Statewide professional antigen programs, all three lab directors and their affiliated cohort teams (with the schools lab director and teams leading) devoted extensive time to develop the registration, onboarding training, and skills and knowledge assessments that community members would need to complete to begin testing. Eventually each TTF cohort hired its own training team, but until then various team leads were responsible for training individuals, observing individuals as they practiced administering tests, and learning and training others on the regulatory framework. According to one SME, this was "a large puzzle." On the one hand, it was necessary to let individuals access the test kits so they could train, but to ensure compliance, it was important to not actually begin testing before they had completed their training. The team also piloted quality control procedures and various different testing scenarios, such as determining the number of tests needed before an individual would be allowed to train other people or conduct tests unmonitored by supervisors. According to one SME, this initial phase "helped us figure out how to integrate into CBOs."
- For community-based testing sites who wanted to offer antigen testing (in addition to or as an alternative to PCR testing), the new professional antigen program was intended to offer antigen testing free of charge. Over the next several months, the TTF built out the details of the programs, leveraging the infrastructure it had developed for PCR testing and the VBL. As one leader noted, "the skeleton of what we had created for the PCR programs was applied to the antigen programs—but there was a whole different round of work needed for antigen."
- In order to balance workload and meet the overwhelming demand during the Delta surge of Fall 2021, the TTF's testing program was quickly organized into different seven cohorts, overseen by different CDPH lab directors, each with their own CLIA waiver:
  - Cohort 1: Antigen testing in schools (discussed separately below)
  - Cohort 2: CDSS Professional Antigen Program
  - Cohort 3: CBOs
  - Cohort 4: Sites with own CLIA waivers

  - Cohort 5: State Employees Antigen Testing Program
  - Cohort 6: Color Professional Antigen Program
  - Cohort 7: Color PCR Program
- In addition, to address the large number of sites wanting to onboard to the professional antigen program through a new TTF cohort, the State's vendor Color obtained its own CLIA waiver to offer antigen testing (Cohort 5) to California State employees working in small offices or in remote locations. This cohort played a crucial role in continuing COVID-19 testing during the 2021 wildfires, which coincided with the Delta surge. If other organizations who already had a CLIA waiver (Cohort 4) wanted to participate in the antigen testing program, the TTF would set up their testing and order test kits.
- In order to manage the large volume of sites requesting to join the professional antigen program, the program was organized into cohorts based on organizational type (e.g., schools, CBOS, and CDSS). This led to the creation of multiple TTF teams who were doing very similar work, albeit with different clientele. Some SMEs felt that this was necessitated by the different needs of the various clientele. As one leader noted, "there is a reason to break them up into categories just depending on who the customer is," since schools, facilities, and CBOs have unique needs and challenges.
- However, other leaders who were present during the Delta surge (when over 4,200 sites registered to onboard in less than a week) recognized that a single lab director could never have handled the volume by themselves. Even having three lab directors was insufficient to meet the overwhelming demand for testing, and subsequently the TTF contracted with Color to develop a fourth professional antigen testing program (Cohort 6) to help meet demand. At the time, lab directors were in high demand and challenging to recruit.

A Professional Antigen Program Launched for Different Organizations and Continued to Evolve Over Time

- The Statewide CLIA-waived antigen testing program, also known as the "professional antigen program," was launched in April 2021. The TTF began

enrolling sites; at the time California was between surges, so demand for the program was slow (approximately 5-20 sites onboarded per week.) However, in Summer 2021, several factors combined to prompt increased demand for testing. These factors included the start of the Delta surge, return to in-person school, and the release of State Public Health Officer orders requiring vaccination or testing for certain in-person work (including State employees and schools).

- Consequently, the demand for the professional antigen program skyrocketed and over 4,200 sites registered to onboard within one week. The TTF developed extensive resources to support this program, including a robust step-by-step website and a 100-page playbook that walked sites through the process from start to finish. First, the site or organization needed to identify anticipated testing demand, choose a technology platform for reporting, submit an application, and indicate if it also wanted to enroll in confirmatory PCR testing. The TTF would then review the application. Once approved, the site or organization would focus on preparing site logistics, setting up the technology reporting platform, signing the MOU with the State, completing training (including knowledge of test interpretation, quality assurance tracking and test kit performing skills), ordering professional antigen test kits, and onboarding to the VBL if doing confirmatory PCR testing. Next, site staff had to complete virtual training on how to conduct antigen testing. After site members completed the training and passed the CDPH antigen knowledge and skills competency test, they were allowed to begin offering antigen testing under CDPH's CLIA waiver.
- In addition to helping sites and organizations through this process, the TTF also procured and stored test kits, worked with the warehouse on distribution, managed antigen testing supplies, established partnerships and integration systems for confirmatory PCR testing, and reported and tracked entities utilizing antigen testing. The TTF also continued to enhance the intake, onboarding, and training process.
- The TTF professional antigen teams were able to draw on many resources, especially CDPH's Lab Field Services Division. According to SMEs, staff from this Division were "willing to meet with lab directors as often as needed to make sure we set up a program that would be as good as possible," which included providing the tools, education, and resources for sites to comply

with regulations. The TTF also worked with different departments and stakeholders to get their input on how to best structure the program. Within TTF leadership, "institutionally, there was a continual willingness to adapt and adjust," one SME noted, and this helped the program evolve and improve throughout the pandemic. "Looking back over the past 18 months, it changed dramatically, through continual, gradual improvement," one SME noted.

- The TTF also relied on feedback from CBOs and other organizations who participated in the program to make program improvements. The program focused on finding efficiencies, such as streamlining the approval and onboarding processes. For the professional antigen program, this ethos of adaptability and continuous quality improvement was a "critical success factor," according to one SME.
- In mid-2022, the Department of Social Services antigen testing cohort, which had been operating under a separate CLIA waiver, was integrated into the CBOs cohort. This cohort had successfully administered approximately 82,000 COVID-19 tests at over 380 testing sites including assisted living facilities, rehabilitation centers, and residential care homes.
- In the early Fall 2022 the schools professional antigen lab director also left TTF and this program was also integrated into the CBO cohort underneath its lab director. Simultaneously, since demand for professional antigen testing had substantially waned, the TTF worked to combine the State's three lab directors and cohorts into a single cohort. At this time, a leader noted that having three different antigen cohorts under three different lab directors was creating too many logistical challenges since there were "too many cooks in the kitchen."
- In Winter 2022-23 the Color professional antigen cohort was closed down and its sites were predominantly transferred to the OTC testing program (discussed in further detail below); a small number of sites were integrated into the CBO professional antigen program.
- In 2023, the CBO professional antigen program was renamed the Community Rapid Antigen Testing Program.

SNFs and CBOs Struggled to Understand Antigen Program Requirements.

- The statewide professional antigen testing program introduced a new technology vendor, Primary, into the test registration and reporting process. For antigen testing, CBOs and organizations needed to either use the Primary software platform (which would automatically feed all results to CalREDIE, California's disease surveillance system), or use CalREDIE's Manual Lab Reporting module. Those that switched from the Color (PCR) technology platform to Primary (antigen) led to confusion and frustration. As one SME noted, "a lot of folks were frustrated that in order to do antigen testing they had to use another platform."
- SNFs in particular, who were some of the earliest to receive antigen tests, experienced significant reporting challenges due to a lack of bandwidth and the complex requirements of the reporting process. SNFs, many of which were very small facilities, "just had no ability to handle the arduous reporting requirements," one SME explained. According to SMEs, for many SNFs, the process to onboard into the Statewide antigen program was too lengthy and complex. Some SNFs tried to report using the CalREDIE Manual Lab Reporting Module, but they were required to manually enter demographic information in over 20 fields. Due to these barriers, many SNFs were unable to use the antigen tests that had been sent to them from the federal government. As one SME noted, "they were completely overwhelmed, it was a tremendous waste of time, and there was just a complete inability to use [the tests]." SMEs agreed that in the future, antigen test reporting is "one thing we need to do better next time."
- CBOs also struggled to adapt the requirements of the antigen program. When building the program, the TTF conducted outreach to equity partners, targeting organizations that served populations in the lowest HPI quartiles. At the height of the program approximately 70% of the organizations served populations in HPI quartiles 1 and 2, however, they struggled to understand how to participate in the program and comply with its requirements, according to SMEs.
- Early in the program, CBO sites received initial shipments of antigen test kits and immediately started using them, unaware of the reporting requirements. Even if a site was aware of the requirements, sometimes they struggled to comply. As one SME noted, "some of these sites had no medical background at all, and there was a lot of confusion about program requirements." To overcome this challenge, the TTF cohort

adjusted its communications to deliver key messages in multiple, more accessible ways. Based on feedback from sites about points of confusion, the TTF cohort also passed feedback along to those developing official communications, as one SME noted, "it took a while for the communications to evolve so we could really reach the people that needed it."

Antigen Test Kits Registration and Reporting IT Systems Lacked Quality Control Modules

- According to CDPH lab directors and the TTF cohort staff, ensuring compliance with the antigen program's regulatory requirements—while trying to encourage organizations to enroll in the program—was challenging. Most of the COVID-19 antigen test kits, unlike other CLIA-waived point-of-care tests, lacked a quality control (QC) module, which exacerbated the compliance issues. As SMEs explained, usually CLIA-waived POC tests cannot be "resulted" until the user performs a quality control process. If the user tries to bypass the quality control process, software will "lock out" the test, blocking the test from being "resulted" and preventing non-compliance.
- However, the Primary software tool, as well as later COVID-19 antigen testing software, lacked a quality control module with this feature. In addition, since sites had to have the test in-hand to complete the training, many sites began testing as soon as tests arrived. These factors increased compliance risks for CDPH and the lab directors who were providing the CLIA waivers, SMEs explained. As one leader noted, "rolling this out without a QC module was a very big risk to CDPH." Ultimately, the lack of a QC module, coupled with the ease in which sites could start testing, increased the burden on TTF staff, who had to perform extensive manual record-keeping to bolster reporting.
- In June 2022, TTF staff wanted to build a QC component into its internal MS Dynamics system to help reduce its manual workload. However, this idea was met with resistance as the statewide COVID-19 vaccination campaign was in full swing (and utilizing MS Dynamics), case rates were dropping, and the TTF was needing to restrict expenditures, return redirected staff, and begin laying off staff.

- Ultimately, SMEs agreed that a quality control platform will be essential for future responses, since there will always be organizations who begin testing prematurely. One potential solution could be requiring vendors and test manufacturers to include QC modules with traditional controls and compliance lock-outs. As one leader noted, "we needed to have some kind of platform collecting everything from the beginning, and there needed to be a push for it." According to one leader, it will be crucial for the State to think about test resulting and reporting from a comprehensive, strategic perspective that considers risk, compliance, and usability.

At-Home/Over-the-Counter Antigen Testing

TTF Established OTC Pilot Programs at Schools, Airports, and Other Locations

- With the Statewide CLIA-waived antigen program, CBOs and other sites were responsible to provide staff that would be trained to run and report the test. However, the ease of Over-the-Counter (OTC) antigen tests meant that they could also be used by Californians who wanted to self-test at home. The TTF used this home-based testing model as the basis of its new At-Home/OTC testing program. The TTF's OTC program focused on providing online ordering and direct distribution of antigen test kits to priority populations, especially the uninsured and those with limited access to testing.
- The TTF piloted the OTC program in Fall 2021 for returning travelers at international airports, State employees working in small office or remote locations, and K-12 schools. The TTF leveraged its existing program infrastructure, most notably its online ordering system, for the OTC pilots. Unlike the professional antigen program, no CLIA waiver or official reporting was needed. This was because organizations were not supervising the collection of samples, but simply ordering and receiving the test kits from the State, then distributing them to their populations.
- OTC airport testing began at San Francisco International Airport as a pilot in Summer 2021 and was expanded to include Los Angeles International Airport in December 2021 in an effort to prepare for early identification of the anticipated Omicron variant. The program offered tests to returning international travelers so they could self-test on the day of their arrival and again three to five days later. The program expanded to include Cross

Border Xpress (CBX), a point of entry pedestrian bridge that connects San Diego to Mexico's Tijuana International Airport. Ultimately, travelers from over 120 countries were tested through these programs and over 25,000 OTC tests were distributed.

