File No. 231158 **Committee Item No.** 3
Board Item No. 21

COMMITTEE/BOARD OF SUPERVISORS

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Committee: Public Safety and Ngbh Services **Date:** January 11, 2024
Board of Supervisors Meeting: **Date:** January 23, 2024

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Prepared by: John Carroll **Date:** January 4, 2024
Prepared by: John Carroll **Date:** January 19, 2024
Prepared by: **Date:**

[Health Code - Regulating Medical Specimen Test Collection Sites]

Ordinance amending the Health Code to require that sites that collect medical specimens on behalf of clinical laboratories partner with either a governmental entity, a licensed health care provider located in the City, or an educational or academic institution, establish hygiene, sanitation, and privacy standards, and adhere to the Health Insurance Portability and Accountability Act; prohibiting such sites from paying individuals to take a medical test; and providing that a violation of the specimen collection standards is a misdemeanor offense and a public health nuisance subject to an administrative penalty that may be imposed by the Department of Public Health.

NOTE: **Unchanged Code text and uncodified text** are in plain Arial font.
Additions to Codes are in *single-underline italics Times New Roman font*.
Deletions to Codes are in ~~*strikethrough italics Times New Roman font*~~.
Board amendment additions are in double-underlined Arial font.
Board amendment deletions are in ~~strikethrough Arial font~~.
Asterisks (* * * *) indicate the omission of unchanged Code subsections or parts of tables.

Be it ordained by the People of the City and County of San Francisco:

Section 1. The Health Code is hereby amended by adding Article 49, consisting of Sections 4901 through 4906, to read as follows:

ARTICLE 49:

SPECIMEN TEST COLLECTION SITES

SEC. 4901. FINDINGS AND PURPOSE.

(a) Since the onset of the COVID-19 emergency, it has become increasingly common for City residents to see organizations and businesses operate clinical testing sites on City sidewalks and in

other public locations. Medical testing sites that both collect specimens and then perform clinical tests on those specimens are called "laboratories" or "clinical laboratories," and are licensed and regulated by federal Centers for Medicare and Medicaid Services and the California Department of Public Health or the applicable state agency for laboratories outside California. By contrast, sites that collect specimens but do not actually perform clinical tests, and merely send the specimens to a laboratory for testing ("Specimen Collection Sites") are not subject to CMS or CDPH regulation or oversight.

(b) Generally, under the Health Insurance Portability and Accountability Act and its implementing regulations (collectively, "HIPAA"), Specimen Collection Sites that collect specimens on behalf of covered entities, such as clinical laboratories, are business associates of those covered entities as those terms are defined under HIPAA. Business associates are obligated to follow HIPAA's privacy and safety requirements.

(c) It is critically important that Specimen Collection Sites in San Francisco protect the privacy of individuals' health information and comply with health and safety protocols for handling and testing infectious disease specimens. Accordingly, the purpose of this Article 49 is to set forth the minimum privacy and health and safety requirements for Specimen Collection Sites to ensure that such sites are operating in a safe and lawful manner.

SEC. 4902. DEFINITIONS.

For purposes of this Article 49, the following terms have the following meanings:

"CDC" means the federal Centers for Disease Control and Prevention.

"CDPH" means the California Department of Public Health.

"City" means the City and County of San Francisco.

"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.

"CMS" means the federal Centers for Medicare and Medicaid Services.

"Covered Operator" means a private, for-profit or non-profit person, company, or other organization operating one or more Specimen Collection Sites anywhere in the City. Covered Operator includes a person, company, or organization that collects specimens without charge to the Examinee, regardless of whether reimbursement or payment is sought from insurance companies or federal, state, or local governmental agencies. Covered Operator does not include government entities or any facility (such as a general acute care hospital, skilled nursing facility, or ambulatory clinic) that directly collects specimens and is subject to regulation by CDPH.

"Department" means the San Francisco Department of Public Health.

"Director" means the Director of Health, or the Director's designee.

"Examinee" means an individual providing a specimen to the Specimen Collection Site.

"Personnel" means employees, contractors and sub-contractors, including but not limited to those who sell goods or perform services onsite or who deliver goods for the Covered Operator, vendors who are permitted to sell goods onsite, volunteers, and other individuals who regularly provide services to a Covered Operator.

"PPE" means Personal Protective Equipment.

