



This Letter of Understanding is made effective as of April 6, 2020 (the "Effective Date") by and between Color Genomics, Inc. ("Color"), a Delaware corporation, and the City of San Francisco ("San Francisco") (each a "Party" and collectively, the "Parties").

Color provides clinical testing for COVID-19 and distributed testing infrastructure to support essential personnel and frontline workers in accessing testing through onsite testing facilities; and

The Parties desire to enter into this Letter of Understanding and the attached Addendum, setting forth the terms under which Color would provide COVID-19 testing to San Francisco's essential workers at cost to such workers.

1. Color will provide COVID-19 testing, including sample collection kits, patient onboarding, clinical testing, resulting to patients, reporting to city and state health authorities, and transport/logistics (collectively, "COVID-19 Testing Platform"), to the City of San Francisco.
2. San Francisco will identify eligible frontline workers for COVID-19 testing and provide healthcare workers, personal protective equipment (PPE), and facilities in which to collect samples.
3. Color will provide the COVID-19 Testing Platform to San Francisco at a cost of \$75 per test completed, including:
  - a. Sample collection kits (swab kits)
  - b. Sample collection paperwork (barcodes, instructions, order forms)
  - c. Transport of sample collection kits: Daily drop-off of kits, 1x-2x/day sample pickup from facilities
  - d. Clinical support (bulk ordering authorization flow, results dashboard)
  - e. Clinical testing results & reporting to patients (negatives & positives) by HIPAA secure method. Results ready notifications by text/phone/email
  - f. Daily reporting of results to calREDIE and San Francisco DPH
  - g. Positive patient routing (e.g., support for contact tracing)
4. At the request of the City of San Francisco, Color may sub-contract the following, as a pass-through cost to the City of San Francisco: (a) collection site healthcare worker staffing and onsite logistics to a clinical partner at a rate to be determined by such clinical partner, (b) technical components of the diagnostic assay test, in certain situations, to Clinical Research Sequencing Platform, LLC, at the Broad Institute of MIT and Harvard, and (c) site collection logistics and operations.
5. San Francisco and Color will announce the COVID-19 testing collaboration for the city's frontline workers upon mutual agreement of the parties. Until the Parties publicly announce the provision of the testing collaboration, neither Party will disclose this Letter of Understanding. Upon announcement, neither Party will disclose the specific terms of this partnership agreement.
6. The parties intend to launch the COVID-19 Testing Platform on April 6, 2020.

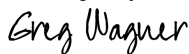




IN WITNESS WHEREOF, the parties hereto have executed this Letter of Understanding and the attached Addendum Agreement as of the Effective Date.


**CITY**

Recommended by:

DocuSigned by:  
  
28527524752949F  
\_\_\_\_\_  
Grant Colfax, MD  
Director of Health  
Department of Public Health


**CONTRACTOR**

Color Genomics, Inc.


DocuSigned by:  
  
C40516314A7A4B7  
\_\_\_\_\_  
Caroline Savello  
Chief Commercial Officer  
Supplier ID: 0000042840

Approved as to Form:

Dennis J. Herrera  
City Attorney

By: DocuSigned by:  
  
BD54168A4C3B452  
\_\_\_\_\_  
Louise S. Simpson  
Deputy City Attorney

Approved:

DocuSigned by:  
  
42E99F6456604C0...  
\_\_\_\_\_  
Alaric Degrafinried  
Director of the Office of Contract Administration, and  
Purchaser



## **Color Genomics, Inc. City Addendum**

This Agreement is an emergency contract awarded pursuant to procedures applicable under the Local Emergency declared by Mayor London Breed on Tuesday, February 25, 2020, attached in Appendix G, in accordance with San Francisco Administrative Code Chapter 21.

Contractor's Test Authorization and Request Form, including the Order of the Health Officer C19-10, is attached hereto as Appendix D.

### **Article 1      Definitions (Reserved)**

### **Article 2      Term of the Agreement**

#### **2.1      Term.**

The term of this Agreement shall commence on April 6, 2020, and expire sixty (60) calendar days after expiration of the Local Emergency as further declared by the Mayor or her designee, unless earlier terminated as otherwise provided herein.

### **Article 3      Financial Matters**

#### **3.1      Certification of Funds; Budget and Fiscal Provisions.**

This Agreement is subject to the budget and fiscal provisions of the City's Charter. Charges will accrue only after prior written authorization certified by the Controller, and the amount of City's obligation hereunder shall not at any time exceed the amount certified for the purpose and period stated in such advance authorization. This Agreement will terminate without penalty, liability or expense of any kind to City at the end of any fiscal year if funds are not appropriated for the next succeeding fiscal year. If funds are appropriated for a portion of the fiscal year, this Agreement will terminate, without penalty, liability or expense of any kind at the end of the term for which funds are appropriated. City has no obligation to make appropriations for this Agreement in lieu of appropriations for new or other agreements. City budget decisions are subject to the discretion of the Mayor and the Board of Supervisors. Color's assumption of risk of possible non-appropriation is part of the consideration for this Agreement.

THIS SECTION CONTROLS AGAINST ANY AND ALL OTHER PROVISIONS OF THIS AGREEMENT.

#### **3.2      Guaranteed Maximum Costs.**

The City's payment obligation to Color cannot at any time exceed SEVEN MILLION NINE HUNDRED NINETY THOUSAND SEVEN HUNDRED TWO DOLLARS (\$7,990,702), certified by City's Controller for the purpose and period stated in such certification. Absent an authorized Emergency per the City Charter or applicable Code, no City representative is authorized to offer or promise, nor is the City required to honor, any offered or promised payments to Color under this Agreement in excess of the certified maximum amount without the Controller having first certified the additional promised amount and the Parties having modified this Agreement as provided in Section 11.5, "Modification of this Agreement."

##### **3.2.1      LBE Payment and Utilization Tracking System. (Reserved)**

#### **3.3      Getting paid by the City for goods and/or services.**

3.3.1 All City vendors receiving new contracts, contract renewals, or contract extensions must sign up to receive electronic payments through, the City's Automated Clearing House

(ACH) payments service/provider. Electronic payments are processed every business day and are safe and secure. To sign up for electronic payments, visit [www.sfgov.org/ach](http://www.sfgov.org/ach).