OTC Program Started During Omicron Surge and Evolved Over Time to include Test-to-Treat

- When the OTC program began in November 2021, the TTF purchased test kits in advance of the Omicron surge (which occurred over Winter 2021-2022). However, multiple issues—including an international supply chain shortage, nationwide winter storms, and transportation issues—coincided to disrupt the delivery of 15 million tests to the State for further distribution. It was a "perfect storm of everything that could go wrong during a surge," one SME noted.
- These factors delayed the delivery of 15 million test kits to California and also disrupted supply chains to private industry; within days, drugstores and supermarkets also ran out of OTC kits. Consequently, the TTF had to carefully ration the minimal available OTC kits. The TTF developed three key goals to prioritize OTC test allocations: prevent morbidity and mortality, keep the economy open, and keep children in school.
- In January 2022, the federal government required that health care insurance companies provide up to eight tests per month per insured for free. In late February, the supply chain issues and OTC test kit shortages gradually improved. Around this time, the TTF learned that some insurance companies were running the federal program as a reimbursement program—e.g., requiring individuals to purchase OTC tests up front, fill out paperwork, and then wait for reimbursement. California's OTC program subsequently focused on getting tests to uninsured populations and populations for whom the reimbursement process was cost prohibitive. As one SME noted, for many Californians having to pay up front for tests was a significant barrier, so "we focused on supporting those folks" in addition to the uninsured and those with limited access to testing.
- As the Omicron surge and the supply chain issues resolved, TTF leadership advocated for securing test kits and developing a stockpile of OTC kits in order to ensure the State had available supplies during subsequent surges. Any future recipients of the State's stockpiled OTC test kits will be required

to provide tracking details (e.g., name and contact information) to obtain the free kits so that the State can seek reimbursement from FEMA.

- In early 2022, TTF staff worked on streamlining its processes to make it as easy as possible for CBOs and other organizations to order and receive tests. Organizations filled out one form and TTF staff would then arrange to have the tests shipped to them. Initially, the TTF thought that organizations would have to register the test kits in individuals' names in order for the State to receive FEMA reimbursement. Ultimately, however the TTF received key FEMA tracking metrics that did not require kit registration at the individual level. After attempting in several different ways to track millions of test kits across California, the TTF designed a QR code ordering system, which simplified the process and allowed the tracking of over 80 million tests kits. Once the State had tests in its inventory, the OTC program initiated a "massive push to get tests to the organizations in need that met the equity metrics," according to SMEs.
- In general, "sites were very excited to receive the kits," especially for sites that were struggling to provide on-site testing due to staffing and other challenges. The OTC program offered an alternative way to access free testing in fewer steps and with no reporting requirement.
- The OTC program continued to evolve over time. For example, for-profit organizations became aware of the program and were interested in ordering, according to SMEs. Consequently, the program instituted ordering criteria based on its equity metrics in order to ensure that tests continued to reach the uninsured, under-insured, and other populations with limited testing access. "It was continually evolving as we identify areas of greater need," one SME noted.
- In March 2022, the federal government had announced the federal Test-to-Treat initiative, which included an online locator to help the public find sites with testing, prescribing, and dispensing of oral therapeutics all at one location. "Test-to-treat" is a concept of facilitating expedited access to treatment as soon as someone tests positive for a disease. However, many of California's clinics that treated low-income, uninsured, and/or under-insured patients struggled to develop operational workflows to facilitate access to therapeutics or coordinated with LHJs to make their services visible on the federal Test-To-treat locator.

- To help remedy these inequities, in May 2022, the TTF partnered with Optum Serve to convert the Optum Serve testing sites into Test-to-Treat sites and support operations at 146 of these sites in high-need, low-access areas of the State. Test-to-Treat was initially piloted in 10 sites and then expanded across all Optum Serve sites over the course of a 2-week period in May-June 2022. Regulatory barriers were overcome with the California Department of Consumer Affairs and the California State Board of Pharmacy to allow for the direct distribution of prescribed Paxlovid at the testing sites following consultation with Optum Serve's telehealth provider (SteadyMD). Approximately ninety percent of patients testing positive and prescribed oral therapeutics opted to pick up their medications at the Optum Serve sites as opposed to going to their local pharmacy. California's was the first Statewide Test-to-Treat program in the country
- In Fall 2022, the TTF's OTC program was linked to California's new telehealth provider (Sesame) to launch Test-to-Treat availability through OTC test kits, which was operated by CDPH's Therapeutics Task Force. According to SMEs, the effort to join the OTC program with the Test-to-Treat program was successful. Ultimately, the OTC program distributed over 107,069,000 test kits to program participants. For more information on California's Test-to-Treat program, see the Therapeutics chapter in this AAR.

OTC Program Did Not Require Any Reporting

- The OTC program did not require individuals to report results because CalREDIE did not have the capacity to receive the results, and OTC tests results were not reportable to the CDC. While this lowered the barrier to testing for many, it also created challenges. For those who did want to report their results, the lack of required reporting and thus a centralized, consistent approach made reporting challenging. By Spring 2022, a variety of OTC test kits produced by different manufacturers were available, and many had their own vendor-based reporting platform.
- This created confusion, as "people don't really differentiate between where they got the tests—from the State, from the pharmacy, or from UPS," one SME explained. Depending on which test was used and where it was procured, there were multiple ways to report results, including through Primary's software application, Color's software application, or individual

LHJs' call centers. Some individuals, confused about how to report their test result, called their doctor's office to let them know their results. The lack of required OTC reporting for local, state, and federal surveillance (and lack of a standardized reporting mechanism) contributed to California's case rates being artificially low in late 2022 and early 2023—especially as PCR testing waned in popularity. . Additionally, in order for employees to receive the State's COVID-19 supplemental sick pay, some employers would only accept a PCR test result or a supervised antigen result.

- This was a nationwide issue that was not unique to California, and for testing conducted at home, SMEs acknowledged that "we'll never have comprehensive data on OTC results." However, some states succeeded in implementing reporting for OTC tests, which resulted in more accurate case counts through better data. In future pandemic responses, SMEs recommended test kit companies include in their development auto-reporting from the test kits themselves. If companies do not develop this, CDPH should establish a simple, centralized way to report OTC results.

PCR and Antigen Testing in Schools

Antigen Testing was Piloted and Subsequently Launched in Schools

- As discussed earlier, the TTF started to develop a professional antigen testing pilot program in K-12 schools during late 2020 and early 2021. During this time, it explored partnerships with schools who wanted to participate in the pilot, developed training, explored reporting and funding options, and addressed regulatory hurdles. The TTF sought out schools in disadvantaged locations for the pilot. Although the TTF did not yet have a refined formula to identify these schools (this would be developed later), it was clear that some schools were able to pay for testing programs while others could not. Based on data provided by the California Department of Education, the TTF prioritized higher-need schools for targeted outreach. In the spring of 2021, CDPH partnered with Safely Opening Schools (SOS), a non-profit organization that provided early funding. Together with SOS, CDPH oversaw a pilot program in 10 school districts to gain insights on the use of rapid antigen testing to prepare for schools re-opening and keeping students in classrooms during the COVID-19 pandemic.
- The TTF schools cohort was supported by dedicated medical officers throughout the pandemic; this role reported directly to the TTF CDPH Chair.

The TTF's schools cohort had its own TTF schools medical officer lead (drawn from UCSF) starting in January 2021.

- From March to June 2021, the TTF worked to recruit school districts to enroll in antigen testing over the summer. At this phase in the pandemic, interest in antigen testing was low due to numerous reasons, according to SMEs: Californians were fatigued, many schools had just finished a year of remote instruction, and all adults were now eligible to be vaccinated. Ten schools participated in the pilot and reported test results to their LHJs via Excel spreadsheets.
- Based on feedback from the pilot, the TTF schools professional antigen testing program was organized as a separate TTF cohort with its own lab director. The cohort also had a State medical officer and was supported by two additional contracted medical officers and a large team over 20 staff, a State-sponsored CLIA waiver, and ordering physician. Reporting was changed from Excel spreadsheets to Primary software, based on lessons learned from the pilot. Initially, schools who wanted to participate in the program needed to pay for their own reporting software and could choose between software offered by Primary or Color. However, the software was expensive and only well-off schools could afford it, according to SMEs. Shortly thereafter, the TTF received additional federal Epidemiology and Laboratory Capacity (ELC) funding for schools, which enabled the TTF to offer the Primary software at no cost to all interested schools in California. As one SME noted, "the biggest win was when they no longer had to pay for the software." For further discussion of this funding, see the TTF Administration section below.
- In February and March 2021 SMEs devoted considerable effort to convince TTF and CDPH stakeholders that the State needed to purchase access to the Primary reporting software and provide it to schools for free. Some within CDPH and TTF disagreed since at the time the TTF had limited funding to support testing for everyone across the State, and State could instead use the free Abbott application that came with the test kits. However, SMEs advocated that the program needed the enhanced functionality in Primary's software, and "we had to push and push and push to convince people that we needed to get Primary," one leader noted. Once there was dedicated federal ELC funding for schools, TTF purchased the Primary software.

- The TTF developed an onboarding flow checklist which outlined the steps to enrolling in the program. The program was modeled after earlier pilots and utilized some of the original infrastructure created for VBL. This infrastructure underwent significant revisions and updates for antigen testing topics including onboarding, training, and implementation workflows and processes. Schools had to review the California K-12 School Antigen Testing Program Playbook, sign the MOU with the State, identify team leads and staff members to be trained, attend various trainings (on testing and on maintaining confidentiality), onboard to the Primary platform, order testing supplies, and pass the program's competency quiz.
- Schools and school districts also needed to determine if they wanted to enroll in confirmatory PCR testing through the Valencia Branch Laboratory. Confirmatory PCR testing was recommended for several different scenarios, including all positive antigen tests, ambiguous antigen test results, or symptomatic individuals who received a negative antigen test result. For confirmatory PCR testing, the TTF relied on two vendors (Primary and Color): schools would order the test and view results using the Primary platform, but the actual test kits were branded and mailed by Color. To transport the PCR samples to the VBL lab, schools needed to either sign up to use the State's COVID-19 California Courier Network or use an independent courier or transportation system.
- For some schools, running and staffing the professional antigen program was overwhelming. To support these schools, TTF contracted with an additional vendor to offer more robust "end-to-end" antigen testing, in which contractors supplied personnel and additional support to help with implementation. The end-to-end program is discussed further below.
- With the CLIA waiver in place and ELC funding secured, the schools antigen program was now a "one-stop-shop" for schools to receive training, test kits, and reporting software for free, according to SMEs. This was attractive to many schools, and enrollment in the program skyrocketed during the Delta surge of late Summer 2021, which coincided with back to in-person school preparations. Consequently, during August and September 2021 the program experienced its "first massive enrollment," according to one SME. "We went from 100 school districts to 2,000 [onboarded] in a month," another noted, which was "hugely challenging." During Fall 2021, the cohort was exceptionally busy with

onboarding schools and conducting virtual training for hundreds of attendees. The TTF cohort struggled to keep up with the demand, and administrative staff worked to quickly bring on, onboard and train additional staff. In September 2021, following the resignation of the schools medical officer lead, a new medical officer (drawn from UC Davis) took over the role and remained in the role throughout the 2021-2022 academic year.