"Specimen Collection Site" means a site where a Covered Operator or its Personnel obtain specimens for testing for medical or health conditions, including by way of example but not limitation, COVID-19 and flu, from an Examinee and for delivery to an off-site CLIA-certified laboratory for clinical processing. Specimen Collection Sites do not include sites regulated by CMS or CDPH where clinical laboratory tests are performed on the premises.

"Test" means the diagnostic test used to detect any infectious, contagious, or communicable disease and that the Covered Operator sends to a CLIA-certified laboratory for clinical processing.

"Well-Fitted Mask" means a face covering that is well-fitted to an individual and covers the nose and mouth while talking. A Well-Fitted Mask does not include a scarf, ski mask, balaclava, bandana, turtleneck, collar, or single layer of fabric, or any mask that has an unfiltered one-way exhaust valve.

SEC. 4903. REQUIREMENTS FOR SPECIMEN COLLECTION SITES.

(a) Each Covered Operator must provide its Personnel with guidelines for wearing appropriate PPE based on the type of specimen to be collected by Personnel. Covered Operators must provide Personnel with information and training on the proper procedures for putting on and taking off PPE based on the type of specimen collected by the Personnel. Each Covered Operator's guidelines for wearing appropriate PPE must include the following minimum standards:

(1) If collecting specimens or working within six feet of Examinees, Personnel must wear a Well-Fitted Mask, eye protection, gloves, and a gown.

(2) 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 Examinee, must wear a Well-Fitted Mask and gloves.

(3) Personnel must change gloves after handling a specimen or whenever their gloves become soiled or torn.

(b) 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 a specimen; (3) when visibly soiled; (4) in the event of a specimen spill; and (5) at the end of every day. Each Covered Operator must at all times during hours of operation make hand sanitizer available for use by Personnel and Examinees.

(c) Each Covered Operator must provide all Examinees a written informed consent form consenting to the collection of the specimen and the testing of that specimen. Before the specimen is collected, the Examinee must sign the informed consent form. Personnel must provide a copy of the signed form, either in hard copy or electronically, to the Examinee.

(d) Each Covered Operator must have written policies covering the following topics:

(1) 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.

(2) Training of Personnel in PPE requirements; specimen collection, storage, and transport; and protection of personal information of Examinees seeking or considering seeking medical testing at the Specimen Collection Site.

(3) Test Result Notification, including how results are provided to Examinees either by the Covered Operator, its Personnel, or by the CLIA-certified laboratory where the specimens are tested.

(4) A privacy policy regarding Examinees' medical and health information, biological samples, and test results.

The written policies and procedures specified in subsection (d)(1) through (d)(4) must be provided to: all Personnel; any member of the public, upon request, including, but not limited to, Examinees seeking or considering seeking medical testing at a Specimen Collection Site; City, state, or federal employees conducting inspections or investigations; and any CLIA-certified laboratory where the specimens will be tested to enable the lab to verify the integrity of the specimens being collected.

(e) Covered Operators may use human biological/viral specimens only for (1) clinical testing and (2) laboratory validation and quality control, to the extent such uses are allowed by applicable laws, rules, regulations, and licensure requirements.

(f) Upon request by any member of the public, including, but not limited to, Examinees seeking or considering seeking testing at a Specimen Collection Site, and City, state, or federal employees conducting inspections or investigations, Personnel at Specimen Collection Sites must produce the name of the Specimen Collection Site's ordering/prescribing provider, where a prescription is required for collection of samples and processing by CDPH-approved laboratories.

(g) Upon request by any member of the public, including, but not limited to, Examinees seeking or considering seeking testing at a Specimen Collection Site, and City, state, or federal employees conducting inspections or investigations, Personnel at Specimen Collection Sites must produce the following documentation from the laboratory that will be processing/performing Ttests 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) A Specimen Collection Site operated by a Covered Operator must comply with all applicable privacy laws, including but not limited to 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 Examinee confidentiality and medical information.

(i) Each Covered Operator must partner with one of the following entities to perform Tests on behalf of the entity: (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 has requested the Specimen

Collection Site perform Tests on behalf of the entity. The ordering prescriber's standing order, required by subsection (f), shall not constitute sufficient evidence of a partnership.

(j) Covered Operators shall not offer or pay Examinees any remuneration, including anything of value, directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in exchange for, the Examinee using a Test offered by the Covered Operator. The prohibition on remuneration shall not apply to clinical testing performed pursuant to an institutional review board-approved research study or with the approval of the Department.

