



ORDER OF THE HEALTH OFFICER No. C19-20

**ORDER OF THE HEALTH OFFICER
OF THE CITY AND COUNTY OF SAN FRANCISCO ESTABLISHING SAFETY
REQUIREMENTS FOR COLLECTING AND HANDLING CLINICAL SPECIMENS
FOR COVID-19 TESTING BY PRIVATE OPERATORS OF SPECIMEN COLLECTION
SITES**

DATE OF ORDER: January 25, 2022

Please read this Order carefully. Violation of or failure to comply with this Order is a misdemeanor punishable by fine, imprisonment, or both. (California Health and Safety Code § 120295, *et seq.*; California Penal Code §§ 69, 148(a)(1); and San Francisco Administrative Code § 7.17(b).)

Summary: San Francisco is currently experiencing a surge in new COVID-19 cases and hospitalizations due to the highly contagious Omicron variant, with the increase in hospitalizations mostly among the unvaccinated. Due to the nature of the Omicron variant, people who are fully vaccinated, including people who have received a booster, have been infected mainly with mild disease and are showing mild symptoms. Very few fully-vaccinated or boosted people have required hospitalization. An important way to address the current surge and potential future surges and to allow people to isolate or quarantine is for everyone who has a COVID-19 symptom or who has been a close contact of someone with COVID-19 to get tested as quickly as possible. As a result, ensuring the integrity of COVID-19 testing operations is of the utmost importance. COVID-19 testing sites sometimes offer on-site testing for serological (antibody) tests or rapid molecular or antigen tests; they sometimes also collect specimens for molecular testing, which are then submitted to an off-site laboratory for clinical testing. Operators of some sites are doing both. Operators of sites that do not actually perform clinical laboratory tests for SARS-CoV-2 on the premises are operating as Specimen Collection Sites (as defined below). It is critically important that collection and testing at Specimen Collection Sites in San Francisco observe best health and safety practices for handling and testing infectious disease specimens. Testing sites that perform clinical laboratory tests on the premises are licensed and regulated by the United States Centers for Medicare & Medicaid Services and the California Department of Public Health. But sites that operate solely as Specimen Collection Sites are not subject to CMS or CDPH regulation or oversight. Accordingly, this Order sets forth minimum health and safety requirements for private operators acting solely as COVID-19 Specimen Collection Sites to help ensure that such sites are operating in a safe and lawful manner.

**UNDER THE AUTHORITY OF CALIFORNIA HEALTH AND SAFETY CODE
SECTIONS 101040, 101085, AND 120175, THE HEALTH OFFICER OF THE CITY AND
COUNTY OF SAN FRANCISCO ORDERS:**

1. Definitions.

For purposes of this Order, the following initially capitalized terms have the meanings given below:



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- a. *City*. The “City” means the City and County of San Francisco.
- b. *Covered Operators*. “Covered Operators” has the meaning given in Section 2.
- c. *COVID-19*. “COVID-19” means coronavirus disease 2019, the disease caused by the SARS-CoV-2 virus and that resulted in a global pandemic.
- d. *CDPH*. “CDPH” means the California Department of Public Health.
- e. *DPH*. “DPH” means the San Francisco Department of Public Health.
- f. *Personnel*. “Personnel” means the following people: employees; contractors and sub-contractors (such as those who sell goods or perform services onsite or who deliver goods for the Covered Operator); independent contractors; vendors who are permitted to sell goods onsite; volunteers; and other individuals who regularly provide services onsite.
- g. *PPE*. “PPE” means personal protective equipment, including gowns or other protective clothing, gloves, face shields, goggles, Well-Fitted Masks, and other equipment designed to protect the wearer and those around the wearer from the spread of COVID-19.
- h. *Specimen Collection Site*. “Specimen Collection Site” means sites where specimens for COVID-19 Testing are obtained from a person and then sent to an off-site CLIA certified lab for clinical processing. Specimen Collection Sites do not include sites where clinical laboratory tests are performed on the premises, which are regulated by CDPH and the United States Centers for Medicare & Medicaid Services (CMS). (CMS regulates all laboratory testing (except research) performed on humans in the United States through the Clinical Laboratory Improvement Amendments (CLIA).)
- i. *Testing*. “Testing” (also being “Tested” or a “Test”) means the use of a diagnostic test to detect SARS-CoV-2 using a test that is approved or has emergency use authorization for diagnosis by the United States Food and Drug Administration, including “molecular” or nucleic acid amplification tests—such as polymerase chain reaction (“PCR”) or loop-mediated amplification (“LAMP”) testing—or antigen tests.
- j. *Well-Fitted Mask*. A “Well-Fitted Mask” means a face covering that is well-fitted to an individual and covers the nose and mouth especially while talking, consistent with the Face Covering Requirements. United States Centers for Disease Control and Prevention guidance regarding Well-Fitted Masks may be found at www.cdc.gov/coronavirus/2019-ncov/your-health/effective-masks.html. A well-fitting non-vented N95, KN95, or KF94 respirator is strongly recommended as a Well-Fitted Mask, even if not fit-tested, to provide maximum protection. A well-fitting surgical/procedural mask with a cloth mask worn over it to increase fit is also recommended. Given higher transmissibility of the Omicron variant, cloth masks alone are no longer recommended. A Well-Fitted Mask does not include a scarf, ski