- Simultaneously, the industry experienced a shortage of antigen tests. During the summer, when interest in antigen testing was low, manufacturing plants that produced the test used by the program (for the Abbott BinaxNOW Rapid Antigen test) had decreased their volumes or shut down. As a result, although TTF pre-emptively purchased 11 million tests ahead of the surge, these tests were not delivered. It was challenging for the TTF to navigate this shortage while dealing with the increased demand for professional antigen testing from schools and community organizations (which was discussed earlier in this chapter).
- The TTF made adjustments to its program structure and increased its communications to schools, while it simultaneously processed millions of orders. "It was chaotic, but we did a really good job of communicating with schools that the tests were coming," one SME noted. Another agreed that "even in the wake of a huge shortage and schools onboarding all at once, we went through it relatively well—the entire program could have collapsed, but we collaboratively found solutions to the major problems." SMEs attributed these successes to the dedication, passion, and energy of its team members.

Antigen Schools Program Team Navigated Reporting and Training Challenges

- All schools who were testing under CDPH's CLIA waiver were required to report both positive and negative test results to CDPH. Consequently, TTF staff had to balance motivating schools to test with requiring them to comply with the reporting requirement. "It has to be easy enough for them to continue testing, but at the back end we have [to] make sure they're compliant and reporting," one SME explained. This was sometimes a delicate balance to strike, since running an antigen testing program while simultaneously running a school "is not an easy lift," one SME noted. It was a challenge for schools to complete the necessary training.

- During the program's rapid expansion in Fall 2021, the TTF tried to use a "train the trainer" model to meet demand, in which nurses could be trained to train others. But this model was ultimately not successful as the TTF found that the quality of training was insufficient. Schools were not incorporating crucial program requirements and as a result the program experienced data quality issues. "We were trying to meet the challenges of training lots and lots of schools, but it didn't work out quality-wise," one SME noted. As a result, the TTF abandoned this training model for the schools.
- The TTF cohort then advocated for full training but faced some internal resistance as the TTF struggled to meet unprecedented demand for testing in the face of substantially inadequate staffing across the TTF. Other TTF stakeholders "suggested making training truncated or optional," one SME said. Ultimately, full training was required but there was "a lot of back and forth" internally to reach this determination.

Antigen Schools Program Team Encountered Internal TTF Resistance and Challenges between Cohorts

- In Spring 2022 and academic year 2022-2023 the antigen schools program navigated internal challenges within the TTF. These challenges stemmed from the numerous cohorts and programs, as well as the resignation of key personnel (including the TTF schools lead and medical officers) that were unable to be replaced, as CDPH prepared to downsize response efforts. For the 2022-2023 academic year, the schools medical officer lead position was filled with a CDPH medical officer (and, temporarily, a contracted medical officer when the CDPH medical officer was on leave).
- By this point, the TTF was comprised of seven cohorts, who each managed separate testing programs and modalities. The cohorts sometimes found themselves misaligned with other cohorts or in competition with them for resources. For instance, the TTF's CLIA-waived professional antigen program, which offered free testing to CBOs and other community organizations, had also been launched in April 2021. By Summer 2021 it had grown substantially, as it had faced similar surges in demand during the Delta surge. This program operated under a different CLIA license and different lab director.

- The TTF did not have data and epidemiological support from CDPH staff and was also not successful in hiring staff with these skill sets. For further discussion, see the Data and Technology section in this chapter below. Therefore, the TTF relied on a consultant (McKinsey) who used their own data and technology systems. When the TTF schools antigen cohort learned that other cohorts were using MS Dynamics for reporting, they requested access to the tool. However, according to SMEs, this request was denied by McKinsey consultants, who informed the team that the software was not available because McKinsey no longer had sufficient expertise to support adding more programs. Eventually, the team did gain access to MS Dynamics, which helped them streamline reporting. Ultimately, SMEs were frustrated by the disparities between cohorts. TTF leadership attributed these disparities to a situation in which demand outstripped supply.
- Despite these challenges, the schools cohort program team felt that schools were generally well-supported by State, CDPH, and TTF leadership. When the cohort indicated that schools needed more tests and asked for schools to be prioritized, "it was instantly done," one SME noted. The steadfast support for the antigen schools program at all levels of government was beneficial for the team, who felt supported in carrying out their programmatic work.

TTF Provided Additional Operational Support to Schools Through End-to-End and Direct Funding for Personnel

- For some schools, the requirements to participate in the State's antigen or PCR testing programs (whether individual, pooled, or confirmatory) were too difficult to meet especially in underserved communities. To assist these schools, the TTF developed two supplemental ways to provide additional support: the State would provide either end-to-end (E2E) vendors (Operational Support) or provide direct funding grants to schools to enable them to hire testing personnel (Personnel Grant Funding Program). According to one SME, the "whole point of the end-to-end and direct funding program was to address equity issues." Both programs were funded through the ELC grant for schools. Hence, in collaboration with the California Department of Education equity-based formulas were used to determine which schools and districts to offer end-to-end vendors and personnel grants.

- During the school testing pilots of Spring 2021, the TTF successfully piloted its E2E Operational Support model, which was a "white glove" service for schools, according to SMEs. In the E2E model, the TTF provided an external vendor, who would set up the collection site, provide personnel to conduct testing, and manage the collection site supplies and transportation of tests. The TTF contracted with Vestra for E2E services to conduct PCR testing at a handful of school districts over Spring and Summer 2021. However, the initial work with Vestra "gave us a sense of how a vendor would work to help with testing," according to one SME. According to SMEs, during Spring and early Summer 2021 many schools were not yet interested in doing testing.
- School interest in Operational Support or Personnel Grants drastically increased at the start of the 2021-2022 academic year during the Delta surge
- The TTF staff members (including schools staff) worked around the clock to recruit vendors, review proposals, and work with CPR and TTF leadership to execute contracts and quickly bring onboard eight vendors to provide operational support to schools. Subsequently, the schools team continued to work on building the Operational Support program for both antigen and PCR testing, since both testing modalities were available for the 2021-2022 school year. "The different testing modalities dictated the program details," one SME explained. Multiple vendors each offered different services (e.g., registration, different test types, test results reporting, and personnel), depending on the testing modality. The State offered eight vendors to schools who could provide end-to-end services for PCR only, PCR pooling, or antigen with confirmatory PCR.
- Ultimately, almost 1,000 K-12 schools in 120 school districts received end-to-end vendor support for antigen, PCR, and pooled PCR testing for the 2021-2022 school year. And over 3,500 K-12 schools in 341 school districts received direct funding for testing in the 2021-2022 school year. (For a discussion of the administrative difficulties and resulting funding delays associated with the personnel grants program, see the TTF Administration section later in this chapter.)
- The TTF's end-to-end program for schools continued to operate at full scale for the 2021-2022 school year and in a scaled-down version for the 2022-2023 school year. Funding had decreased, and consequently the TTF only

offered the end-to-end program and discontinued the direct funding program. With less funding available, the TTF cohort responsible for operational support programs conducted its own internal retrospective analysis and streamlined its processes. The team reached out to CDPH's Office of Health Equity (OHE) to help determine metrics and formulas to prioritize schools for the program.

- The process of determining new equity metrics and determining the 2022-2023 program coincided with vendor contract re-negotiations. As one SME noted, "everything was a variable" and there was no "solid ground." The resulting 2022-2023 end-to-end program and its more rigorous equity-driven process received important "buy in" from key educational stakeholders, including the California Department of Education, California State Board of Education, CalHHS leadership, and CDPH leadership.
- All end-to-end vendors rolled off over the months of March and April 2023 as utilization had declined substantially during the academic year.

Several PCR Testing Options Were Offered to Schools

- As the State worked to establish the Valencia Branch Laboratory and the numerous community-based collection sites, the TTF also began offering free PCR testing to California's K-12 schools, starting with a pilot in January 2021. In the 2021-2022 school year PCR testing in schools was led by a contracted schools medical officer. PCR testing in schools was offered through one vendor, Color. Schools had the option to enroll in different types of PCR testing:
  - **Individual PCR:** This involved testing individual students.
  - **Confirmatory PCR:** This modality was offered as an add-on to the antigen program, and was used to either confirm positive or inconclusive antigen tests. Most schools who participated in confirmatory PCR were in the end-to-end antigen program.
  - **Pooled PCR:** This modality involved testing up to 25 asymptomatic students in one group. Group specimens were combined ("pooled") and tested with a single test. If the pool was negative, all students had a negative test result. If the pool was positive, follow-up individual antigen testing was offered.

- The process to establish PCR testing in schools was similar to the process to establish community-based testing sites. Schools went through the TTF's onboarding, registration, and training processes. Since PCR samples needed to be processed at VBL, the schools were given the option to enroll in the State's courier transportation network. The TTF schools cohort included both the antigen and PCR testing programs; within the schools cohort, different teams supported each program.
- There were pros and cons associated with PCR testing in schools. One of its strengths was its ease of enrollment and stable supply of tests, especially compared to the antigen program. As discussed earlier, during fall 2021, several factors (including the Delta surge and requirements for school staff vaccination or testing) contributed to a spike in schools' demand for professional antigen testing. The TTF was not able to accommodate all schools who wanted to join the antigen testing program, so some schools enrolled in the PCR testing program instead. During the times of antigen shortages, PCR testing was especially helpful to meet the weekly school staff testing requirements. As one SME noted, "PCR was able to fill the gap when antigen wasn't readily available—it kept staff in school."
- The barriers to entry were much lower for the PCR program than for the schools professional antigen program. PCR tests only required individuals to be swabbed on school sites; the collected specimens were shipped to the lab for processing and interpretation. Therefore there was no need for schools to go through extensive training to meet the CLIA regulatory requirements. Because the TTF had already built the framework of the PCR program for its community-based sites, it was simple to "plug and play" schools who wanted to enroll in confirmatory PCR testing along with antigen testing. "If the overall PCR program wasn't already in place, it wouldn't have been as easy to do that," one SME mentioned.
- Reflecting on the pros and cons of PCR testing in schools, SMEs noted that individual PCR testing was not best suited for schools due to its lengthy turnaround times. While waiting the 48 to 72 hours for PCR test results, a symptomatic student who may not be infected with COVID-19 but had symptoms would need to stay home from school; this time period could be even longer during surges. This was a major obstacle for school-based PCR testing, the entire purpose of which was to keep students in schools and keep schools open. Even though PCR testing is more sensitive than antigen

testing, PCR testing is "just not a realistic testing method for schools" and "doesn't meet the need" of keeping children in schools," one SME noted.