3.3.2 The following information is required to sign up: (i) The enroller must be their company's authorized financial representative, (ii) the company's legal name, main telephone number and all physical and remittance addresses used by the company, (iii) the company's U.S. federal employer identification number (EIN) or Social Security number (if they are a sole proprietor), and (iv) the company's bank account information, including routing and account numbers.

### **3.4 Federal and/or State Funded Contracts.**

3.4.1 **Disallowance.** If Color requests or receives payment from City for Services, reimbursement for which is later disallowed by the State of California or United States Government, Color shall promptly refund the disallowed amount to City upon City's request. At its option, City may offset the amount disallowed from any payment due or to become due to Color under this Agreement or any other agreement between Color and City.

#### **3.4.2 Grant Terms. (Reserved)**

### **3.5 Budgeting Revisions.**

The City shall have authority, without the execution of a Formal Amendment, to purchase additional Services and/or make changes to the work in accordance with the terms of this Agreement (including such terms that require Color's agreement), not involving an increase in the Compensation or the Term by use of a written City Program Budget Revision.

### **3.6 Audit and Inspection of Records.**

Color agrees to maintain and make available to the City, during regular business hours, accurate books and accounting records relating to its Services. Color will permit City to audit, examine and make excerpts and transcripts from such books and records, and to make audits of all invoices, materials, payrolls, records or personnel and other data related to all other matters covered by this Agreement, whether funded in whole or in part under this Agreement.

#### **3.7 Submitting False Claims. (Reserved)**

#### **3.8 Payment of Prevailing Wages (Reserved)**

## **Article 4 Services Color Agrees to Perform.**

### **4.1 Qualified Personnel.**

Color shall utilize only competent personnel under the supervision of, and in the employment of, Color (or Color's authorized subcontractors) to perform the Services. Color will comply with City's reasonable requests regarding assignment and/or removal of personnel, but all personnel, including those assigned at City's request, must be supervised by Color. Color shall commit adequate resources to allow timely completion within the project schedule specified in this Agreement.

### **4.2 Subcontracting.**

Color may subcontract portions of the Services only upon prior written approval of City. Color is responsible for its subcontractors throughout the course of the work required to perform the Services. All Subcontracts must incorporate the terms of Article 10 "Additional Requirements Incorporated by Reference" of this Agreement, unless inapplicable. Neither Party shall, on the basis of this Agreement, contract on behalf of, or in the name of, the other Party. Any agreement made in violation of this

provision shall be null and void. For clarity, the City approves Color to subcontract the following: Color will sub-contract (i) collection site healthcare worker staffing and onsite logistics to a clinical partner at a rate to be determined by such clinical partner, (ii) technical components of the diagnostic assay test, in certain situations, to Clinical Research Sequencing Platform, LLC, at the Broad Institute of MIT and Harvard, and (iii) site collection logistics and operations. All costs for this subcontracted services will be included as an estimate in Appendix B (Calculation of Charges).

#### 4.3 **Independent Color (Reserved)**

#### 4.4 **Assignment.**

The Services to be performed by Color are personal in character and neither this Agreement nor any duties or obligations hereunder may be assigned or delegated by Color unless set forth in Section 4.2 herein or otherwise approved by City by written instrument executed and approved in the same manner as this Agreement. Any purported assignment made in violation of this provision shall be null and void.

#### 4.5 **Warranty.**

Color warrants to City that the Services will be performed with the degree of skill and care that is required by current, good and sound professional procedures and practices, and in conformance with generally accepted professional standards prevailing at the time the Services are performed so as to ensure that all Services performed are correct and appropriate for the purposes contemplated in this Agreement.

#### 4.6 **Liquidated Damages. (Reserved)**

#### 4.7 **Bonding Requirements. (Reserved)**

### **Article 5 Insurance and Indemnity**

#### 5.1 **Insurance.**

5.1.1 **Required Coverages.** Insurance limits are subject to Risk Management review and revision, as appropriate, as conditions warrant. Without in any way limiting Color's liability pursuant to the "Indemnification" section of this Agreement, Color must maintain in force, during the full term of the Agreement, insurance in the following amounts and coverages:

a) **Workers' Compensation**, in statutory amounts, with Employers' Liability Limits not less than \$1,000,000 each accident, injury, or illness; and

b) **Commercial General Liability Insurance** with limits not less than \$1,000,000 each occurrence for Bodily Injury and Property Damage, including Contractual Liability, Personal Injury; and

c) **Commercial Automobile Liability Insurance (Reserved).**

d) **Healthcare Professional and Products Liability Insurance**, applicable to Color's profession, with limits not less than \$1,000,000 for each claim with respect to negligent acts, errors or omissions in connection with the Services.

e) **Technology Errors and Omissions Liability coverage (Reserved)**

f) **Cyber and Privacy Insurance** with limits of not less than \$2,000,000 per claim. Such insurance shall include coverage for liability arising from theft, dissemination, and/or use of confidential information, including but not limited to, bank and credit card account information or

personal information, such as name, address, social security numbers, protected health information or other personally identifying information, stored or transmitted in any form.

5.1.2 Commercial General Liability Insurance policies must be endorsed to name as Additional Insured the City and County of San Francisco, its Officers, Agents, and Employees.

5.1.3 Color's Commercial General Liability Insurance policies shall provide that such policies are primary insurance to any other insurance available to the Additional Insureds, with respect to any claims arising out of this Agreement, and that the insurance applies separately to each insured against whom claim is made or suit is brought.

5.1.4 All policies shall be endorsed to provide thirty (30) days' advance written notice to the City of cancellation for any reason, intended non-renewal, or reduction in coverages. Notices shall be sent to the City address set forth in Section 11.1, entitled "Notices to the Parties."

5.1.5 Should any of the required insurance be provided under a claims-made form, Color shall maintain such coverage continuously throughout the term of this Agreement and, without lapse, for a period of one year beyond the expiration of this Agreement, to the effect that, should occurrences during the contract term give rise to claims made after expiration of the Agreement, such claims shall be covered by such claims-made policies.

5.1.6 Should any of the required insurance be provided under a form of coverage that includes a general annual aggregate limit or provides that claims investigation or legal defense costs be included in such general annual aggregate limit, such general annual aggregate limit shall be double the occurrence or claims limits specified above.

5.1.7 Should any required insurance lapse during the term of this Agreement, requests for payments originating after such lapse shall not be processed until the City receives satisfactory evidence of reinstated coverage as required by this Agreement, effective as of the lapse date. If insurance is not reinstated, the City may, at its sole option, terminate this Agreement effective on the date of such lapse of insurance.