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mask, balaclava, bandana, turtleneck, collar, or single layer of fabric or any mask that has an unfiltered one-way exhaust valve.

2. Application. This Order applies to private for-profit and nonprofit persons, companies, or other organizations in the business of operating one or more Specimen Collection Sites anywhere in the City (“Covered Operators”). It does not apply to government entities or to any facility (such as a general acute care hospital, skilled nursing facility, or ambulatory clinic) that is subject to regulation by CDPH. The business of collecting specimens for COVID-19 Testing includes, without limitation, collecting specimens without charge to the person seeking a COVID-19 Test, regardless of whether reimbursement or payment is sought from insurance companies or federal, state, or local governmental agencies.
3. Requirements for Specimen Collection Sites. Covered Operators of Specimen Collection Sites in the City must comply with all of the following health and safety requirements:
 - a. Personal Protective Equipment (PPE).
 - i. If collecting specimens or working within six feet of patients, Personnel must wear a well-fitting N95 (or higher-level) respirator, eye protection, gloves, and a gown.
 - ii. Personnel who handle specimens, but are not directly involved in collection (*e.g.*, handling self-collected specimens) and not working within six feet of the person providing the specimen, must wear a Well-Fitted Mask and gloves.
 - iii. Personnel must change gloves after handling a specimen and whenever their gloves become soiled or torn.
 - iv. Covered Operators must provide Personnel with information and training on the proper procedures for putting on and taking off PPE. Examples include: www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf.
 - b. Sanitation and Hygiene.
 - i. Personnel at Specimen Collection Sites must designate a surface area for specimen collection and handling and disinfect that area—using products on the EPA-approved “N” list, which can be found online at www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2, at all of the following times:
 - Before specimen collection begins each day;
 - At least hourly during the day;
 - When visibly soiled;
 - In the event of a specimen spill; and
 - At the end of every day.



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- ii. Specimen Collection Sites must at all times during hours of operation make hand sanitizer available for use by Personnel and people providing specimens for COVID-19 Testing.
- c. Informed Consent. Covered Operators must provide all individuals from whom a specimen is collected at the Specimen Collection Site a written informed consent form. The form must be signed by the individual from whom the specimen is collected and a copy of the form must be provided (either in hard copy or electronically) to the individual.
- d. Written Policies and Procedures.
 - i. Covered Operators must have written policies as follows:
 - (1) Written policies concerning specimen collection, storage, and transport that are consistent with the U.S. Centers for Disease Control and Prevention’s “Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing” (available at www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html) or the test manufacturers’ instructions.
 - (2) Written policies detailing how Personnel are trained in (a) PPE requirements; (b) specimen collection, storage and transport; and (c) protection of personal information of people seeking or considering seeking COVID-19 Testing at the Specimen Collection Site.
 - (3) Written policies concerning result notification—*i.e.*, how results are provided to people providing specimens, including whether results are provided by the company running the Specimen Collection Site or by the CLIA certified laboratory where the specimens are tested.
 - ii. The written policies specified above must be provided to:
 - (1) all Personnel;
 - (2) any member of the public, upon request—including, but not limited to, people seeking or considering seeking COVID-19 Testing at a Specimen Collection Site operated by the Covered Operator, and City, state, or federal employees conducting inspections or investigations; and
 - (3) any CLIA certified laboratory where the specimens will be tested, to enable the lab to verify the integrity of the specimens being collected, as required by CDPH Lab Field Services “Guidance for COVID-19 Collection and Testing Sites” (available at www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/COVID-19Guidance.aspx).



