



ORDER OF THE HEALTH OFFICER No. 2023-03

**ORDER OF THE HEALTH OFFICER
OF THE CITY AND COUNTY OF SAN FRANCISCO ESTABLISHING SAFETY
REQUIREMENTS FOR COLLECTING AND HANDLING CLINICAL SPECIMENS
FOR INFECTIOUS DISEASE TESTING BY PRIVATE OPERATORS OF SPECIMEN
COLLECTION SITES DURING THE FALL AND WINTER SEASON**

DATE OF ORDER: October 11, 2023

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).)

Summary: Starting now in the fall of this year and continuing until the beginning of next spring 2024, viruses that cause respiratory infections, including COVID-19, influenza (flu), and respiratory syncytial virus (RSV), will pose a significant health risk for many individuals in San Francisco. While a large number of San Franciscans received the initial vaccines and boosters against COVID-19, fewer San Franciscans are vaccinated with the currently recommended vaccine dose, due in part to slow national distribution. Given the risk of multiple respiratory viruses circulating at the same time, accurate, timely, and safe testing is critical to notify individuals that they should isolate and stay home, seek early treatment options (including drugs such as Paxlovid for COVID-19), and tell other individuals that they may have been exposed. The California Department of Public Health recommends that individuals who have tested positive for COVID-19 should isolate for at least five days and individuals who are close contacts should test within three to five days after their last exposure. The United States Centers for Disease Control and Prevention (CDC) recommends individuals with suspected or confirmed flu should stay home at least four to five days after the onset of symptoms. Accordingly, ensuring the integrity of, and public trust in, testing operations for COVID-19, flu, RSV, and other respiratory infections is of the utmost importance for public health in the community.

Sites that test for viruses such as SARS-CoV-2, the virus that causes COVID-19, sometimes offer on-site testing and analysis, but some operators may collect specimens that are then submitted to an off-site laboratory for clinical testing and analysis. Operators of sites that do not actually perform clinical laboratory tests on the premises are operating as Specimen Collection Sites (as defined below). It is 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 to ensure there is no inadvertent risk of transmission of communicable diseases to collection site personnel from members of the public. Testing sites that perform clinical laboratory tests on the premises are licensed and regulated by the United States Centers for Medicare &



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Medicaid Services (CMS) 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. Additionally, sites that hold themselves out to any member of the general public perform a public health function in which public trust is paramount. Setting minimum standards ensures public trust in these sites, especially if public health authorities need to scale up testing during the fall and winter respiratory virus period.

Accordingly, in preparation for the fall and winter respiratory virus period, this Order sets forth minimum health and safety requirements for private operators of Specimen Collection Sites to help ensure that such sites are operating in a safe and lawful manner. The Health Officer anticipates rescinding this Order if other local rules are adopted covering the same subject matter.

**UNDER THE AUTHORITY OF CALIFORNIA HEALTH AND SAFETY CODE
SECTION 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:

- a. *City*. The “City” means the City and County of San Francisco.
- b. *CDPH*. “CDPH” means the California Department of Public Health.
- c. *CLIA*. “CLIA” means the Clinical Laboratory Improvement Amendments codified at 42 U.S.C. § 263a, as it may be amended from time to time, and including any implementing regulations or guidance promulgated by CMS, the CDC, or the federal Food and Drug Administration.
- d. *Covered Operators*. “Covered Operators” means private for-profit and nonprofit persons, companies, or other organizations in the business of operating one or more Specimen Collection Sites anywhere in San Francisco. The business of collecting specimens for Testing includes, without limitation, collecting specimens without charge to the person seeking a Test, regardless of whether reimbursement or payment is sought from insurance companies or federal, state, or local governmental agencies.
- e. *COVID-19*. “COVID-19” means coronavirus disease 2019, the disease caused by the SARS-CoV-2 virus.
- f. *DPH*. “DPH” means the City’s Department of Public Health.
- g. *Flu*. “Flu” means influenza.