5.1.8 Before commencing any Services, Color shall furnish to City certificates of insurance and additional insured policy endorsements with insurers with ratings comparable to A-, VI or higher, that are authorized to do business in the State of California, and that are satisfactory to City, in form evidencing all coverages set forth above. Approval of the insurance by City shall not relieve or decrease Color's liability hereunder.

5.1.9 The Workers' Compensation policy(ies) shall be endorsed with a waiver of subrogation in favor of the City for all work performed by the Color, its employees, agents and subcontractors.

5.1.10 If Color will use any subcontractor(s) to provide Services, Color shall require the subcontractor(s) to provide all necessary insurance and to name the City and County of San Francisco, its officers, agents and employees and Color as additional insureds.

## **5.2 Indemnification.**

### **5.2.1 General Indemnity (Reserved, Equitable Indemnity Applies)**

### **5.2.2 Infringement Indemnity.**

Color shall indemnify and hold City harmless from all loss and liability, including attorneys' fees, court costs and all other litigation expenses for any infringement of the patent rights, copyright, trade secret or any other proprietary right or trademark, and all other intellectual property claims of any person or persons arising directly or indirectly from the receipt by City, or any of its officers or agents, of Color's Services.



## **Article 6      Liability of the Parties (Reserved)**

### **6.1      Liability of City.**

CITY'S PAYMENT OBLIGATIONS UNDER THIS AGREEMENT SHALL BE LIMITED TO THE PAYMENT OF THE COMPENSATION PROVIDED FOR IN SECTION 3.3.1, "PAYMENT," OF THIS AGREEMENT. NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, IN NO EVENT SHALL CITY BE LIABLE, REGARDLESS OF WHETHER ANY CLAIM IS BASED ON CONTRACT OR TORT, FOR ANY SPECIAL, CONSEQUENTIAL, INDIRECT OR INCIDENTAL DAMAGES, INCLUDING, BUT NOT LIMITED TO, LOST PROFITS, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT OR THE SERVICES PERFORMED IN CONNECTION WITH THIS AGREEMENT.

### **6.2      Liability of Contractor.**

NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, IN NO EVENT SHALL CONTRACTOR BE LIABLE, REGARDLESS OF WHETHER ANY CLAIM IS BASED ON CONTRACT OR TORT, FOR ANY SPECIAL, CONSEQUENTIAL, INDIRECT OR INCIDENTAL DAMAGES, INCLUDING, BUT NOT LIMITED TO, LOST PROFITS, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT OR THE SERVICES PERFORMED IN CONNECTION WITH THIS AGREEMENT. CONTRACTOR'S MAXIMUM LIABILITY FOR ANY DAMAGES ARISING UNDER OR IN CONNECTION WITH THIS AGREEMENT OR THE SERVICES PERFORMED IN CONNECTION WITH THIS AGREEMENT SHALL BE CAPPED IN THE AGGREGATE AT 1.5 TIMES THE TOTAL, NOT TO EXCEED AMOUNT FOR ALL SERVICES AND/OR DELIVERABLES UNDER THIS AGREEMENT.

CONTRACTOR'S LIABILITY LIMIT SET FORTH ABOVE SHALL NOT APPLY TO:

(1) DAMAGES CAUSED BY CONTRACTOR'S GROSS NEGLIGENCE (FOR PURPOSES OF THIS SECTION, "GROSS NEGLIGENCE" SHALL MEAN A WANT OF EVEN SCANT CARE OR EXTREME DEPARTURE FROM THE ORDINARY STANDARD OF CONDUCT) OR WILLFUL MISCONDUCT;

(2) CONTRACTOR'S OBLIGATION TO INDEMNIFY AND DEFEND CITY PURSUANT TO THE GENERAL INDEMNIFICATION AND INFRINGEMENT INDEMNIFICATION PROVISIONS HEREIN;

(3) DAMAGES THAT ARISE FROM THE UNAUTHORIZED USE OR DISCLOSURE OR FAILURE TO MAINTAIN CONFIDENTIALITY OF CITY'S DATA AND INFORMATION, INCLUDING ALL OF CITY'S RELATED COSTS OF INVESTIGATION AND NOTIFICATION, AND STATUTORY FINES AND PENALTIES ("DATA BREACH");

(4) WRONGFUL DEATH CAUSED BY CONTRACTOR, NOT RELATED TO A LICENSED MEDICAL PROVIDER'S USE OR RELIANCE UPON A CONTRACTOR DELIVERABLE; AND

(5) CLAIMS COVERED BY THE INSURANCE.

## **Article 7      Payment of Taxes**

### **7.1      Sales and Use Tax.**

City shall reimburse Color for all sales and use taxes. Payment of any taxes, including possessory interest taxes and California sales and use taxes, levied upon or as a result of this Contract, or the services delivered pursuant hereto, shall be the obligation of Color. Color recognizes and understands that this Contract may create a “possessory interest” for property tax purposes. Color shall include a line item in its invoice and the budget for taxes.

### **7.2      Withholding. (Reserved)**

## **Article 8      Termination and Default**

### **8.1      Expiration of Local Emergency**

8.1.1 This Agreement shall expire on its own accord sixty (60) calendar days after the City provides written notice of the expiration of the City’s Declaration of Local Emergency. In addition, City shall have the option, in its sole discretion, to terminate this Agreement, at any time during the term hereof, for convenience with not less than 14 calendar days’ prior written notice. In either case, the City shall provide written notice that that specifies the date on which termination shall become effective.

8.1.2 Upon receipt of the notice of termination, Color shall commence and perform, with diligence, all actions necessary on the part of Color to effect the termination of this Agreement on the date specified by City and to minimize the liability of Color and City to third parties as a result of termination. All such actions shall be subject to the prior approval of City. Within 30 days after the specified termination date, Color shall submit to City an invoice. City’s payment obligation under this Section shall survive termination of this Agreement.