- According to SMEs, PCR testing worked best in schools when it was used as supplemental to antigen testing – either as a confirmatory test, a pooled test, or as a back-up method during times of antigen test kit shortages. Pooled PCR testing helped the TTF increase the number of schools the State could provide free testing to, since it was more cost-efficient than individual PCR testing. With pooled PCR testing, "you could very quickly test entire classrooms, and a testing typology, it worked very well," one SME noted.
- The transportation options for PCR testing offered by the TTF were also successful. The State's courier network provided a way for schools to get samples to the VBL. In late 2021, it became clear that for some rural schools, the drop-boxes were located too far away. As a result, in early 2022 the TTF contracted with FedEx to provide schools with pre-paid shipping labels, which they could use to ship their samples to the VBL. According to SMEs, this was a major success for the team showcasing its adaptability, responsiveness, and ability to pivot to new solutions. In the future, SMEs recommended that the State consider utilizing both the drop-box network and also focus on providing pre-paid shipping labels, especially for rural school districts.

During the 2022-2023 Academic Year, PCR Testing in Schools Did Not Receive as Much Attention as Other TTF Programs

- During 2021-2022 school year the PCR schools program was overseen by a contracted medical officer. However, in the 2022-23 school year, multiple medical officers resigned, leaving the program without a dedicated medical officer. The entire TTF (including schools) were left with just three medical officers responsible for oversight of all TTF programs. The TTF was directed to not hire or redirect any more staff, since CDPH had begun the process of demobilization from the pandemic response. Hence, during the 2022-2023 school year the schools PCR testing program was managed by staff within the broader TTF who worked to scale it down and decrease the number of sites. A SME noted that the PCR schools testing program team lacked a CDPH medical officer and the team relied primarily on redirected State workers on the broader TTF who came from other State departments to run the schools PCR program.

- The lack of ownership on the PCR schools program during the 2022-2023 school year resulted in confusion and sometimes delayed messaging for the team, according to some SMEs. The team also struggled to keep stakeholders engaged and the program visible, while recognizing that PCR testing in schools was just a small part of the TTF's offerings. It was not always clear how it fit into the wider testing options provided by the State. "Are we still offering it? Is it required? Because it was secondary there was often confusion about what's happening with PCR," one SME explained. In the midst of competing interests and programs, the team did its best to keep stakeholders interested and integrated in the program.
- According to SMEs, key lessons learned include the importance of establishing the same level of ownership of all testing programs throughout the course of a pandemic. This would include making it clear who the decision-maker is and maintaining transparent communications across all programs throughout the course of the pandemic.

TTF Administration

Staffing

Redirected CDPH Staff Helped Operate the TTF's Testing Programs

- Like many other COVID-19 response teams, the TTF included core CDPH staff but also relied on redirected staff from CDPH and other State departments. Early on, the TTF obtained redirected staff from Department of Health Care Services and CalHHS. However, throughout the pandemic most of the redirected TTF staff were from other CDPH centers, programs, and offices.
- There were many challenges associated with redirected staff, beginning with the lengthy process to obtain them. Program managers in the various cohorts would let TTF administrative leadership know of the skillset that was needed, and then TTF leadership would engage with CDPH's Human Resources Division (HRD) to identify candidates for redirection. According to SMEs, one of the TTF's "biggest struggles" was getting other CDPH programs to agree to release staff to the TTF for extended periods of time. This process, while effective, was very time-consuming since redirections were not mandatory.

- After TTF programs successfully obtained redirected CDPH staff, new challenges emerged. According to SMEs, redirected staff needed to be extensively trained and managed, and were not always as responsive as needed. Managing redirected team members could be so challenging and time consuming that one SME "would have preferred to not have any at all." If TTF programs received redirected staff who were "phenomenal," according to SMEs, they were often recalled back to their home programs after training and onboarding. This contributed to disruptions and a lack of continuity. Ultimately, one cohort even felt that managing redirections was a "waste of time and energy."
- To improve the redirection process, TTF SMEs has several suggestions. One leader noted that in the future, emergency redirections should be "more of a directive than an ask." Another SME recommended that redirected staff should be able to volunteer for program areas that they are interested in (e.g., schools) for better alignment of staff preferences with program needs. TTF leadership noted that redirected staff should be redirected for enough time to make it worth the effort to train them. Lastly, SMEs noted that some cohorts would have benefited from redirected staff with more technical skills such as data analysis, epidemiology, and reporting (see the Data and Technology section in this chapter for further discussion).
- Despite these staffing challenges, the TTF and CDPH leadership reiterated that the dedication and hard work of the TTF team represented the "true successes" of the program. TTF team members worked grueling hours (18-20 hours per day, including weekends) for months on end (and in some cases) for more than one or two years. Leadership praised the team for its devotion and perseverance which enabled the State to expand COVID-19 testing "in a record amount of time and at a pace nobody could imagine," one leader noted.
- For discussion on how the redirection process was operationalized, see the Human Resources Administration chapter of this AAR.
- For a discussion of redirections from a staff perspective, see the Effects on Staff chapter in this AAR.
- For a discussion of redirections and the contact tracing program, see the Contact Tracing chapter in this AAR.

TTF Also Relied on Contractors to Staff Its Testing Programs

- In addition to redirected staff, the TTF relied on many contractors to run its large, complex testing programs. The majority of the TTF's team members were contractors from a handful of organizations, including Heluna Health, Hagerty Consulting, the CDC Foundation, and McKinsey Consulting teams. These contractors worked as full-time TTF team members on most program components, including project management, program management, training, analysis, and reporting.
- The TTF had scaled up very quickly, especially early in the pandemic response. Up until June 2021, the TTF did not have a consistent centralized State administrative and fiscal team to oversee and manage its personnel and budget. Although the TTF had intermittently redirected State administrative staff members, at times only administrative contractors supported TTF leadership due to the inability to find State staff to be redirected. When individual program managers within the TTF needed additional staff, they would request and receive contractors, which created challenges with tracking and rostering. "Managers were reaching out individually to contractors," one SME noted. The lack of a State administrative team and standardized processes led to management inconsistencies. Some managers tracked contractors closely, while others did not.
- In June 2021, the TTF received a redirected CDPH position to oversee its program staffing and assigned this position as its hiring manager. At this time, the TTF consisted of approximately 70-80 people. "There wasn't a lot of tracking in terms of who was with us, where they were from, and how long they'd been there," one SME noted. Once the hiring manager was onboard, the TTF maintained a spreadsheet to better track its redirected and contracted personnel, which helped streamline and standardize its internal operations. This hiring manager played an especially critical role in Fall 2021 in helping the TTF meet overwhelming demand for its programs.

Contractors Lacked Public Health Expertise

- The procurement exemption and pandemic funding enabled the TTF to quickly onboard contractors and consultants to help run its programs. SMEs found the process easy to both obtain and release contractors. When a specific program requested more staffing, the TTF leadership "gave it to us

right away," one SME noted. Similarly, releasing contractors was easily accomplished, according to one SME. In their words, "it was such a wonderful and refreshing thing" to solve staffing issues quickly.

- However, it was difficult to obtain contractors with public health, medical, scientific, data analysis, or clinical experience. "We had a lot of very talented people, but they didn't understand the technical aspects of a public health response," one SME explained. Thus, most contractors focused on TTF project management, program management, and reporting functions.
- While contractors did not make policy decisions, their level of involvement and influence regarding policy discussions was not always clear to CDPH staff, and there was sometimes confusion at the staff level around contractors' authorities. In the future, SMEs recommended that contractors should be reminded that they are not able to make policy decisions for the State. Additionally, others felt that the TTF relied too much on some consultants who did not provide value. Lastly, another SME recommended exploring other potential staffing pools that have public health experience.

Funding

CDPH's Center for Preparedness and Response Managed the TTF Budget

- California received State and federal funds for many of its State-administered COVID-19 programs, including testing. The TTF was funded both by State general funds (over $2 billion) and through the CDC's existing ELC Cooperative Agreement. The TTF was allocated approximately $1.1billion from three supplements to the ELC Cooperative Agreement, which is CDC's national funding strategy to support state, local, and territorial capacities for emerging infectious disease control:
  - Enhancing Detection and Enhancing Detection Expansion supplements provided approximately $176 million combined.
  - Reopening Schools provided approximately $882 million. This funding was specifically dedicated to schools.
- Prior to the pandemic, the Center for Infectious Diseases (CID) had a dedicated fiscal agent to manage ELC funding as they did not have sufficient support in CID to manage the grant. However, for these new COVID-19-related ELC supplements, the Department needed to manage

the funding and all oversight of the deliverables; therefore, CDPH established a dedicated ELC team within CPR. The funding received by the TTF enabled it to expand its programs, hire staff and vendors, purchase tests kits and testing supplies, and disburse funds to schools and school districts for testing efforts. For more information on pandemic funding streams and administration, see the Fiscal Administration chapter in this AAR.

- Another layer to the TTF funding that was managed through CPR was the coordination of FEMA reimbursements. Much of the activities within the TTF were eligible for FEMA reimbursement; however, the only eligible reimbursements were those activities covered through the State General Fund. The State funding and ELC funding was all managed in CPR for the entire Department. The CPR team and TTF fiscal team worked closely to identify the potential reimbursements, as well as the use of federal funding. Often this work was done after invoices had been paid, which resulted in numerous transaction corrections and adjustments to maximize reimbursement to CDPH.
- The TTF had been originally established by CalHHS and the Governor's Office (not within CDPH) but its budget was managed by CPR. This presented fiscal and budget tracking challenges within the TTF. As one TTF leader noted, initially, "TTF had a budget and we knew that we could spend against it, but we never saw it and had no idea how much we'd spent." Another noted that "for all we knew, we were deep in the red and had no idea we were there." At this early point in the pandemic the TTF and CPR were focused on the pandemic response, according to SMEs, rather than financial management.
- In January 2021, the TTF leadership requested that CDPH fiscal and administrative staff be redirected to support its testing programs and manage its budget (both of which require State staff to support and oversee such programs). However, due to the many challenges with redirections (discussed earlier), this request took six months to fill. In June 2021, the TTF obtained redirected staff with fiscal expertise and gradually formed a fiscal administration team to work in coordination with CPR. The budgetary lead struggled to find redirected State support staff and ultimately relied on contracted staff to create a budgets team. More structured budgeting and tracking processes were gradually put in place,

including weekly meetings with TTF leadership to track the TTF's numerous contracts and encumbrances.

- The fiscal expert also acted as a liaison between the TTF and CPR, which was critical because the TTF fiscal administration team managed its budgets from the two ELC grants and State general fund in close collaboration with TTF leadership. Multiple TTF programs were often implemented each week, which required rapid contracting turnaround times. TTF leadership kept the fiscal team abreast of incoming contracts and encumbrances so that expenditures could be tracked correctly. Additionally, TTF leadership was also responsible for tracking where expenditures should be applied and if they were eligible for federal reimbursement of third-party billing. Given the numerous programs that had to be stood up very quickly, this was a complex puzzle that required careful tracking by TTF leadership.
- In late 2022, the TTF fiscal expert retired, leaving a gap in the TTF's fiscal support function. CPR added fiscal support within several weeks and TTF leadership worked closely with the CPR budget team to bring them up to speed. Consequently, TTF leadership and the CPR budget leads worked through the Summer 2023 to ensure appropriate tracking and application of billings and invoices to the various funding streams.
- According to SMEs, it was "very complex" to manage multiple vendors drawing from multiple grant sources. At one point, a large invoice was applied to one grant as opposed to being split between two grants, which temporarily created a significant deficit on one grant and the schools team was temporarily misinformed about needing to shut down a program. This error was rectified by TTF leadership, but it underscored the attention to detail needed to manage the complex TTF budget.
- One of the key lessons learned, according to TTF leadership, was the critical importance of having State fiscal administration staff assigned to each emergency response team early on in a pandemic. Unfortunately CDPH staffing was stretched thin throughout the department, so realistically this would require redirection of State fiscal staff from other State departments, especially those experienced with large, complex budgets.