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- h. *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 allowed to sell goods onsite; volunteers; and other individuals who regularly provide services onsite.
 - i. *PPE*. “PPE” means personal protective equipment, including, for example, 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 infectious diseases.
 - j. *RSV*. “RSV” means respiratory syncytial virus.
 - k. *Specimen Collection Site*. “Specimen Collection Site” means any site in San Francisco where specimens for Testing are obtained from an individual and then sent to an off-site CLIA-certified lab for clinical processing. Specimen Collection Sites do not include government entities or sites in San Francisco where clinical laboratory tests are collected and/or performed on the premises, which are regulated by CDPH and/or the United States Centers for Medicare & Medicaid Services (CMS) (such as a general acute care hospital, skilled nursing facility, or ambulatory and/or urgent care clinic).
 - l. *Testing*. “Testing” (also being “Tested” or a “Test”) means the use of a diagnostic test to detect SARS-CoV-2, RSV, flu, or any other infectious, contagious, or communicable disease using a test that is approved or has emergency use authorization for diagnosis by the United States Food and Drug Administration.
 - m. *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. CDC guidance regarding Well-Fitted Masks may be found at www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html, and CDPH guidance may be found at www.cdph.ca.gov/Programs/CID/DCDC/Pages/Respiratory-Viruses/When-and-Why-to-Wear-a-Mask.aspx. A Well-Fitted non-vented N95, KN95, or KF94 respirator is strongly recommended as a Well-Fitted Mask, even if not fit-tested, to provide maximum protection.
2. Purpose and Intent.
- a. Purpose. The public health threat of serious illness or death from COVID-19 has decreased in San Francisco and the Bay Area due to the high rate of vaccination of the community. Although the state-wide emergency declaration and the local health emergency have ended, COVID-19 continues to remain a health consideration for San Francisco residents generally, especially those who are unvaccinated, immunocompromised, or otherwise at risk. Other respiratory viruses, including influenza and RSV, also pose similar considerations every year from fall to spring. In particular, it is likely that all three viruses—COVID-19, influenza, and RSV—will



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simultaneously impact San Franciscans during the winter respiratory virus period from fall 2023 to spring 2024.

This Order is based on evidence of continued community transmission of SARS-CoV-2 within San Francisco as well as current scientific evidence and best practices to prevent severe negative health outcomes due to COVID-19, influenza, RSV, and other respiratory viruses. These best practices include access to accurate, timely, and safe testing to notify individuals that they should isolate and/or stay home, seek early treatment options (including drugs such as Paxlovid for COVID-19), and tell other individuals that they may have been exposed. Accordingly, ensuring the integrity of, and public trust in, testing operations for COVID-19, flu, RSV, and other respiratory infections is of the utmost importance. Requiring certain minimum health and safety standards protects Personnel against the risk of inadvertent transmission of communicable diseases from people seeking a Test and ensures public trust in Specimen Collection Sites that hold themselves out to any member of the public. The Health Officer will continue to monitor data regarding the evolving scientific understanding of the risks posed by COVID-19 and other respiratory viruses and may amend or rescind this Order based on analysis of that data and knowledge.

- b. Intent. The primary intent of this Order is to protect residents who seek medical testing by ensuring the safety, reliability, and integrity of such testing sites and accordingly reduce the risk of severe health outcomes, such as hospitalization or death, due to COVID-19, influenza, RSV, and other respiratory viruses. This Order is intended to last through the duration of the fall 2023 and winter 2024 respiratory virus period or until applicable laws are enacted to regulate Specimen Collection Sites, whichever is earlier.
 - c. Interpretation. All provisions of this Order must be interpreted to effectuate the purpose and intent of this Order as described above. The summary at the beginning of this Order as well as the headings and subheadings of sections contained in this Order are for convenience only and may not be used to interpret this Order. In the event of any inconsistency between the summary, headings, or subheadings and the text of this Order, the text will control. Certain initially capitalized terms used in this Order have the meanings given them in Section 1 above.
 - d. Effect of Failure to Comply. Failure to comply with any of the provisions of this Order constitutes an imminent threat and menace to public health, constitutes a public nuisance, and is punishable by fine, imprisonment, or both, as further provided in Section 6 below.
3. Requirements for Specimen Collection Sites. Covered Operators of Specimen Collection Sites in the City must comply with all of the following requirements at those sites:
 - a. Personal Protective Equipment (PPE). If collecting specimens or working within six feet of people providing specimens, Personnel must wear PPE based on the type of specimen to be collected by the Personnel. Covered Operators must provide



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Personnel with guidelines for wearing appropriate PPE, as well as information and training on the proper procedures for taking on and off PPE. Each Covered Operator's guidelines for wearing PPE must include the following minimum standards:

- i. Personnel who collect specimens from or work within six feet of people providing specimens must wear a Well-Fitted Mask, 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 each specimen and whenever their gloves become soiled or torn.
- b. Sanitation and Hygiene. Personnel at Specimen Collection Sites must designate a surface area for specimen collection and handling and disinfect that area using a disinfectant product registered with the federal Environmental Protection Agency for use against contagious, infectious, or communicable diseases. Personnel must disinfect the surface areas at the following times: (1) before specimen collection begins each day; (2) after Personnel collect each specimen; (3) when visibly soiled; (4) in the event of a specimen spill; and (5) at the end of every day. Specimen Collection Sites must at all times during hours of operation make hand sanitizer available for use by Personnel and people providing specimens.
- 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. Before Personnel collect the specimen, the individual must sign the informed consent form. A copy of the form must be provided (either in hard copy or electronically) to the individual.
- d. Written Policies and Procedures. Covered Operators must have written policies covering the following topics:
- i. Specimen collection, storage, and transport that addresses the specific types of specimens the Specimen Collection Site will collect or are consistent with the test manufacturers' instructions.
 - ii. Training of Personnel in: PPE requirements; specimen collection, storage, and transport; and protection of personal information of individuals seeking or considering seeking medical testing through the Specimen Collection Site.
 - iii. Test result notification, including how results are provided to people who provided a Test, by the Covered Operator, its Personnel, or the CLIA-certified laboratory where the specimens are tested.



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- iv. A privacy policy regarding protecting the medical and health information, biological samples, and test results of an individual who provides a specimen.

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 Testing at a Specimen Collection Site operated by the Covered Operator; (3) City, state, or federal employees or other personnel conducting inspections or investigations; and (4) any CLIA-certified laboratory where the specimens will be tested, to enable the lab to verify the integrity of the specimens being collected.

- e. Use of Human Biological/Viral Specimens. Covered Operators may use human biological/viral specimens only for (1) clinical Testing and (2) 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 Testing at a Specimen Collection Site operated by the Covered Operator, and City, state, or federal employees or other personnel 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 Testing at a Specimen Collection Site operated by the Covered Operator, and City, state, or federal employees or other personnel 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.
- h. Adherence to Privacy Requirements. A Specimen Collection Site operated by a Covered Operator must comply with all applicable privacy laws, including but not limited to the Health Insurance Portability and Accountability Act and its implementing regulations (“HIPAA”). In the event HIPAA does not apply to the Covered Operator, then the Covered Operator must adhere to the same standards as provided by HIPAA to safeguard an individual’s confidentiality and medical information.
- i. Required Partnership with Government, Health Care Provider, or Educational Institution. To help ensure public trust in the integrity of the Tests collected by Covered Operators and encourage individuals to use those sites, each Covered



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Operator must partner with one or more of the following entities: (a) a governmental entity; (b) a licensed health care provider located in the City; or (c) an educational or academic institution (including but not limited to licensed child care providers, preschools, public and private schools, colleges, universities, and similar institutions of higher learning). Upon request, Personnel at a Specimen Collection Site must demonstrate evidence of the partnership with one of the foregoing entities by producing a written agreement, memorandum, letter, or similar document that shows the entity endorses the Specimen Collection Site's collection of specimens. For clarity, document of the ordering prescriber's standing order, required by Section 3(f), does not, by itself, constitute sufficient evidence of a partnership.

4. Incorporation of Federal, State, and Local Orders and Guidance. The Health Officer is issuing this Order in accordance with, and incorporates by reference, any applicable federal, state, and local orders and guidance, including COVID-19 isolation and quarantine guidance issued by CDPH (available at <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Guidance-on-Isolation-and-Quarantine-for-COVID-19-Contact-Tracing.aspx>) and flu isolation guidance issued by the CDC (available at: <https://www.cdc.gov/flu/business/stay-home-when-sick.htm>). But this Order also functions independent of those orders and guidance. 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, consistent with the stated purposes above.
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 City ensure compliance with and enforce this Order. The violation of this Order may constitute a public nuisance and is punishable by fine, imprisonment, or both.
7. Copies. The City must promptly provide copies of this Order as follows: (1) by posting on the City's website (available at <https://sf.gov/healthrules>); (2) by providing the opportunity for any member of the public to sign up for an email distribution list relative to changes to Health Officer orders and guidance (available at <https://signup.e2ma.net/signup/1965323/1948363/>); 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.
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



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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: October 11, 2023