

**Monterey County Public Health Laboratory's (MCPHL) Innovative Response to Ramp Up COVID-19 Testing and Sequencing**

**OVERVIEW:** MCPHL used innovative approaches to ramp up COVID-19 testing, implement a new SARS-CoV-2 sequencing platform and assist other labs with expanding testing and sequencing capacity.

**CHALLENGE:** Early in the pandemic MCPHL was the only COVID testing lab in Monterey County. As COVID cases increased, the lab struggled to meet testing demand complicated by a continuum of unexpected challenges. The first major challenge was a month-long delay in testing due to contaminated CDC test kits. While awaiting release of new CDC test kits, MCPHL put together a SARS-COV-2 PCR Lab Developed Test (LDT) and requested Emergency Use Authorization from the FDA. To our knowledge, MCPHL was the only Public Health Laboratory (PHL) in California with a SARS-COV-2 PCR LDT in review by FDA at that time. The second challenge was meeting increasing testing demand. With only three public health microbiologists and limited testing equipment, MCPHL was limited to testing a maximum of 20 specimens per day. As testing increased worldwide, shortages in testing supplies and reagents diminished testing capacity for testing labs, forcing some labs to stop testing. Few labs in California had the knowledge, experience and instruments needed to sequence SARS-CoV-2 to identify emerging variants of concern. Thus, public health departments across the state waited three weeks or more to obtain sequencing results, hampering their ability to track the spread of SARS-COV-2 variants and take timely action to control outbreaks.

**SOLUTION:** To our knowledge, MCPHL was the first PHL in California to bring on a team of college students to assist with COVID-19 testing and data entry resulting in increased testing from 20 to 120 specimens per day. Unlike other labs, MCPHL never stopped testing due to testing supply chain issues. MCPHL stockpiled testing supplies and reagents during early days of the pandemic which allowed MCPHL to trade reagents and supplies with other labs throughout the state. Sharing scarce testing supplies with a local hospital lab allowed them to produce virus transport media that was then shared with hospital labs throughout the region. Bartering lab supplies also allowed MCPHL to assemble COVID specimen collection kits which were provided to hospital labs, clinics, skilled nursing facilities and correctional facilities. MCPHL expanded testing capacity using newly developed commercial COVID PCR methods which allowed use of alternate reagents that were readily available. To further expand testing capacity at other labs, MCPHL partnered with California Department of Public Health (CDPH) to procure and distribute over \$1 million in federally provided COVID test kits and instruments to hospitals in Monterey, Santa Cruz and San Benito counties.

CDPH also provided MCPHL with several high-volume testing instruments and testing reagents, further bolstering testing capacity.

**INNOVATION:** MCPHL purchased an affordable, compact high-volume testing instrument using grant funds before COVID funds were available. MCPHL was one of the first PHLs in California to use the KingFisher instrument to ramp up testing from 120 to 720 specimens per day. Soon other PHLs, including the CDPH lab followed our example and procured dozens of KingFisher instruments. MCPHL was among the first few PHLs in California to start sequencing SARS-CoV-2 and the second PHL to implement SARS-CoV-2 whole genome sequencing using the ClearDx, newly developed SARS-CoV-2 sequencing platform that produced results in 24 hours versus 48-72 hours. MCPHL brought together sequencing experts in academia, Chan-Zuckerberg BioHub, CDPH, Clear Labs and other PHLs experienced in SARS-CoV-2 sequencing and bioinformatics and hosted weekly meetings attended by over 60 participants statewide which helped other labs implement and/or expand sequencing and train laboratorians on bioinformatics. After several months, Theiagen and CDPH took over hosting these weekly meetings. MCPHL also partnered with Dr. Charles Chiu's research lab at the University of San Francisco to sequence specimens from our region, including a SARS-CoV-2 strain responsible for the first reported case of COVID-19 recurrence in Monterey County. The sequencing results were published in a scientific paper entitled *"Emergence of a novel SARS-CoV-2 variant containing the L452R spike protein mutation in California: evidence for increased transmissibility, disease severity, and resistance to antibody neutralization"*. This paper played a key role in CDC elevating the L452R variant as a "Variant of Interest" to a "Variant of Concern".

**RESULTS:** MCPHL is considered a small to moderate sized PHL relative to 23 other PHLs in California. Amazingly, for several months, MCPHL was among the top 5 PHLs with the fastest testing turnaround times and highest volumes of testing. Partnerships with laboratorians locally and statewide enhanced our ability to implement novel COVID testing and sequencing methods, obtain high throughput lab instruments and assist other labs in California to expand testing and sequencing capacity.

**REPLICABILITY:** The innovative, resourceful and creative approaches used by MCPHL have been and will continue to be implemented by other laboratories to expand COVID testing capacity.

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