## **Article 9      Rights In Deliverables (Reserved)**

## **Article 10      Additional Requirements Incorporated by Reference**

### **10.1      Laws Incorporated by Reference.**

The full text of the laws listed in this Article 10, including enforcement and penalty provisions, are incorporated by reference into this Agreement. The full text of the San Francisco Municipal Code provisions incorporated by reference in this Article and elsewhere in the Agreement ("Mandatory City Requirements") are available at [http://www.amlegal.com/codes/client/san-francisco\\_ca/](http://www.amlegal.com/codes/client/san-francisco_ca/)

### **10.2      Conflict of Interest.**

By executing this Agreement, Color certifies that it does not know of any fact which constitutes a violation of Section 15.103 of the City’s Charter; Article III, Chapter 2 of City’s Campaign and Governmental Conduct Code; Title 9, Chapter 7 of the California Government Code (Section 87100 *et seq.*), or Title 1, Division 4, Chapter 1, Article 4 of the California Government Code (Section 1090 *et seq.*), and further agrees promptly to notify the City if it becomes aware of any such fact during the term of this Agreement.

### **10.3      Prohibition on Use of Public Funds for Political Activity. (Reserved)**

### **10.4      Consideration of Salary History. (Reserved)**

### **10.5 Nondiscrimination Requirements.**

In the performance of this Contract, Color covenants and agrees that it will not discriminate against an applicant for employment because of race, color, religion, sex, age, ancestry, national origin, sexual orientation, handicap, veteran's status, medical condition, marital status, or citizenship because of habit, local custom, or otherwise. All applicants for employment and employees are to be treated without regard to their race, color, religion, sex, age, ancestry, and national origin, sexual orientation, handicap, veteran's status, medical condition, marital status, or citizenship. Such equal treatment shall apply, but not be limited to, employment, upgrading, demotion, or transfer; recruitment or recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship.

#### **10.6 LBE and Non-Discrimination in Contracting Ordinance. (Reserved)**

#### **10.7 Minimum Compensation Ordinance. (Reserved)**

#### **10.8 Health Care Accountability Ordinance. (Reserved)**

#### **10.9 First Source Hiring Program. (Reserved)**

#### **10.10 Alcohol and Drug-Free Workplace.**

City reserves the right to deny access to, or require Color to remove from, City facilities personnel of any Color or subcontractor who City has reasonable grounds to believe has engaged in alcohol abuse or illegal drug activity which in any way impairs City's ability to maintain safe work facilities or to protect the health and well-being of City employees and the general public. City shall have the right of final approval for the entry or re-entry of any such person previously denied access to, or removed from, City facilities. Illegal drug activity means possessing, furnishing, selling, offering, purchasing, using or being under the influence of illegal drugs or other controlled substances for which the individual lacks a valid prescription. Alcohol abuse means possessing, furnishing, selling, offering, or using alcoholic beverages, or being under the influence of alcohol.

### **Article 11 Limitations on Contributions. (Reserved)**

#### **11.1 Slavery Era Disclosure. (Reserved)**

#### **11.2 Working with Minors. (Reserved)**

#### **11.3 Consideration of Criminal History in Hiring. (Reserved)**

#### **11.4 Public Access to Nonprofit Records and Meetings. (Reserved)**

#### **11.5 Food Service Waste Reduction Requirements. (Reserved)**

#### **11.6 Distribution of Beverages and Water. (Reserved)**

#### **11.7 Tropical Hardwood and Virgin Redwood Ban. (Reserved)**

#### **11.8 Preservative Treated Wood Products. (Reserved)**

### **Article 12 General Provisions**

#### **12.1 Notices to the Parties.**

**If to:** San Francisco Department of Public Health  
Office of Contract Management and Compliance  
101 Grove St. Rm. 410  
San Francisco, CA 94102  
Attn: Robert Longhitano

**With a copy to:**

San Francisco Department of Public Health  
101 Grove St. Rm. 308  
San Francisco, CA 94102  
Attn: Dr. Susan Philips, MD

**If to:**

Color Genomics, Inc.  
831 Mitten Road, Suite 100  
Burlingame CA 94010  
Attn: Caroline Savello

**12.2 Compliance with Americans with Disabilities Act.**

Color shall provide the Services in a manner that complies with the Americans with Disabilities Act (ADA), including but not limited to Title II's program access requirements, and all other applicable federal, state and local disability rights legislation.

**12.3 Incorporation of Recitals. (Reserved)**

**12.4 Sunshine Ordinance.**

**12.4.1 Public Records Request:** Contractor acknowledges that this Agreement and all records related to its formation, Contractor's performance of Services, and City's payment are subject to the California Public Records Act, (California Government Code §6250 et. seq.), and the San Francisco Sunshine Ordinance, (San Francisco Administrative Code Chapter 67). Such records are subject to public inspection and copying unless exempt from disclosure under federal, state or local law.

**12.4.2 Contractor's Obligations:** If the Department of Public Health receives a Public Records Request pertaining to Contractor, the Department will use its best efforts to notify Contractor of the Request and to provide Contractor with a description of the material that the Department deems responsive and the due date for disclosure ("Response Date"). If Contractor asserts that some or all of the material requested contains or reveals valuable trade secrets or other information belonging to Contractor that is exempt from disclosure and directs the City in writing to withhold such material from production ("Withholding Directive"), then the City will comply with the Withholding Directive on the condition that Contractor seeks judicial relief on or before the Response Date. If any third-party initiates or threatens to initiate legal action to compel the production of Contractor's material, Contractor shall defend, indemnify and save harmless City and its officers, agents and employees from any and all such third party claims. Should Contractor fail to seek judicial relief on or before Response Date, the City shall proceed with the disclosure of responsive documents.

**12.4.3 Agreement not to Sue:** Contractor agrees that it will not sue the City for damages in connection with the disclosure by the City of information that Contractor asserts is exempt from disclosure, so long as such disclosure was inadvertent and the City uses reasonable efforts to mitigate the effects of the inadvertent disclosure and/or uses reasonable efforts to retrieve the information as appropriate.

**12.5 Modification of this Agreement.**

This Agreement may not be modified, nor may compliance with any of its terms be waived, except as noted in Section 12.1, "Notices to Parties," regarding change in personnel or place, and except by written instrument executed and approved in the same manner as this Agreement.

**12.6 Dispute Resolution Procedure. (Reserved)**

## **12.7 Government Code Claim Requirement.**

No suit for money or damages may be brought against the City until a written claim therefor has been presented to and rejected by the City in conformity with the provisions of San Francisco Administrative Code Chapter 10 and California Government Code Section 900, et seq. Nothing set forth in this Agreement shall operate to toll, waive or excuse Color's compliance with the California Government Code Claim requirements set forth in San Francisco Administrative Code Chapter 10 and California Government Code Section 900, et seq.

