



Office of the Health Officer

**1000 Broadway, 5th Floor
Oakland, CA 94607**

**Erica Pan, MD, MPH
Interim County Health Officer
(510) 267-8010
(510) 267-8000**

March 30, 2020

Given the currently inadequate availability of clinical outpatient testing for COVID-19, the Alameda County Public Health Department (ACPHD) supports expanded access to COVID-19 testing focused on certain groups with compatible symptoms, as prioritized by the U.S. Centers for Disease Control and Prevention (CDC). For testing conducted in ambulatory settings, CDC priority groups include health care workers, long-term care facility residents, persons >65 years old, with underlying conditions, and first responders.

ACPHD supports reliable, accurate, and safe COVID-19 testing processes that are compliant with the relevant medical, laboratory, safety, and public health regulations and reporting requirements. Clinicians of record who are ordering the tests shall ensure appropriate notification of testing results to individuals and their primary care providers if they have one, and relevant public health instructions including isolation orders for those who test positive for COVID-19.

For testing provided outside the healthcare setting, several key elements should be in place before initiating testing, and we will support programs that have demonstrated they meet the standards and requirements outlined below.

Protocols for COVID-19 testing in non-medical settings must include the following elements.

1. Appropriate infection control procedures including use of personal protective equipment (PPE) per CDPH guidance
2. Training procedures for staff in specimen collection and PPE use, including donning and doffing of PPE appropriately to avoid contamination
3. Measures to prevent transmission of COVID-19 between patients of the program
4. Procedures to ensure informed consent of patients
5. Physician order for laboratory testing for each patient
6. Screening Form and Data Collection includes required data fields for mandatory reporting and public health investigation
7. Procedures to isolate all patients being tested for COVID-19 including use of Isolation and Quarantine (for contacts) Orders and instructions from ACPHD
8. Use of proper testing technique and specimen collection, including appropriate storage and transport to testing laboratory
9. Use of a Clinical Laboratory Improvement Amendments (CLIA) Approved laboratory
10. Use of validated laboratory test allowable under FDA regulations (FDA-EUA pending or approval)
11. Procedures to disclose results to patients along with relevant instructions for follow up care and ACPHD instructions and orders for isolation to prevent infection of others

12. Notification of ACPHD (or the health jurisdiction of patient residence) by ordering medical provider or designee of all cases of COVID-19 identified through the program, immediately by telephone as required by law (see California Code of Regulations (CCR) Title 17 §2500). Reporting of all required information regarding patient data must be transferred in a secure and electronic format to ACPHD within 1 working day, as required by law
 - a. Reports must include if known, name of the disease or condition being reported; the date of onset; the date of diagnosis; the name, address, telephone number, occupation, race/ethnic group, Social Security number, gender, pregnancy status, age, and date of birth for the case or suspected case; the date of death if death has occurred; and the name, address and telephone number of the person making the report. (see 17 CCR § 2500 (d))
13. Reporting of all positive, inconclusive and negative COVID-19 tests by testing laboratory through the state Electronic Laboratory Reporting system (ELR) to CalRedie or by other secure electronic transfer to ACPHD (or the health jurisdiction of patient residence) as required by law (see 17 CCR §2505) and Alameda County Health Officer Order 20-02.
 - a. Lab results may be reported securely to ACPHD via FAX (510) 273-3744, to the attention of the Acute Communicable Disease Team, or sent securely to AcuteCD@acgov.org
 - b. Lab reports must include the date the specimen was obtained, the patient identification number, the specimen accession number or other unique specimen identifier, the specimen site, the diagnosis codes, the laboratory findings for the test performed, and the date that the laboratory findings were identified. In addition, all reports to the local health officer and all test requisitions must include the name, gender, address, telephone number, pregnancy status, and date of birth of the person from whom the specimen was obtained, and the name, address, and telephone number of the health care provider for whom such examination or test was performed (see 17 CCR §2505)

Requested:

- Process for ambulatory care providers to refer priority patients for specimen collection (and prioritized over others)
- Process for ACPHD to refer priority individuals for specimen collection

We appreciate your efforts to improve access to COVID-19 testing in Alameda County, and we will support initiation of testing once the program can demonstrate that these requirements can be met. For questions, please contact Dr. Deanna Aronoff at Deanna.Aronoff@acgov.org.

Reference & Resources:

- California Code of Regulations, Title 17, Section [2500 \(provider reporting\)](#), Section [2505 \(lab reporting\)](#).
- [CDPH Title 17, 2500 & 2505 Reference](#)
- [Alameda County Health Officer Order 20-02](#)
- [FDA EUA COVID-19 Diagnostic Lab Approval Page](#)
- [CDC Guidance for Specimen Collection for COVID-19](#)
- [CDC PPE guidance for specimen collection](#)
- [CDC Clinical Criteria for testing](#)
- [Project Baseline Community Based Testing Program for COVID-19](#)