TTF Leadership and CPR Developed TTF Fiscal Processes

- The vast majority of TTF contracts were executed by a highly experienced State contracting lead and the TTF relied heavily on this expertise.
- Given the limited staff (in particular State staff) available to support the complex TTF budget, TTF leadership collaborated with the TTF fiscal team and CPR to develop processes and procedures to track and verify invoices. An invoice would be reviewed and verified by the overseeing programmatic team to ensure billing aligned with the vendors' assigned program. Next, the invoices were reviewed by the TTF fiscal administration team, followed by the TTF chair. Following review and approval, invoices were sent to CPR for final approval and payment. If discrepancies were identified during the invoice review and approval process, the TTF would reach out to the vendor for clarification or corrections.
- TTF fiscal administration team experienced numerous changes, including frequent staff turnover and the retirement of the state TTF fiscal team lead in late 2022. In late 2022, one program manager indicated that "I still couldn't fully tell you" who was on the TTF fiscal administration team. In general, SMEs felt that "the fiscal part is very under supported." Consequently, some program managers found themselves increasingly involved in financial matters, which they felt was not a part of their role. Program managers reported fielding questions about their program's finances without the proper authority.
- In the future, SMEs recommended that a State-staffed fiscal administration team should be responsible for all financial and invoice processes, and that program staff should not create or manage these functions.

Personnel Grants Program was Difficult to Administer

- According to SMEs, one of the most challenging programs to administer was direct funding to schools for personnel grants, referred to internally as the "personnel grants" program. For eligible schools that needed additional operational support, the State provided either personnel grants (for schools to use to hire testing personnel) or end-to-end vendors, who would oversee all testing aspects. These programs are discussed earlier in this section.
- Early TTF school leadership had conceptualized the personnel grants program which was handed off to TTF leadership and the fiscal team to

operationalize. One of the main challenges was the extensive administrative and fiscal workload to provide direct funding to schools and school districts, which one SME described as a "massive amount of paperwork." Because all letters and invoices had to be approved and signed off on by State staff with appropriate authority, much of this paperwork burden fell onto the TTF leaders. TTF leadership reviewed over 1,000 letters and invoices for this program alone.

- The funding process involved many steps, which was completed for about 250 schools and districts. The complex, multi-step process to generate signed agreements and invoices led to significant backlogs. The payments were then processed by a separate accounting State team. Additionally, the lack of clear processes on how to implement such a program made it challenging. The TTF fiscal administration team developed these processes, but this took time and occurred in the midst of numerous other State fiscal priorities and rapid deadlines. This created confusion for the program team. According to one SME, "there were multiple times when we didn't know what our deadline was."
- As a result of these many challenges, personnel grant funds often took months to reach recipients. Once schools received their funds, they often only had one to two months left to utilize them, but schools were able to bill for efforts undertaken from the start of the program. One leader questioned the effectiveness of the program since the processes were so burdensome and funds were often delayed. However, schools expressed that the program was valuable.
- If such an extensive personnel grants program were to be implemented in a future pandemic; TTF leadership recommended ensuring sufficient State fiscal and administrative staff to support it.

Vendors

TTF Quickly Hired Numerous Vendors to Deliver Testing Services

- Early in the pandemic response, in 2020, the TTF contracted with numerous vendors to provide PCR test kits, reporting and registration software, laboratory operations and test processing, and test transportation services. As the professional antigen testing programs and the OTC programs grew in popularity, a growing list of new vendors offered services related to this testing modality. The TTF then contracted with vendors to provide mobile

testing services, including personnel who could conduct tests in the field. The TTF's vendor contracts ranged from contracts with vendors to provide specific, targeted services to multi-million dollar contracts to provide a suite of services across different testing modalities. Vendor management was a critical task.

- When California received its initial ELC grant to implement Statewide testing programs, the TTF's first challenge was to operationalize its programs and expand testing capacity rapidly. "It's hard to go from 0 to 100 that quickly, and stand up something at this scale that's never been done before," one SME noted. As the TTF established various pilot testing programs, TTF team members researched and identified testing vendors. CDPH TTF team members found this challenging due their general lack of experience and expertise in vendor identification, evaluation, and selection. Additionally, these were new business models that had not existed prior to the pandemic and many new testing vendors were being established of varying degrees of quality. The TTF team, the State, and the country lacked knowledge of how to begin identifying potential vendors or evaluate them.
- The TTF SMEs felt that "we needed to have a specialist in hiring these types of organizations, and we didn't do a good job of having those people around," given this modality and approach to testing did not previously exist before the pandemic. Other TTF SMEs indicated that the expedited timeframe to hire vendors was also challenging. One SME recounted reading over 40 proposals in a single day. "It had to happen fast, but probably didn't need to happen that fast," the SME noted, emphasizing that in the future the vendor hiring and vetting process could benefit from lessons learned during the COVID-19 pandemic and implement a more methodical approach.
- The TTF schools cohort experienced similar challenges when selecting vendors for its end-to-end operational support program in Summer 2021. As one SME commented, "a key mistake in the beginning was not being able to properly calibrate the vendor support we needed." At the peak, 250 school districts wanted end-to-end vendor support and the TTF struggled to contract with enough vendors who could deliver these services. In Fall 2021 the TTF had already contracted with three end-to-end-vendors, but some had overpromised what they could deliver and were experiencing quality

control issues, according to one SME. Some of these companies had just formed and the TTF lacked sufficient staffing or methods to evaluate their work. These vendors were operating under a CDPH CLIA waiver, thus CDPH had to mitigate the risks with having private companies using the State's CLIA waiver.

- Consequently, when trying to expand the end-to-end program to meet demand in schools, the TTF school's cohort team developed a more robust process to vet vendors. This included creating multiple structured interviews to recruit companies systematically. CDPH used a list of companies that had been compiled by McKinsey, which was helpful and time-saving, according to SMEs. Ultimately, the TTF contracted with five additional vendors, which enabled it to sufficiently expand the end-to-end program. However, this was only accomplished after delays of several months, which SMEs noted was "embarrassing and frustrating."
- The main lesson learned, according to SMEs, the importance of having experienced and knowledgeable State personnel in positions where they could help vet companies and engage in the contracting processes. TTF leadership added that it was important to have experienced vendors, and to implement methods for tracking and monitoring the vendors once selected, Finally, TTF leadership recommended using processes and procedures developed by TTF staff during COVID-19 for vetting and monitoring vendors in the future.

Importance of Including Equity in Vendor Contracts

- Ensuring testing equity was a primary goal of the TTF's programs throughout the pandemic response. Incorporating equity requirements into the TTF's vendor contracts became critically important. As one SME explained, vendors knew that they needed to address equity when proposing their services. But in practice, vendors had different understandings of what equity meant and how to operationalize it. One SME recounted the significant time and effort spent working with vendors to reinforce the importance of equity and modifying programs to make them more equitable. In one example, a vendor claimed to have bilingual staff, but it was actually just one staff person in a county where half of the population spoke Spanish. One SME noted the extensive time and energy spent on reinforcing the State's equity priorities to vendors, which was "not easy and

not something vendors were used to." TTF members indicated that it would quickly become very clear when a vendor did not prioritize equity.

- A key lesson learned included adding specific equity requirements in contract language, for instance stipulating language access and translation requirements. "Having equity written into contracts and making sure vendors understand equity is a key to success," one leader noted. The TTF learned from these early experiences to include required languages in vendor contracts.
- Another lesson learned was the importance of having the State monitor equity performance by vendors, such as requiring vendors to report equity metrics. For instance, Optum Serve and other vendors were required to provide record-level data, which the TTF used to measure testing access by race, ethnicity, HPI quartiles, and other equity categories. As one leader summarized, it was "critically important" to think about the information that will be needed from vendors to help monitor and determine whether equity-targeted populations are being reached.
- For further discussion the TTF's equity work, see the Equity section later in this chapter.

Outbreak Response Team

Outbreak Response Team Offered Mobile Testing and Vaccination Services

- In summer 2021, leadership from TTF, CDPH, CalHHS, and the Governor's Office determined that the State needed to respond more rapidly to outbreaks. Several factors contributed to this determination. At the time, there was a significant international shortage of antigen test kits, which coincided with rising demand for testing due to the Delta surge and State Public Health Officer orders requiring vaccination or testing for school staff and state employees and other settings. Simultaneously, CDPH leadership was concerned about the potential for outbreaks in K-12 schools, which were preparing to resume in-person instruction for the 2021/2022 academic year.
- Consequently, the TTF formed the Outbreak Response Team (ORT) program, an operational team of vendors who were on standby and ready to deploy quickly to outbreaks. The TTF contracted with two vendors

(Mobile Med and Snap Nurse) to provide these services at no cost to communities. Originally, it was envisioned that the ORT teams would provide only testing services in response to outbreaks. However, CDPH leadership later determined that the teams should also provide COVID-19 vaccination services. Ultimately, the ORT program consisted of 10 teams that could provide both testing and vaccination services, and four teams who provided testing services. The ORT program represented another innovative concept that CDPH had not implemented before. The program was managed by a TTF representative and a representative from CDPH's Center for Preparedness and Response (CPR).

- The ORT resources were strategically deployed around the State. Much was unknown at this point. "We really had no idea what the need was going to be and how much demand we would get," one SME noted. Concerned that demand for the outbreak response teams would be overwhelming, the program team required that deployments (or "missions") be requested through the State's public health and medical resource requesting process. Schools and facilities submitted requests for ORT resources through their LHJs, and the requests would then be reviewed and approved through the Medical Health Operational Area Coordinator (MHOAC) and Regional Disaster Medical Health Specialist (RDMHS) program. Although the ORT program used the standardized resource requesting channel, they did not use the Public Health Ordering System (PHOS), which is typically used for resource requests. PHOS was deemed to be "too complicated," according to one SME, and the ORT program instead set up a separate online intake form to collect information about deployment requests. This request form was disseminated to local response partners, LHJs, MHOACs, and RDMHSs.
- CDPH maintained a "no wrong door" policy for COVID-19 assistance, so requests for ORT deployments that came in via other channels were not turned away. Especially during surges and busier periods of the response, CDPH focused on providing State resources as quickly as possible, no matter how the request came in. However, CDPH's Medical Health Coordination Center (MHCC) Operations Team found this new process to request and deploy ORT resources challenging. For further discussion, see the Resource Requesting and Public Health Ordering System chapter in this AAR.

- In retrospect, the program team noted that requiring ORT requests to be approved by LHJs, MHOACs, and RDMHSs was a deterrent. Consequently, the teams were not fully utilized. One SME explained that "we would have gotten more utilization of teams if we'd made it easier for people to request them—but also could have potentially gotten more requests than we could handle."