## **12.8 Health and Human Service Dispute Resolution Procedure. (Reserved)**

## **12.9 Agreement Made in California; Venue.**

The formation, interpretation and performance of this Agreement shall be governed by the laws of the State of California. Venue for all litigation relative to the formation, interpretation and performance of this Agreement shall be in San Francisco.

## **12.10 Construction.**

All paragraph captions are for reference only and shall not be considered in construing this Agreement.

## **12.11 Entire Agreement.**

This contract sets forth the entire Agreement between the parties and supersedes all other oral or written provisions. This Agreement may be modified only as provided in Section 12.5, "Modification of this Agreement."

## **12.12 Compliance with Laws. (Reserved)**

## **12.13 Severability.**

Should the application of any provision of this Agreement to any particular facts or circumstances be found by a court of competent jurisdiction to be invalid or unenforceable, then (a) the validity of other provisions of this Agreement shall not be affected or impaired thereby, and (b) such provision shall be enforced to the maximum extent possible so as to effect the intent of the parties and shall be reformed without further action by the parties to the extent necessary to make such provision valid and enforceable.

## **12.14 Cooperative Drafting.**

This Agreement has been drafted through a cooperative effort of City and Color, and both Parties have had an opportunity to have the Agreement reviewed and revised by legal counsel. No Party shall be considered the drafter of this Agreement, and no presumption or rule that an ambiguity shall be construed against the Party drafting the clause shall apply to the interpretation or enforcement of this Agreement.

## **12.15 Order of Precedence.**

Color expressly understands and agrees that should any provision of Color's terms and conditions conflict with this City addendum, the terms of this City Addendum take precedence and control.

## **12.16 Notification of Legal Requests. (Reserved)**

# **Article 13 Department Specific Terms**

## **13.1 Third Party Beneficiaries.**

No third parties are intended by the parties hereto to be third party beneficiaries under this Agreement, and no action to enforce the terms of this Agreement may be brought against either party by any person who is not a party hereto.

### 13.2 Federal and State Financial Participation (Reserved)

## Article 14 Data and Security (Reserved)

### 14.1 Nondisclosure of Private, Proprietary or Confidential Information.

**14.1.1 Protection of Private Information.** If this Agreement requires City to disclose "Private Information" to Color within the meaning of San Francisco Administrative Code Chapter 12M, Color and subcontractor shall use such information only in accordance with the restrictions stated in Chapter 12M and in this Agreement and only as necessary in performing the Services. Color is subject to the enforcement and penalty provisions in Chapter 12M.

**14.1.2 Confidential Information.** In the performance of Services, Color may have access to City's proprietary or Confidential Information, the disclosure of which to third parties may damage City. If City discloses proprietary or Confidential Information to Color, such information must be held by Color in confidence and used only in performing the Agreement. Color shall exercise the same standard of care to protect such information as a reasonably prudent Color would use to protect its own proprietary or Confidential Information.

### 14.2 Payment Card Industry ("PCI") Requirements. (Reserved)

### 14.3 Business Associate Agreement.

The parties acknowledge that CITY is a Covered Entity as defined in the Healthcare Insurance Portability and Accountability Act of 1996 ("HIPAA") and is required to comply with the HIPAA Privacy Rule governing the access, use, disclosure, transmission, and storage of protected health information (PHI) and the Security Rule under the Health Information Technology for Economic and Clinical Health Act, Public Law 111-005 ("the HITECH Act").

**The parties acknowledge that Color will:**

1. ☐ Do **at least one** or more of the following:
  - A. Create, receive, maintain, or transmit PHI for or on behalf of CITY/SFDPH (including storage of PHI, digital or hard copy, even if Color does not view the PHI or only does so on a random or infrequent basis); or
  - B. Receive PHI, or access to PHI, from CITY/SFDPH or another Business Associate of City, as part of providing a service to or for CITY/SFDPH, including legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial; or
  - C. Transmit PHI data for CITY/SFDPH and require access on a regular basis to such PHI. (Such as health information exchanges (HIEs), e-prescribing gateways, or electronic health record vendors)

**FOR PURPOSES OF THIS AGREEMENT, COLOR IS A BUSINESS ASSOCIATE OF CITY/SFDPH, AS DEFINED UNDER HIPAA. CONTRACTOR MUST COMPLY WITH AND COMPLETE THE FOLLOWING ATTACHED DOCUMENTS, INCORPORATED TO THIS AGREEMENT AS THOUGH FULLY SET FORTH HEREIN:**

- a. **Appendix E SFDPH (BAA) (04-12-2018) (Reserved)**
  1. SFDPH Attestation 1 PRIVACY (06-07-2017) (Reserved)

2. SFDPH Attestation 2 DATA SECURITY (06-07-2017) (**Reserved**)2. ☒ **NOT do any of the activities listed above in subsection 1;**

Color is not a Business Associate of CITY/SFDPH. Appendix E and attestations are not required for the purposes of this Agreement.

The parties acknowledge and agree that the City and Color are each HIPAA Covered Entities and as such may use and disclose Protected Health Information for treatment, payment and health care operations and for other purposes to the extent permitted by HIPAA and other applicable law.

**14.4 Protected Health Information.**

Color, all subcontractors, all agents and employees of Color and any subcontractor shall comply with all federal and state laws regarding the transmission, storage and protection of all private health information disclosed to Color by City in the performance of this Agreement. Color agrees that any failure of Color to comply with the requirements of federal and/or state and/or local privacy laws shall be a material breach of the Contract. In the event that City pays a regulatory fine, and/or is assessed civil penalties or damages through private rights of action, based on an impermissible use or disclosure of protected health information given to Color or its subcontractors or agents by City, Color shall indemnify City for the amount of such fine or penalties or damages, including costs of notification. In such an event, in addition to any other remedies available to it under equity or law, the City may terminate the Contract.

**Article 15 MacBride And Signature (Reserved)**

IN WITNESS WHEREOF, the parties hereto have executed this Agreement on the day first mentioned above.

**Appendices**

- A: Scope of Services
- B: Calculation of Charges
- C: Insurance Waiver
- D: Test Authorization and Request Form, including the Order of the Health Officer C19-10
- E: Reserved
- F: Invoice
- G: Local Emergency Declaration





## **Appendix A Scope of Services**

**A. Contract Administrator:**

In performing the Services hereunder, Color shall report to **Susan Philips, MD**, Contract Administrator for the City, or his / her designee.