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- e. Use of Human Biological/Viral Specimens. Covered Operators may use human biological/viral specimens only for (1) COVID-19 clinical testing and (2) COVID-19 laboratory validation and quality control as allowed by applicable laws, rules, regulations, and licensure requirements, and for no other purpose.
 - f. Documentation of Ordering Prescriber. Upon request by any member of the public—including, but not limited to, people seeking or considering seeking COVID-19 Testing at a Specimen Collection Site operated by the Covered Operator, and City, state, or federal employees conducting inspections or investigations—Personnel at Specimen Collection Sites must be able to produce the name of a valid ordering/prescribing provider, as required for collection of samples and processing by CDPH-approved laboratories.
 - g. Documentation Regarding Lab for Clinical Processing. Upon request by any member of the public—including, but not limited to, people seeking or considering seeking COVID-19 Testing at a Specimen Collection Site operated by the Covered Operator, and City, state, or federal employees conducting inspections or investigations—Personnel at Specimen Collection Sites must be able to produce the following documentation from the lab that will be processing/performing tests on the specimens collected at the Specimen Collection Site: (1) a current and valid CLIA license and (2) a current and valid Clinical and Public Health Laboratory License from CDPH.
4. Incorporation of State and Local Emergency Proclamations and Federal and State Health Orders.

The Health Officer is issuing this Order in accordance with, and incorporates by reference, the emergency proclamations and other federal, state, and local orders and other pandemic-related orders described below in this Section. But this Order also functions independent of those emergency proclamations and other actions, and if any State, federal, or local emergency declaration, or any State or federal order or other guidance, is repealed, this Order remains in full effect in accordance with its terms (subject to Section 5 below).

- a. State and Local Emergency Proclamations. This Order is issued in accordance with, and incorporates by reference, the March 4, 2020 Proclamation of a State of Emergency issued by the Governor, the February 25, 2020 Proclamation by the Mayor Declaring the Existence of a Local Emergency, and the March 6, 2020 Declaration of Local Health Emergency Regarding Novel Coronavirus 2019 (COVID-19) issued by the Health Officer, as each of them have been and may be modified, extended, or supplemented.
- b. State Health Orders. This Order is also issued in light of the various orders, directives, rules, and regulations of the State, including, but not limited to, those of the State's Public Health Officer and Cal/OSHA. The State has expressly acknowledged that local health officers have authority to establish and implement



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public health measures within their respective jurisdictions that are more restrictive than those implemented by the State Public Health Officer.

- c. Federal Orders. This Order is further issued in light of federal emergency declarations and orders, as each of them may have been and may be modified, extended or supplemented.
- d. If a separate state, local, or federal order or directive imposes different requirements of Covered Operators, the more health protective requirement applies.

5. Effective Date.

This Order becomes effective immediately on issuance and will continue, as updated, to be in effect until the Health Officer rescinds, supersedes, or amends it in writing.

6. Enforcement.

Under Government Code sections 26602 and 41601 and Health and Safety Code section 101029, the Health Officer requests that the Sheriff and the Chief of Police in the County ensure compliance with and enforce this Order. The violation of any provision of this Order constitutes an imminent threat and immediate menace to public health, constitutes a public nuisance, and is punishable by fine, imprisonment, or both. DPH is authorized to respond to such public nuisances by issuing Notice(s) of Violation and ordering Specimen Collection Sites closed until the owner or manager submits a written plan to eliminate all violations and DPH finds that plan satisfactory. Such Notice(s) of Violation and orders to vacate and close may be issued based on a written report made by any City employees writing the report within the scope of their duty. DPH must give notice of such orders to vacate and close to the Chief of Police or the Chief's designee to be executed and enforced by officers in the same manner as provided by San Francisco Health Code section 597. As a condition of allowing a Specimen Collection Site to reopen, DPH may impose additional restrictions and requirements on the site as DPH deems appropriate to reduce transmission risks, beyond those required by this Order.

7. Copies.

The City must promptly provide copies of this Order as follows: (1) by posting on the DPH website (www.sfdph.org/healthorders); (2) by posting at City Hall, located at 1 Dr. Carlton B. Goodlett Pl., San Francisco, CA 94102; and (3) by providing to any member of the public requesting a copy. Also, the owner, manager, or operator of each Specimen Collection Site operated by the Covered Operator in the City is strongly encouraged to post a copy of this Order onsite and must provide a copy to any member of the public asking for a copy.



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8. Severability.

If a court holds any provision of this Order or its application to any person or circumstance to be invalid, then the remainder of the Order, including the application of such part or provision to other persons or circumstances, shall not be affected and shall continue in full force and effect. To this end, the provisions of this Order are severable.

IT IS SO ORDERED:

A handwritten signature in black ink, appearing to read "Susan Philip", written over a horizontal line.

Susan Philip, MD, MPH,
Health Officer of the
City and County of San Francisco

Dated: January 25, 2022