ORT Coordinated with Other Teams to Deliver Testing and Vaccination Services

- When California's schools reopened in Fall 2021, many ORT resources were deployed to respond to school-related outbreaks. ORT teams were also frequently deployed to jails, correctional facilities, and homeless shelters. The ORT program also collaborated with the CDPH Outbreak Consultation Team (OCT). The OCT was formed in Fall 2021 within CDPH's Coronavirus Science Branch and was composed of physicians, industrial hygienists, epidemiologists, and health educators. While the ORT was an operational program focused on rapid interventions, the OCT was a consultative program focused on providing technical assistance, consultation, and education to help prevent outbreaks.
- Both teams began to collaborate and met weekly. They also began to provide cross-referrals for each other's services. For instance, during deployments, ORT teams would gather information on facilities in need of outbreak consultations, and would pass this information to the OCT. Conversely, as the OCT program grew and began to receive actionable epidemiological information, they would refer facilities in need of testing or vaccination services to the ORT.
- The ORT's core program involved providing outbreak response teams. However, during slower periods or in between surges the program experimented with what it called "other use cases" to keep the deployment teams utilized (since they were already on standby). The program team would coordinate with other response teams, such as the Vaccinate All 58 Campaign and CDPH's Office of Health Equity, to have the ORT teams offer testing and vaccination services at specific events. The ORT teams were a flexible resource and the program tried to pivot its approach to respond to changing needs while maximizing its resources. Oftentimes, just as ORT teams would get busier with these "other use cases," COVID-19 case numbers and outbreaks would rise, and the ORT

program would pivot back to rapid outbreak response. As one SME noted, the program was "great at being nimble".

- Ultimately, the ORT program deployed response teams to over 1,150 sites and administered over 24,000 COVID-19 tests and over 12,400 COVID-19 vaccinations throughout the State. The program was demobilized in October 2022 as demand waned, but the vendor contracts remained in place with the capability to re-mobilize until June 2023.
- Overall, the program was successful and SMEs indicated pride in its implementation. "We got so much positive feedback and people still love the concept," one SME noted, pointing out that the program was dedicated to "helping out partners in a bind or during stressful times." While the program was demobilized, SMEs indicated that the concept of CDPH rapidly deploying community mobile resources should be "continue to be kept in our back pocket" in case of future need.
- If the ORT (or similar) program were to be resurrected in the future, one key lesson learned relates to the possibility of separating the testing and vaccination teams, instead of bundling these services together. The concept of a "dual team" that provided both services proved to be under-utilized. SMEs felt that it was a "good concept" in case people who got tested also wanted to receive vaccination. In practice, "the vaccine component never really caught on," and the dual services was rarely used. The most frequent requests where for either separate testing or separate vaccination services.
- From a resource efficiency perspective, the vaccination teams were more costly to maintain on standby than testing teams. In the future, SMEs recommended bifurcating the teams. "We could have probably constructed the contracts with two kinds of teams instead of combination teams," one SME noted. The combination teams were a "costly resource to have people on standby if they're not being well used," another added.
- Another lesson learned was the importance of continuously publicizing the program to make sure that schools and other facilities were aware of it. "This resource requires constant marketing and reminding people that it exists," one SME noted, pointing out the program team could have publicized it more directly in communities. However, to accomplish this the program would have needed a health educator or a communications

resource, since the program team was occupied with running the program, coordinating vendors and requests, and managing deployments.

Equity

This section describes equity considerations specific to this chapter.

Equity Was a Cornerstone of All TTF Programs

- Equity in testing was an early and constant focus of the TTF. In summer 2020 the TTF focused on improving testing equity for its PCR programs, since the first State-run PCR testing sites had equity barriers related to required online registration and minimal walk up (as opposed to scheduled) services. During this time, there was also growing awareness in public health of inequities in COVID-19 outcomes and the disproportionate impact of COVID-19 on disadvantaged Californians. With the launch of TTF 2.0 in summer 2020, the State prioritized testing equity and this remained a priority for all subsequent TTF programs. "We did a ton of work to make sure that we introduced an equity lens in testing access, and it was very successful," one leader noted. Another SME echoed that "our programs as a whole were very much focused on equity." The TTF established a dedicated Equity Lead who oversaw all equity efforts, including monitoring and tracking equity metrics.
- To increase testing equity in 2020, the TTF used a multipronged approach that was based on a gap assessment. Once it became clear that the earliest PCR testing sites had barriers for rural populations, the TTF implemented a variety of solutions. These included establishing more fixed sites in rural locations and introducing mobile testing units, which one leader termed "groundbreaking." The Optum Serve PCR sites were also modified to allow walk-up appointments, since requiring advance registration proved to be an equity barrier. One credited the LHJs with identifying this barrier, noting that "it was a really good collaboration with LHJs to bring forward." As one leader recounted, the State developed a multitude of different strategies to decrease testing inequities and increase access in "testing deserts".
- As discussed earlier, the TTF worked with CBOs and other non-traditional partners to establish a network of thousands of State-supported testing collection sites, also known as community sites, which were supported by the State's PCR collection program and the State's professional antigen program. These sites often served vulnerable populations, including the unhoused and uninsured, and were specifically located in lower HPI

quartiles. Another SME agreed that "setting up thousands of organizations where you could get tested" was "the most innovative thing we did." In addition to considering equity needs when choosing site locations, the TTF also identified other issues that could be potential barriers to testing—such as technology, language, or that individuals might not want to provide their address to get tested. These were all "important things that we worked on to make sure they weren't [creating] barriers," one SME noted. The TTF's COVID-19 Courier Network (discussed earlier in this chapter), which offered free transportation of test samples, was also an equity intervention designed to help make testing easier for rural locations. Later in the pandemic, the TTF amended its contract with Color to include additional equity considerations for PCR test collection services, such as supporting sites with technology and physical materials, as well as offering smaller test quantities for shipping to remote locations.

- For the professional antigen testing program, the TTF worked to provide additional resources to organizations who were burdened by the program's operational and reporting requirements. As one SME explained, sometimes the State's hardest-hit communities were not necessarily able to implement the State's recommended testing program. In such cases the TTF offered support supplies (including iPads and other equipment) and the team members would spend extra time meeting with communities and identifying other potential wraparound services or funding that the State could provide. "We knew it was so important that these equity partners were given the chance to have these resources," one SME noted.
- TTF SMEs described the continual process of researching and identifying what additional types of support the State could provide, such as additional funding to wi-fi access. For instance, one of these additional equity supports was a Standing Up Testing grant, which funded organizations that served farmworkers, Black and Latinx communities, and immigrants at the California-Mexico Border. The TTF funded 37 organizations (representing approximately 90 testing sites) with the Standing Up Testing grant. According to SMEs, an important lesson learned included the need to continue identifying the best methods to get resources to communities faster and reduce barriers to testing. As a lesson learned, a leader highlighted the need for CDPH to create an equity playbook on how to operationalize equity into emergency responses. The

playbook would include templates on how to implement equity, methods on measuring inequities, and developing equity solutions.

- Lastly, to support communities, TTF executed a translation contract for up to 15 priority languages with 170 possible languages and a language line contract with 350 languages for translation to be used by community testing sites, Optum Serve, and TTF staff as needed.
- For discussion of how equity was operationalized in TTF's schools programs and the OTC program, see the Analysis of Activities section above.

Importance of Data to Operationalize Equity

- To successfully embed equity in every TTF program, the TTF established and monitored a variety of equity metrics and data points to measure progress. On a weekly basis, the TTF measured testing volumes, testing turnaround time, and testing locations in the lowest Healthy Places Index (HPI) quartiles. Other metrics that were incorporated in the TTF's data models included race data, ethnicity data, case rate data, and death rate data. The TTF compared race and ethnicity testing metrics to case counts and death counts in the same populations to help understand if the TTF's programs were populations most at risk for COVID- 19 and its complications and death.
- The TTF's equity metrics were measured for all programs on a weekly basis to identify communities in need of more testing, confirm that testing resources were getting to the right populations, and other potential equity concerns. When the analysis revealed communities or populations with higher case rates, higher death rates, or other equity concerns, the TTF performed outreach to help them receive more testing support and resources. The TTF continued testing equity monitoring on a weekly basis for over a year and a half after its inception before shifting to a less frequent cadence.
- TTF also used data metrics to determine allocations of professional and OTC antigen testing supplies to be distributed to LHJs and their affiliated organizations. Data used included cases counts, case rates, change in rates, ICU capacity, and HPI quartiles.
- Having accurate, representative data was important to tracking testing equity. However, race and ethnicity testing data were not originally captured by CalREDIE, the Statewide disease surveillance system used by

labs to report testing results. Before the pandemic, these data elements had not been required to be reported. However, early in 2020 as public health officials began to realize the disproportionate impact of COVID-19 on communities of color and other traditionally underserved populations, a process was initiated to collect race and ethnicity testing data. This was not a simple process, as it required extensive programming for CalREDIE to be able to accept the new data elements. Labs also had to update their systems to be able to send this data to the State. "People were working night and day" to make these changes, one SME explained, noting that for labs who had previously not collected this information, requiring them to do so was a significant undertaking. In addition to these changes being made to the CalREDIE system, the TTF required its vendors, including Optum Serve and Color, to incorporate race and ethnicity data in their registration platforms. The TTF was able to integrate demographic data elements with sample data, which provided valuable insights on who was getting tested. Ultimately, the efforts to improve the data quality and infrastructure resulted in the creation of analytics, metrics, and data points that helped the TTF operationalize and monitor testing equity. "It's really changed how we operate within the State," one SME noted.

- For further discussion of CalREDIE and lab reporting, see the Data and Reporting chapter in this AAR.

Data and Technology

This section describes data and technology specific to this chapter.

- Throughout the pandemic response, the TTF collected, monitored, distributed, and reported on testing-related data to guide testing efforts Statewide. Some of California's most important metrics throughout the response were its COVID-19 case rates, test positivity rates, and race and ethnicity cases and case rates, which were derived from laboratory test results. The relationship between case data and testing data is discussed in the Data and Reporting chapter in this AAR.
- In addition to these key metrics, the TTF also developed its own program-specific metrics to evaluate and track its various testing programs. For instance, for TTF vendors PerkinElmer, Color, Optum Serve, the TTF tracked test volumes across the State as well as throughout of the TTF programs and cohorts. This included test turnaround time, test invalid rates (for State-sponsored testing), and test utilization rates. It also tracked metrics related to PCR test kit supply and distribution (via Color's vendor dashboard) and site-level utilization rates (via Optum Serve's vendor dashboard). The TTF also tracked the number of tests performed, positivity rates, and the number of tests ordered and utilized in its professional antigen testing programs and OTC kits. These and other metrics were frequently published via dashboards and reports to TTF and State leadership on a weekly basis (at the county level), and were used internally to help manage the TTF's testing programs.
- One of the main challenges was the lack of an existing system to collect and report on testing data. Unlike the Vaccine Task Force, which was able to leverage the State's existing immunization registry (CAIR2), there was no existing Statewide system that could be used to comprehensively track testing data. CalREDIE, the State's disease surveillance system, captured positive and negative COVID-19 PCR test results submitted by labs, but was not prepared to track professional antigen test results and OTC test results. Hence, for TTF programmatic metrics, the TTF relied on McKinsey to develop tracking systems for the PCR, professional, and OTC antigen programs. The TTF also relied on its various PCR, and antigen test vendors to provide the data from their program activities.