**B. Reports:**

For services solicited under a Group Purchasing Organization (GPO) the Color shall report all applicable sales under this agreement to the respective GPO.

**C. Evaluation:**

Color shall participate as requested with the City, State and/or Federal government in evaluative studies designed to show the effectiveness of Color's Services. Color agrees to meet the requirements of and participate in the evaluation program and management information systems of the City.

For contracts for the provision of services at San Francisco General or Laguna Honda Hospital and Rehabilitation Center, the evaluation program shall include agreed upon performance measures as specified in the Performance Improvement Plan and Performance Measure Grid which is presented in Attachment 1 to Appendix A. Performance measures are reported annually to the Zuckerberg San Francisco General performance improvement committees (PIPS and Quality Council) or the to the Administration Office of Laguna Honda Hospital and Rehabilitation Center.

The City agrees that any final written reports generated through the evaluation program shall be made available to Color within thirty (30) working days. Color may submit a written response within thirty working days of receipt of any evaluation report and such response will become part of the official report.



**Attachment 1 to Appendix A****PERFORMANCE IMPROVEMENT PLAN  
AND PERFORMANCE MEASURE GRID****Contract Services**

**AIM:** All services provided through contractual agreement are provided safely and effectively for patient care and support services, annually.

<b>Contract Name</b>	<b>Services Provided</b>	<b>Measure Name</b>	<b>Metric (What data is being collected? )</b>
1. Color	As-needed COVID-19 Testing Services	Completed Tests	Color completed tests on all submitted samples.



## **Appendix B Calculation of Charges**

### **1. Method of Payment**

A. Color shall submit monthly invoices by the fifteenth (15th) working day of each month, in the format attached in Appendix F, based upon the number of units of service that were delivered in the immediately preceding month. All deliverables associated with the Services listed in Section 2 of Appendix A, times the unit rate as shown in the Program Budgets listed in Section 2 of Appendix B shall be reported on the invoice(s) each month. City shall pay all invoices within thirty (30) days' of receipt, unless otherwise indicated in Appendix B-1.

### **2. Program Budgets and Final Invoice**

A. Program Budgets are listed below and are attached hereto.

#### **Appendix B-1 COVID-19 Testing Services**

B. Color understands that, of the maximum dollar obligation listed in section 3.2 of this Agreement, **\$856,147** is included as a contingency amount and is neither to be used in Program Budgets attached to this Appendix, or available to Color without a modification to this Agreement executed in the same manner as this Agreement or a revision to the Program Budgets of Appendix B, which has been approved by Contract Administrator. Color further understands that no payment of any portion of this contingency amount will be made unless and until such modification or budget revision has been fully approved and executed in accordance with applicable City and Department of Public Health laws, regulations and policies/procedures and certification as to the availability of funds by Controller. Color agrees to fully comply with these laws, regulations, and policies/procedures.

C. Color agrees to comply with its Program Budgets of Appendix B in the provision of Services. Changes to the budget that do not increase or reduce the maximum dollar obligation of the City are subject to the provisions of the Department of Public Health Policy/Procedure Regarding Contract Budget Changes. Color agrees to comply fully with that policy/procedure.

D. A final closing invoice clearly marked "FINAL," shall be submitted no later than forty-five (45) calendar days following the closing date of the Agreement, and shall include only those Services rendered during the referenced period of performance. If Services are not invoiced during this period, all unexpended funding set aside for this Agreement will revert to City. City's final reimbursement to the Color at the close of the Agreement period shall be adjusted to conform to actual units certified multiplied by the unit rates identified in the Program Budgets attached hereto, and shall not exceed the total amount authorized and certified for this Agreement.

**3.** No invoices for Services provided by law firms or attorneys, including, without limitation, as subcontractors of Color, will be paid unless the provider received advance written approval from the City Attorney.



**Appendix B-1**  
**Calculation of Charges**  
**(Budget)**  
**COVID-19 Testing Services**

<b>COVID-19 Test</b>	<b>Price</b>
<p>Color will provide the COVID-19 Testing Platform to San Francisco at a cost of \$75 per test completed, including:</p> <ul style="list-style-type: none"> <li>a. Sample collection kits (swab kits)</li> <li>b. Sample collection paperwork (barcodes, instructions, order forms)</li> <li>c. Transport of sample collection kits: Daily drop-off of kits, 1x-2x/day sample pickup from facilities</li> <li>d. Clinical support (bulk ordering authorization flow, results dashboard)</li> <li>e. Clinical testing results &amp; reporting to patients (negatives &amp; positives) by HIPAA secure method. Results ready notifications by text/phone/email</li> <li>f. Daily reporting of results to calREDIE and San Francisco DPH</li> <li>g. Positive patient routing (e.g., support for contact tracing)</li> </ul>	\$75 / test
<p>Subcontractor Cost: Clinical partner</p> <p>Subcontractor shall provide Healthcare worker staffing at the testing site and shall be responsible for all Personal Protect Equipment for its staff. Prior to execution of any subcontractor agreement, Contractor shall provide to the City a work plan and budget for subcontractor services. The budget shall represent the total cost of the subcontractor and shall be used as the basis for billings. City must approve in writing the submitted subcontractor proposal and budget.</p>	\$18,600 per 5 day week, based on estimate of 200 tests/day (to be revised in the event of volume increase)
<p>Subcontractor Cost: Logistics partner</p> <p>Subcontractor shall provide site logistics (for example, site setup / breakdown / rental costs). Prior to execution of any subcontractor agreement, Contractor shall provide to the City a work plan and budget for subcontractor services. The budget shall represent the total cost of the subcontractor and shall be used as the basis for billings. City must approve in writing the submitted subcontractor proposal and budget.</p>	\$17,528 per 5 day week, based on current site design
<p>One-time Startup Fee: Color will incur startup costs for Subcontractor efforts and pass-through of Subcontractor startup costs, including site design, setup, and project management. Color's startup costs include one-time site setup costs estimated at \$64,795.49 and \$150,000.00 costs for site and project management costs from Color. City agrees to pay such One-Time Startup Fee within five (5) days of full signature of the Agreement.</p>	\$214,795.49

Services are as needed and billed on a per test basis. Subcontractor costs shall be passed through this agreement. The Parties acknowledge and agree that Subcontractor costs may increase if additional sites are added or volume increases, and in such event, the Parties will promptly meet to revise the Budget and payments herein before Services can continue.