SEC. 4904. ADMINISTRATION AND ENFORCEMENT.

(a) This Article 49 shall be administered and enforced by the Department. The Director may adopt regulations, guidelines, and forms to carry out the provisions and purposes of this Article 49.

(b) For purposes of assessing penalties for violation of Section 4903, each instance that a Specimen Collection Site violates any provision of Section 4903 shall constitute a separate violation.

(c) The Director may issue a notice of violation for violations of Section 4903. The Director may impose an administrative penalty of not less than $250 and not more than $1,000 per violation. Administrative Code Chapter 100, "Procedures Governing the Imposition of Administrative Fines," is hereby incorporated in its entirety, except: (1) as it relates to the definition of a violation and the calculation of penalty amounts, addressed in Sections 4904(b) and (c); and (2) that the Director shall appoint the hearing officer to conduct hearings for appeals.

(d) A violation of Section 4903 shall be considered a nuisance under Health Code Section 581, or any successor provision.

(e) The Department shall have authority to enforce Section 4903 under Health Code Sections 594, 595, 596, 596.5, 599, 600, and 610.

SEC. 4905. VIOLATION A MISDEMEANOR.

Any person who violates Section 4903 is guilty of a misdemeanor. Any person convicted of a misdemeanor hereunder is punishable by a fine of not more than $500 or by imprisonment for a period of not more than six months, or by both. A person who violates the provisions of Section 4903 is guilty of a separate offense for each day, or portion thereof, during which the violation continues.

SEC. 4906~~5~~. UNDERTAKING FOR THE GENERAL WELFARE.

In enacting and implementing this Article 49, the City is assuming an undertaking only to promote the general welfare. It is not assuming, nor is it imposing on its officers and employees, an obligation for breach of which it is liable in money damages to any person who claims that such breach proximately caused injury.

SEC. 4907~~6~~. SEVERABILITY.

If any section, subsection, sentence, clause, phrase, or word of this Article 49, or any application thereof to any person or circumstance, is held to be invalid or unconstitutional by a decision of a court of competent jurisdiction, such decision shall not affect the validity of the remaining portions or applications of this Article. The Board of Supervisors hereby declares that it would have passed this Article and each and every section, subsection, sentence, clause, phrase, and word not declared invalid or unconstitutional without regard to whether any other portion of this Article or application thereof would be subsequently declared invalid or unconstitutional.

Section 2. Effective Date. This ordinance shall become effective 30 days after enactment. Enactment occurs when the Mayor signs the ordinance, the Mayor returns the

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ordinance unsigned or does not sign the ordinance within ten days of receiving it, or the Board of Supervisors overrides the Mayor's veto of the ordinance.

APPROVED AS TO FORM:
DAVID CHIU, City Attorney

By: /s/
HENRY L. LIFTON
Deputy City Attorney

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FILE NO. 230866

REVISED LEGISLATIVE DIGEST

(11/07/2023, Amended in Board)

[Health Code - Regulating Medical Specimen Test Collection Sites]

Ordinance amending the Health Code to require that sites that collect medical specimens on behalf of clinical laboratories partner with either a governmental entity, a licensed health care provider located in the City, or an educational or academic institution, establish hygiene, sanitation, and privacy standards, and adhere to the Health Insurance Portability and Accountability Act; prohibiting such sites from paying individuals to take a medical test; and providing that a violation of the specimen collection standards is a misdemeanor offense and a public health nuisance subject to an administrative penalty that may be imposed by the Department of Public Health.

Existing Law

Existing law does not address medical specimen test collection sites.

Amendments to Current Law

The proposed ordinance would:

- Authorize the operation of medical specimen test collection sites that partner with: (1) a governmental entity; (2) a licensed health care provider in the City; or (3) an educational or academic institution to operate in the City.
- Require specimen collection sites to provide their employees with personal protective equipment and meet sanitation standards.
- Have written policies and procedures covering: (1) specimen collection, storage, and transport; (2) training of employees; (3) test result notification; and (4) a privacy policy.
- Require specimen collection sites to produce documentation of an ordering prescriber, current and valid CLIA and CDPH licenses, and partnership with an appropriate entity.
- Require specimen collection sites to comply with applicable privacy laws and in the event that HIPAA does not apply to the site, the site must adhere to the same standards as HIPAA.
- Prohibit specimen collection sites from paying individuals to take a medical test.
- Make violations of the ordinance a misdemeanor offense, and a public health nuisance subject to administrative penalties.