- McKinsey performed the bulk of the data metrics tracking, integration, and reporting for the entirety of the TTF. McKinsey met with programmatic leads to determine data variables and metrics as well as methods for capturing data and then vetted these with TTF leadership before implementing them. This was a large undertaking and required multiple McKinsey staff to meet with TTF staff to determine metrics and implement data tracking methods. The TTF tried to obtain redirected State staff to do this work but there were no data analytics, epidemiology, or surveillance staff available to be redirected to support this work. Additionally, the TTF tried to hire contract staff with these skillsets, but this effort was unsuccessful. According to one leader, after multiple job postings for over nine months received no applicants, it was clear that the expertise was not available internally or externally.
- One of the many data and analytics challenges was to integrate the TTF's disparate vendor data into comprehensive leadership reports to inform decision-making. This challenge grew over time, as antigen testing and subsequent new TTF programs made it even more difficult to share and integrate data between vendors. Vendors provided data in various forms and standards that were not always compatible with other datasets.
- As a solution, McKinsey managed a data working group and also created the "Golden Tracker" program for the schools data, an Excel-based workflow management tool that helped generate the summary-level data needed for TTF's reporting. The Golden Tracker process involved significant manual data entry as well as complicated data manipulation. As one SME explained, because the TTF's vendors were so "discordant," this process was needed "just to be able to generate [weekly] reports to keep the programs going." SMEs noted that data integration would have been easier if the TTF had established data requirement parameters for all its vendors up front, especially the need to report and communicate in a simple, consolidated way.
- Unfortunately, this type of data reporting infrastructure had not existed prior to COVID-19, and many vendors were stood up simultaneously during surges. The TTF's data reporting needs changed over the course of the programs from tracking implementation data (to ensure programs were on track to reach the populations and communities most at risk) to tracking tests performed, turnaround, positivity rates, and equity metrics.

- When McKinsey rolled off the TTF in Summer 2022, with the plan to transition data and analytics to the CDPH data and analytics team, the TTF's ability to track and report on its data diminished. Despite the goal to transition this workload to CDPH's data and analytics team, there continued to be limited available expertise within CDPH to support the numerous metrics and dashboards that McKinsey had created.
- CDPH data and analytics staff worked with TTF leadership to streamline and limit required data efforts since there was little bandwidth to support this work. Data efforts focused on CalREDIE testing volumes across the state, and statewide PCR testing turnaround time. CDPH data and analytics staff also created LHJ test allocation numbers using equity formulas with CalREDIE data to determine how many tests could be allocated to each LHJ.
- All other data regarding TTF testing programs (e.g., the data associated with its CBOs, CDSS, and schools) had to be generated by existing TTF staff or vendors. As such, the TTF team members struggled to take over the complex data and reporting processes originally created by McKinsey with minimal documentation and training. The TTF SMEs were frustrated by the inability to revise, change, or update many of the systems and processes built by McKinsey. Unable to sustain the products and infrastructure that McKinsey had created, the TTF created a new data working group to understand, review, and manage the MS Dynamics data migration. Ultimately TTF staff created their own simplified data systems to track State-run programs.
- The experience resulted in multiple lessons learned, including the missed opportunity to involve CDPH's expertise when the TTF's data reporting was first established. According to one SME, while CDPH had epidemiologists, data analysts, and other staff who could have helped build sustainable data streams, "we were never given that infrastructure." A TTF leader noted that this was due to the fact that there were not enough staff with these skillsets available at CDPH to support the numerous programs that required them during the pandemic.
- Another lesson learned involved the need for standardization and sustainability. In the future, if the State were to rely on contractors for extensive data reporting needs, a SME felt that it was important to "keep

things simple" and require the use of sustainable software tools that can be adopted by the State.

- Some SMEs advocated for the importance of thinking strategically ahead of the next pandemic to ensure sufficient epidemiologists, data analysts, and other similar staff are available within the State structures to avoid the creation of unsustainable processes in the long-term. One SME noted that consultants, vendors, and contractors can be valuable partners, but felt that it was important to understand if possible whether "the consultant [is] going to complicate our end goal" by creating processes and work that cannot be ultimately taken over by the State.
- For a discussion of the Lab Testing Metrics Application (LTM), CalREDIE, and how CDPH worked with labs to help them report test data, see the Data and Reporting chapter in this AAR.

Communications

This section describes communications specific to this chapter.

External

Communication with the Public

- The TTF leadership worked closely with the Governor's Office and CalHHS on public communications related to testing. These included holding occasional press conferences with high-level officials. Additionally, the TTF had numerous stakeholder meetings where it both reported out and received feedback on programmatic work.
- In the initial two years of the of the TTF, TTF leadership reported out regularly to the California Legislature when in it was in session. The TTF also reported out to local elected officials (initially daily, then twice weekly and later weekly).
- Early on in the pandemic, the TTF developed a weekly stakeholder group that included a broad spectrum of key organizations including public and private stakeholders (e.g., academics, hospital and healthcare foundations, long-term care associations, LHJs, and State department leadership). This group continued to meet through the first two years of the pandemic (initially meeting weekly then twice a month and later monthly). As the TTF's programs were fully launched and interest waned in this meeting, the meeting was discontinued.
- TTF also met regularly with the County Health Executives Association of California (CHEAC) and the California Conference of Local Health Officers (CCLHO) to report on progress and receive feedback from LHJs. Initially this was twice a month and then later monthly. These meetings continued throughout the pandemic and stopped when the TTF closed in June of 2023.
- TTF also reported out weekly on other CDPH weekly calls including All Facilities calls, SNF calls and LHJ check-In calls.
- Beginning in summer of 2020, after TTF 1.0 closed and prior to the start of TTF 2.0 (when turnaround times were 7-10 days long), TTF in combination with CalHHS and CDPH leadership called a meeting with California public and

private lab directors across the State to understand the barriers and facilitators to lab turnaround time. TTF held these meetings weekly during this surge and subsequent surges to communicate what was being seen at the State level and understand barriers the labs were facing across the State. These meetings were discontinued after the Omicron surge, as the TTF was winding down. The same lab directors were queried about their lab capacity via a survey weekly until June 2022, and then monthly from July 2022 to June 2023.

- The TTF maintained a robust website for the public, the media, and for participants interested in its COVID-19 testing programs. The TTF regularly posted its key metrics and reports on the website. The website also included information on where to access testing services and sign up for state testing programs
- For a discussion of the public-facing COVID-19 data dashboard, which included testing data, see the Data and Reporting chapter in this AAR.

Communication with CBOs

- The approaches to communicating with organizations who participated in TTF programs varied by cohort. CBOs who participated in the professional antigen testing program needed extensive and ongoing communications. The State "asked these CBOS to rise up and become medical providers," one SME explained. To accomplish this the TTF provided education, training, tracked testing results, and ensured compliance and quality. Therefore, communication needed to be customized to the needs of the CBOs. In addition to the formal trainings and sessions that sites had to go through to offer testing, the TTF also offered regularly scheduled office hours and many ad hoc one-on-one meetings so that CBOs had the opportunity to ask questions and receive assistance. As one SME noted, "building relationships with trusted community members has been huge for us in terms of word of mouth."
- The TTF's communications evolved and improved over time. For instance, after receiving feedback on its training and onboarding, the TTF made adjustments based on that feedback. In general, SMEs felt that the TTF was successful at developing communications, identifying the most successful methods, and then implementing improvements. However, one SME felt that it would be beneficial to establish "a more formalized process for

consolidating best practices." The SME noted that while this was impossible during the emergency response, it would have been helpful to establish a systematic way of gathering lessons learned and implementing best practices into ongoing programs.

Communication with LHJs

- Early on, the TTF did not recognize the need for transparency with LHJs, according to leadership. Many efforts, including the distribution of antigen test kits (e.g., BinaxNOW) and the development of systems would have benefited from more local input.
- Eventually, the TTF established weekly (or bi-weekly) meetings with LHJ's, public health officers, and local public health stakeholders. In advance of these meetings, the TTF supplied them with county specific dashboards to help guide the discussion. The main focus of these check-in meetings were testing equity and testing utilization.

Communication with Schools

- The TTF schools cohort, which included both its professional antigen and PCR testing programs, developed communication strategies tailored towards California's K-12 schools. According to SMEs, schools are "very high-touch" and "constant communication with schools is imperative." As a result, the TTF developed multiple ways and channels to communicate with schools and maintained a dedicated Schools Testing Lead and schools team and cohort members. Within the schools antigen program, members focused on communicating with schools, school communities, parents, and other education stakeholders. These included the California State Board of Education, the California Department of Education (CDE), the State Superintendent of Public Instruction, the county offices of education (COEs) and school district superintendents. Additionally, the TTF also needed to communicate to LHJs about schools testing within their jurisdiction, and with the Safe Schools for All team (SS4A), which coordinated the work of different response teams (e.g., testing, vaccines) within schools.
- The TTF distributed e-mails via school list serves and followed up with phone calls and individual emails to help schools better understand their testing options. The TTF also communicated to schools directly via the testing programs they had implemented, since the software associated with these

programs allowed for direct communication to the sites onboarded on those programs. The TTF also hosted office hours and frequently asked questions (FAQ) meetings several times per week with schools because schools preferred having a live forum.

- The schools antigen testing team had challenges effectively using communications software. For instance, the team had trouble leveraging tools such as Constant Contact. Because many schools and some government agencies block these tools, the team had to rely on list serves and regularly scheduled meetings instead. Additionally, the team reported challenges with obtaining approval for messaging and website content. This process could take months and oftentimes by the time it was approved, the communication was outdated and no longer accurate.
- The school's PCR testing team participated in weekly office hours and also implemented separate outreach for schools that wanted PCR testing. This included meeting with county offices of education and LHJs to share information about the program, and invite interested participants to additional meetings to learn more.
- The TTF conducted focus groups with schools and according to SMEs, the main feedback was that CDPH's communications could be confusing. As a solution, SMEs recommended that CDPH work more closely with its education partners. CDPH shared public health information with schools, but according to one SME, "we should've collaborated a bit more with education partners to leverage their relationships with schools." This would have included potentially relying on CDE's local relationships to communicate information. As one SME summarized, CDPH and the TTF could have reached more schools if "we had actually used our partners more effectively to spread the word in a more trusted way that's more familiar to them." However, now a significant opportunity exists for deepening the collaboration between public health and public education to benefit California's students, SMEs said.

Internal

Communication within the TTF and CDPH

- TTF leadership reported out regularly at CDPH leadership morning check-in calls. The cadence of these report-outs changed over the course of the pandemic (from daily, to twice weekly and later weekly).
- Early in the pandemic response, the TTF established internal weekly reporting cadences for all programs. At these "All Hands" meetings cohorts would report on their metrics, including equity metrics, site onboarding metrics, testing volumes, and test positivity rates. Summaries of these reports were also disseminated to CDPH leadership, CalHHS, and other policy-makers. However, as the TTF expanded in size and brought on new contractors and vendors, the All Hands meeting grew increasingly challenging to manage. Each cohort had a unique set of stakeholders with very different needs and would raise multiple unique issues needed to be solved in each meeting.
- As the TTF's McKinsey consultants decreased their own staffing levels beginning in Spring 2022, they recommended that TTF leadership hold two separate meetings (one for the schools cohort and one for the community cohorts) to manage the sheer volume of work associated with the different programs. The rationale behind this recommendation was to ensure that the large schools programs had enough support given the anticipated decrease in CDPH and McKinsey staffing levels. Consequently, the All Hands meeting was discontinued. A few months later, a smaller, higher-level meeting (the Products and Shared Services meeting) was established with all cohort leadership to address emerging cohort questions. Cohort leaders would bring issues from their cohort team members to be addressed with TTF leadership at the Products and Shared Services meeting.
- SMEs from many different cohorts lamented the lack of an All Hands meeting and felt that discontinuing it contributed to silos and inefficiencies. Without a forum for all TTF members to share information, earlier opportunities to consolidate similar processes were missed. As one SME noted, "our processes are all different even though we have similar workstreams," adding that having more standardization across cohorts would have been beneficial in the long-term.
- Many described a split between the professional antigen programs and the PCR programs. One SME described working on an antigen program for six months before learning of the existence of the PCR programs. "We had

no collaboration at all with the other cohorts," one SME noted. In late 2022 when volume and demand had substantially subsided (with less than 1,000 sites of the original 4,200 remaining) the professional antigen programs were integrated into a single cohort and the PCR programs were wound down. This consolidation resulted in better communication and improved efficiencies.