#### **Budget Summary**

<b>Charge Item</b>		<b>Estimated Budgeted Amount</b>
<b>1 Completed Test = 1 Unit of Service</b>		
Budgeted amount for testing services		\$5,800,000
Subcontractor Cost: Clinical Partner		\$297,600
Subcontractor Cost: Site Logistics		\$280,448
One-Time Startup Fee		\$214,795
Taxes		\$541,712
Contingency 12%		\$856,147
<b>Total not to Exceed Amount of the Contract</b>		<b>\$7,990,702</b>



**Appendix C**  
**Insurance Waiver**

## Re: Confirmation: No company car usage

Goldstein, Peter (ADM) <peter.goldstein@sfgov.org>

Sun 4/5/2020 12:15 PM

To: Longhitano, Robert (DPH) <robert.longhitano@sfdph.org>; Fitzgerald, Elizabeth (ADM) <elizabeth.fitzgerald@sfgov.org>

Cc: SIMPSON, LOUISE (CAT) <Louise.Simpson@sfcityatty.org>

Auto Liability insurance is hereby waived via this email for DPH contract with Color for this testing engagement at Pier 30/32

PG

Peter Goldstein  
Office of the City Administrator  
City & County of San Francisco  
Deputy Director, Risk Mgmt Division  
Suite 750  
25 Van Ness Avenue  
San Francisco , Ca 94102  
415-554-2305

---

**From:** Longhitano, Robert (DPH) <robert.longhitano@sfdph.org>

**Sent:** Sunday, April 5, 2020 11:54 AM

**To:** Goldstein, Peter (ADM) <peter.goldstein@sfgov.org>; Fitzgerald, Elizabeth (ADM) <elizabeth.fitzgerald@sfgov.org>

**Cc:** SIMPSON, LOUISE (CAT) <Louise.Simpson@sfcityatty.org>

**Subject:** Re: Confirmation: No company car usage

peter the port has changed the location to Pier 30/32 can you update and send over ASAP. Or take out the location from your approval.

This e-mail is intended for the recipient only. If Protected Health Information (PHI) is contained in this email, unauthorized disclosure may subject the discloser to civil or criminal penalties under state and federal privacy laws. If you received this email in error, notify me and destroy the email immediately.

---

**From:** Goldstein, Peter (ADM) <peter.goldstein@sfgov.org>

**Sent:** Saturday, April 4, 2020 10:27 AM

**To:** Longhitano, Robert (DPH) <robert.longhitano@sfdph.org>; Fitzgerald, Elizabeth (ADM) <elizabeth.fitzgerald@sfgov.org>

**Cc:** SIMPSON, LOUISE (CAT) <Louise.Simpson@sfcityatty.org>

**Subject:** Re: Confirmation: No company car usage

Auto Liability insurance is hereby waived via this email for DPH contract with Color for this testing engagement at Lot A

PG

Peter Goldstein  
Office of the City Administrator  
City & County of San Francisco  
Deputy Director, Risk Mgmt Division  
Suite 750  
25 Van Ness Avenue  
San Francisco , Ca 94102  
415-554-2305

---

**From:** Longhitano, Robert (DPH) <robert.longhitano@sfdph.org>  
**Sent:** Saturday, April 4, 2020 9:58 AM  
**To:** Goldstein, Peter (ADM) <peter.goldstein@sfgov.org>; Fitzgerald, Elizabeth (ADM) <elizabeth.fitzgerald@sfgov.org>  
**Cc:** SIMPSON, LOUISE (CAT) <Louise.Simpson@sfcityatty.org>  
**Subject:** Fw: Confirmation: No company car usage

Hi Peter and Elizabeth

below is an email request to waive auto can you please review and approve. this is for emergency testing at lot A. the vendor is a testing company.

This e-mail is intended for the recipient only. If Protected Health Information (PHI) is contained in this email, unauthorized disclosure may subject the discloser to civil or criminal penalties under state and federal privacy laws. If you received this email in error, notify me and destroy the email immediately.

---

**From:** Caroline Savello <caroline@color.com>  
**Sent:** Saturday, April 4, 2020 9:10 AM  
**To:** Longhitano, Robert (DPH) <robert.longhitano@sfdph.org>; SIMPSON, LOUISE (CAT) <Louise.Simpson@sfcityatty.org>  
**Cc:** Sherwin Chen <sherwin@color.com>; Ilana Landsman <ilana@color.com>  
**Subject:** Confirmation: No company car usage

This message is from outside the City email system. Do not open links or attachments from untrusted sources.

Rob and Louise,

I'm writing to confirm that Color employees will not be driving company vehicles to perform the services in our SF First Responder site program/contract.

Please let me know if you have any questions. Regards,  
Caroline

--

**Caroline Savello**

Chief Commercial Officer

[caroline@color.com](mailto:caroline@color.com)

(650) 714-6621

color

## **Appendix D**

### **Test Authorization and Request Form, including the Order of the Health Officer C19-10**





**TO BE USED FOR CITY AND COUNTY OF SAN FRANCISCO ("City")  
FIRST RESPONDER AND HEALTH CARE WORKER PATIENTS  
("City FR/HCW Patients") ONLY**

**Organization:** City and County of San Francisco, acting by and through its Department of Public Health

**Form:** Test Authorization and Request

**To Color Genomics, Inc. ("Color"):**

- A. Testing is limited to City FR/HCW Patients identified by City;**
- B. City will provide pre-approval and/or identification of City FR/HCW Patients invited and approved for testing;**
- C. Each City FR/HCW Patient must show First Responder and/or Healthcare Worker identification before consenting to COVID-19 Testing;**
- D. Each City FR/HCW Patient must provide verbal informed consent, recorded by Color or through its subcontractor, to submit to testing in accordance with Color or its subcontractor's intake/informed consent protocol.**

By my signature below, I attest that I am the Deputy Health Officer for the City with the authority and responsibility to authorize the ordering and delivery of COVID-19 Testing for First Responder City Patients ("City FR/HCW Patients").

By signing below, I confirm that the City has agreed to procure from Color the COVID-19 Test for City FR/HCW Patients and that this Test Authorization and Request serves as a blanket physician order for Color to perform the Color COVID-19 Tests for City FR/HCW Patients.