Specimen collection sites already regulated by CLIA or the California Department of Public Health (CDPH) would not be subject to the proposed ordinance.

Background Information

Medical testing sites that both collect specimens and then perform clinical tests on those specimens are called “laboratories” or “clinical laboratories,” and are licensed and regulated by federal Centers for Medicare and Medicaid Services (CMS) and CDPH or the applicable state agency for laboratories outside California. By contrast, sites that collect specimens but do not actually perform clinical tests, and merely send the specimens to a laboratory for testing are not subject to CMS or CDPH regulation or oversight.

This ordinance is a duplicate of the ordinance in Board File No. 230866. On November 7, 2023, at a meeting of the full Board of Supervisors, the Board duplicated that file, and amended the duplicate to 1) prohibit specimen collection sites from paying individuals to take a medical test; and 2) provide that violation of the ordinance is a misdemeanor, in addition to a public health nuisance.

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BOARD of SUPERVISORS

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M E M O R A N D U M

TO: Dr. Grant Colfax, Director, Department of Public Health

FROM: John Carroll, Assistant Clerk, Public Safety and Neighborhood Services Committee, Board of Supervisors

DATE: July 31, 2023

SUBJECT: LEGISLATION INTRODUCED

The Board of Supervisors' Public Safety and Neighborhood Services Committee has received the following proposed legislation, introduced by Supervisor Preston on July 25, 2023:

File No. 230866

Ordinance amending the Health Code to require that sites that collect medical specimens on behalf of clinical laboratories partner with either a governmental entity, a licensed health care provider located in the City, or an educational or academic institution, establish hygiene, sanitation, and privacy standards, and adhere to the Health Insurance Portability and Accountability Act; and providing that a violation of the specimen collection standards is a public health nuisance subject to an administrative penalty that may be imposed by the Department of Public Health.

If you have any comments or reports to be included with the file, please forward them to me at the Board of Supervisors, City Hall, Room 244, 1 Dr. Carlton B. Goodlett Place, San Francisco, CA 94102.

CC:
Offices of Chair Stefani and Supervisor Preston
Greg Wagner, Department of Public Health
Dr. Naveena Bobba, Department of Public Health
Sneha Patil, Department of Public Health
Ana Validzic, Department of Public Health

Introduction Form

(by a Member of the Board of Supervisors or the Mayor)

I hereby submit the following item for introduction (select only one):

- [x] 1. For reference to Committee (Ordinance, Resolution, Motion or Charter Amendment)
- [ ] 2. Request for next printed agenda (For Adoption Without Committee Reference)
  (Routine, non-controversial and/or commendatory matters only)
- [ ] 3. Request for Hearing on a subject matter at Committee
- [ ] 4. Request for Letter beginning with "Supervisor _____ inquires…"
- [ ] 5. City Attorney Request
- [ ] 6. Call File No. _____ from Committee.
- [ ] 7. Budget and Legislative Analyst Request (attached written Motion)
- [ ] 8. Substitute Legislation File No. _____
- [ ] 9. Reactivate File No. _____
- [ ] 10. Topic submitted for Mayoral Appearance before the Board on _____

The proposed legislation should be forwarded to the following (please check all appropriate boxes):

☐ Small Business Commission ☐ Youth Commission ☐ Ethics Commission

☐ Planning Commission ☐ Building Inspection Commission ☐ Human Resources Department

General Plan Referral sent to the Planning Department (proposed legislation subject to Charter 4.105 & Admin 2A.53):

☐ Yes ☐ No

(Note: For Imperative Agenda items (a Resolution not on the printed agenda), use the Imperative Agenda Form.)

Sponsor(s):

Preston, Ronen

Subject:

Health Code - Regulating Medical Specimen Test Collection Sites

Long Title or text listed:

Ordinance amending the Health Code to require that sites that collect medical specimens on behalf of clinical laboratories partner with either a governmental entity, a licensed health care provider located in the City, or an educational or academic institution, establish hygiene, sanitation, and privacy standards, and adhere to the Health Insurance Portability and Accountability Act; and providing that a violation of the specimen collection standards is a public health nuisance subject to an administrative penalty that may be imposed by the Department of Public Health.

Signature of Sponsoring Supervisor: /s/ Dean Preston