Managing Inbox Communications

- Due to sheer volume and uniqueness of stakeholders the TTF maintained multiple email inboxes, including a general inbox and approximately four inboxes devoted to testing in schools. Later in 2022, when the total number of sites had substantially decreased (to aproximately1,300) and the programs were being integrated, the communication silos between TTF cohorts resulted in difficultly aligning messaging that was delivered through the TTF's multiple email inboxes. There was "a ton of information going out," one SME noted, and it was often difficult to align communications across teams. When consolidation was underway, different cohorts conducted community outreach and onboarded organizations into the newly-consolidated testing programs, they would often provide organizations with the general inbox email address. However, the team members who managed this inbox often were not aware of this and received questions on topics they did not know how to answer. As a result, team members would have to figure out what the question was referencing, identify the right point of contact to answer it, and then learn the subject matter to respond in the future.
- The team who managed the general inbox initially developed a "how to" document with content that could be used to answer emails. However, because information changed rapidly (especially when the TTF was implementing and closing programs), information quickly became outdated and the document grew too unwieldy to manage, so it was discontinued. Team members found it easier to adapt their previous emails and rely on their institutional knowledge.
- It was also a struggle for the TTF to maintain updated organizational charts, especially towards the latter half of the pandemic response. In Summer 2022, the McKinsey consultant team, which had been maintaining the charts, began demobilizing. Simultaneously, CDPH leadership began to discuss plans for winding down the TTF, which took several months due to

the Mpox emergency response and State budget considerations. As the TTF waited to learn whether any of its programs or staff would remain beyond June 2023, its organizational charts were not updated or maintained. Consequently, as certain TTF programs began closing in Fall 2022, it was often difficult to identify the right individuals to answer incoming questions. According to one SME, it was not uncommon for questions to be "bounced around" to five different teams before finding an individual who could answer it, which delayed responses. Ultimately, it would have helped to have more individuals cross-trained in managing the inboxes, look for ways to consolidate inboxes, and align communication between TTF members sending out information and those fielding incoming questions.

Workplan

This section is designed to be used as a workplan for future pandemics.

Definitions:

- **Phase**: The phase of the response in which the major tasks should be conducted (Planning; Initial start-up, Ongoing operations, or Close-out).
- **Major Tasks:** The tasks and activities that have to be conducted as part of the public health emergency response to a respiratory pandemic.
- **Success Criteria:** Criteria used to assess whether a task has been achieved successfully.
- **Considerations Based on COVID-19 Response:** Things to consider, including pitfalls, risks, and lessons learned, based on the COVID-19 response.
- **Finding ID:** The ID(s) from the related Finding/Corrective Action (where applicable).
- **Lead:** The lead person(s) responsible for task completion.

Phase	Major Tasks	Success Criteria	Considerations	Finding ID	Lead
Planning	Improve public health lab infrastructure	• The State's public health lab network is adequately resourced and can rapidly scale testing capacity in the future.	• Improved resources (funding, staffing, equipment, and infrastructure) will require more funding. • Funding may require legislation.	• Testing 19	Center for Lab Services Lab Director
Planning	Remove regulatory barriers and develop	• Regulatory barriers are removed and do not hinder the	• Establish "off the shelf" expedited regulatory	• Testing 7, 8,20	Center for Lab Services Director

Phase	Major Tasks	Success Criteria	Considerations	Finding ID	Lead
	innovative solutions	rapid expansion of testing capacity.	methods in advance. • Involve academics and larger commercial labs early along with State and local labs in order to support rapid scaling of testing. • Implement CLIA waived professional program in the communities impacted by disease; include best practices (Statewide CLIA waiver and scalable software programs to support onboarding and reporting)		
Planning; Initial start-up; Ongoing operations	Launch a Testing Task Force (or similar group) to develop	• The State can offer various free testing modalities and programs depending on changing needs.	• Maintain rapidly-scalable necessary programmatic infrastructure (staffing,	• Testing 1, 4, 6, 7, 9, 10	

Phase	Major Tasks	Success Criteria	Considerations	Finding ID	Lead
	innovative testing programs		technology systems, ordering and distribution systems, administrative processes, etc.) • Pilot and implement new testing programs and modalities (e.g., lab based, CLIA waived, OTC, etc.)		
Initial start-up; Ongoing operations	Establish and maintain program communications	• Testing communications are targeted to reach different audiences across multiple channels.	• Establish key stakeholder groups and associated regular cadence-meetings (e.g., public/private partners, LHJs, lab directors, locally elected officials, State leadership etc.) • Recognize different clientele have unique communications needs and schedule specific meetings and	• Testing 16, 17, 18,	

Phase	Major Tasks	Success Criteria	Considerations	Finding ID	Lead
			office hours (e.g., schools, CBOS, etc.) • Hold all staff meetings on a regular cadence • Develop a public website, weekly calls with LHJs, and individual meetings and office hours with program participants • Develop a process to collect feedback on communications and implement best practices • Leverage partnerships with educational partners to better communicate with schools.		
Planning; Initial start-up; Ongoing operations	Ensure the Testing Task Force is adequately staffed	• The TTF is staffed with individuals who possess the requisite skills, abilities, and experience.	• Improve the redirection process to better align staff skills with program needs.	• Testing 30, 33, 34	

Phase	Major Tasks	Success Criteria	Considerations	Finding ID	Lead
			• Redirect State staff from other state departments (beyond CDPH) to sufficiently staff TTF • Redirect state admin and budgetary staff early on • Spread higher-level State staff, evenly across cohorts/programs. • Hire contractors with public health, clinical, or scientific expertise whenever possible. • Include State staff with experience with vendor selection and contracting processes.		
Planning; Initial start-up; Ongoing operations	Operationalize testing equity in all programs	• Testing equity is implemented through a multi-pronged, data-driven approach.	• Appoint an Equity Lead • Develop and track equity metrics. • Consider creating an equity	• Testing 2, 35	

Phase	Major Tasks	Success Criteria	Considerations	Finding ID	Lead
			playbook based on the TTF's processes. • Incorporate equity language in all vendor contracts. • Require vendors to report uniform equity data. • Anticipate that vendors may need education on what equity means.		
Planning; Initial start-up; Ongoing operations	Establish a dedicated schools cohort	• The State can support schools' unique testing needs.	• Recognize that schools have unique testing considerations. • Provide additional operational support to under-funded schools (can leverage the E2E and direct funding program developed for COVID-19). • Consider whether or not to offer a direct funding program, to	• Testing 11, 12, 29	

Phase	Major Tasks	Success Criteria	Considerations	Finding ID	Lead
			schools given its heavy fiscal administrative burden.		
Planning; Initial start-up; Ongoing operations	Establish and maintain internal communication and coordination	• TTF cohorts are equally resourced and provided a forum to coordinate and communicate internally.	• Ensure sufficient administrative support staff throughout the response to maintain an up-to-date organizational chart. • Institute and maintain regular All-Hands meetings to avoid silos. • Shift limited resources as needed to provide the sufficient support to all programs/cohorts.	• Testing 31, 32	
Planning; Initial start-up; Ongoing operations	Establish and maintain robust fiscal and budgetary processes	• The TTF has its own budgetary staff sufficient to support the size of budget and complexity of operations.	• For the TTF (and other response teams), create a dedicated State fiscal team sufficient in size to meet budget	• Testing 36, 37	CPR Fiscal Lead

Phase	Major Tasks	Success Criteria	Considerations	Finding ID	Lead
		• TTF has full ownership of the budget. • TTF budgetary staff are sufficient, and roles and responsibilities are delineated and clear to team members who may need quick consultations.	budgeting demands and complexities, as early as possible. • Anticipate the need for State staff, since they can perform contracting/fiscal functions that contractors cannot. • Clearly establish and communicate roles and responsibilities for fiscal and budgetary processes. • Ensure fiscal staff have an understanding of incoming contracts, programmatic work and how billing and invoices can be applied to various funding sources		

Phase	Major Tasks	Success Criteria	Considerations	Finding ID	Lead
Planning; Initial start-up; Ongoing operations	Launch an Outbreak Response Team	• The State can respond rapidly to outbreaks by deploying mobile resources.	• Execute vendor contracts that allow for separation or combination of testing and vaccination services for greater cost-efficiency. • Continuously promote the program to increase utilization. • Include a health educator or communication specialist to assist with program promotion. • Collaborate with other CDPH teams working on outbreaks (e.g., investigations and consultation.)	• Testing 13, 14, 15	
Initial start-up; Ongoing operations	Consider implementing a State-run lab network	• A network ensures the capacity to level load specimens when	• Apply lessons learned from the Valencia Branch Lab to a future	• Testing 3, 22, 23, 24, 25	Center for Lab Services Director

Phase	Major Tasks	Success Criteria	Considerations	Finding ID	Lead
		testing volume is high. • The State has access to a large, flexible, and scalable lab network.	similar State-run lab network. • Incorporate robust State oversight of testing lab operations into State run lab. vendor contracts. • Clarify turnaround time metric requirements in vendor contracts. • Require vendors to use simple registration systems. • Require vendors to report data metrics. • Anticipate and plan for staffing shortages. • Anticipate and plan for shortages in testing supplies.		
Initial start-up; Ongoing operations	Establish a courier network	• Specimens can be transported timely from community collection sites to labs for processing.	• Use the California COVID-19 Courier Network as a model. • The CCN offered over 100 drop-box	• Testing 5, 6	TTF Programmatic / operations team member

Phase	Major Tasks	Success Criteria	Considerations	Finding ID	Lead
		• Community testing sites are not burdened with the cost and inconvenience of specimen transportation.	locations throughout the State, and, later, prepaid shipping labels. • Evaluate whether to solely offer prepaid labels for shipping, or labels in addition to drop-boxes depending on volumes and locations		
Initial start-up; Ongoing operations	Increase testing capacity at a reasonable pace	• Bring in academic and private commercial labs early to support more scalable testing early on. • State resting capacity is expanded at a reasonable pace.	• Balance the need to expand testing capacity quickly with the need to avoid quality control, equity, and operational challenges, which are likely to result from rushing. • Heed recommendations from CDPH laboratory experts regarding timing.	• Testing 21, 23	Center for Lab Services Director
Initial start-up;	Streamline reporting and administrative	• Participants in testing programs understand and	• If possible, use the same reporting and registration	• Testing 26, 27, 28	

Phase	Major Tasks	Success Criteria	Considerations	Finding ID	Lead
Ongoing operations	requirements for testing programs	can comply with reporting and program requirements. • Requirements are not a barrier to program participation.	tool for all programs/cohorts • Explore ways to reduce reporting burdens associated with CLIA-waived testing programs. • Work with vendors to implement QC modules in their reporting software to enable easier compliance.		
Initial start-up; Ongoing operations	Establish a State-supported data and technology infrastructure for testing programs	• The State can track and report testing and program data with timeliness, accuracy, and self-sufficiency. • TTF members are equipped with the right data and technology tools.	• Involve CDPH data and epidemiology teams in testing data and reporting, especially when setting up data streams. • Avoid over-reliance on contractors for data and reporting needs. • Require all testing vendors to report data in a	• Testing 38, 39, 40	

Phase	Major Tasks	Success Criteria	Considerations	Finding ID	Lead
			standardized fashion. • Require testing contractors to build infrastructure that can be easily transitioned to the State.		