I am also a physician duly licensed under California law and am authorized under applicable laws and regulations to request Color to render COVID-19 Testing for all such City FR/HCW Patients.

Color (either itself or through its subcontractor(s)) hereby agrees to inform all City FR/HCW Patients, whose samples are sent to Color, about the details of the COVID-19 Test, including its capabilities and limitations, and to obtain a verbal informed consent, recorded by Color or through its subcontractor, to submit to testing in accordance with Color or its subcontractor's intake/informed consent protocol.

In all cases, I hereby instruct Color to report each COVID-19 Test result as required under Health Officer Order C19-10 (attached) and to report the COVID-19 Test result directly to the City FR/HCW Patient and/or a specified telemedicine or clinical service for follow-up consultation.

Approved:  
DocuSigned by:

A handwritten signature in black ink, appearing to read "Susan Philips", written over a blue DocuSign signature line.

4C9D2E27476A474...  
Susan Philips, MD

Deputy Health Officer  
Department of Public Health







**City and County of  
San Francisco**

**Department of Public Health  
Order of the Health Officer**

**ORDER OF THE HEALTH OFFICER No. C19-10**

**ORDER OF THE HEALTH OFFICER  
OF THE CITY AND COUNTY OF SAN FRANCISCO DIRECTING ALL  
LABORATORIES CONDUCTING COVID-19 DIAGNOSTIC TESTS TO  
REPORT COVID-19 TEST INFORMATION – INCLUDING POSITIVE,  
NEGATIVE, AND INCONCLUSIVE TEST RESULTS – TO LOCAL AND  
STATE PUBLIC HEALTH AUTHORITIES.**

DATE OF ORDER: March 24, 2020

**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); San Francisco Administrative Code section 7.17(b).)**

Summary: The virus that causes Coronavirus 2019 Disease (“COVID-19”) is easily transmitted, especially in group settings, and it is essential that the spread of the virus be monitored and slowed to protect the ability of public and private health care providers to handle the influx of new patients and safeguard public health and safety. Because of the risk of the rapid spread of the virus, and the need to protect all members of the community and the Bay Area region, especially our members most vulnerable to the virus and health care providers, this Order requires that all Laboratories conducting COVID-19 Diagnostic Tests comply with mandated Reporting Requirements as defined below. Reporting Requirements include, but are not limited to, promptly reporting all individual positive, negative, and inconclusive test results electronically to the California Department of Public Health (“CDPH”) and, in limited cases where electronic reporting is not possible, to the San Francisco Department of Public Health.

This order begins at 12:01 a.m. on March 25, 2020 and will continue to be in effect until it is rescinded, superseded, or amended in writing by the Health Officer.

**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 (“HEALTH OFFICER”) ORDERS:**



**City and County of  
San Francisco**

**Department of Public Health  
Order of the Health Officer**

## **ORDER OF THE HEALTH OFFICER No. C19-10**

- 1. The intent of this Order is to ensure that any Laboratory conducting Diagnostic Tests adheres to Reporting Requirements established by the Health Officer as those initially capitalized terms are defined in Section 4 and to ensure that complete Diagnostic Test data are promptly shared with individuals from whom the tested samples were taken, their health care providers, if any, and with public health officials, using the California Reportable Disease Information Exchange (“CalREDIE”) system.**
- 2. Every Laboratory that generates any test result that was collected from a resident of the City and County of San Francisco (“City”) or was collected or processed in the City from a Diagnostic Test must fully and timely comply with all Reporting Requirements.**
- 3. Within one hour of receiving Diagnostic test results, Laboratories must report those results to: (1) the tested individual’s health care provider who ordered the test, if any, and other authorized recipients; and (2) public health officials via the CalREDIE system in accordance with all Reporting Requirements.**
- 4. Definitions.**

**For purposes this Order, the following terms will have the meaning given below.**

**a. “Reporting Requirements” means:**

- i. Reporting all positive, negative, and inconclusive Diagnostic Test results in accordance with this Order;**
- ii. Adhering to any and all CDPH reporting and notification requirements for Laboratories conducting Diagnostic Tests, including, without limitation: notification requirements of Chapter 17 of the California Code of Regulations section 2505; the March 9, 2020 CDPH Letter to Laboratory Directors and Managers, attached to this Order as Exhibit A; and the March 9, 2020 CDPH Reportable Conditions: Notification by Laboratories document attached to this Order as Exhibit B, except:**

- 1. Where a Laboratory promptly submits Diagnostic Test results via electronic laboratory reporting to CalREDIE, no further reporting is required. Where a Laboratory is unable to report electronically, it must temporarily report to the San Francisco Department of Public Health via confidential facsimile or telephone as shown at <https://www.sfdcp.org/wp->**



**City and County of  
San Francisco**

**Department of Public Health  
Order of the Health Officer**

## **ORDER OF THE HEALTH OFFICER No. C19-10**

**content/uploads/2018/01/Reportable-Diseases-List-CMR-SFDPH-EFF-10.2019-UPDATED-12.2019.pdf;**

- iii. **Reporting 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;**
    - iv. **If Provided to the Laboratory, the Laboratory shall report in all test requisitions the name, gender, address including ZIP Code, telephone number, pregnancy status, and date of birth, of the individual who is the subject of the Diagnostic Test; and**
    - v. **All Laboratories are requested, but at this time not required, to report to the Health Officer and CDPH whether a specimen was collected from an inpatient or outpatient individual.**
  - b. **“Diagnostic Test” means nucleic acid amplification testing or serologic testing to determine the presence of SARS-CoV-2 (the virus that causes COVID-19) or novel coronavirus infection.**
  - c. **“Laboratory” means any facility meeting the requirements to perform testing classified as high complexity under the Clinical Laboratory Improvement Amendments of section 353 of the Public Health Service Act.**
- 5. **This Order is issued based on evidence of increasing occurrence of COVID-19 within the City and throughout the Bay Area, scientific evidence and best practices regarding the most effective approaches to slow the transmission of communicable diseases generally and COVID-19 specifically, and evidence that the age, condition, and health of a significant portion of the population of the City places it at risk for serious health complications, including death, from COVID-19. Due to the outbreak of the COVID-19 virus in the general public, which is now a pandemic according to the World Health Organization, there is a public health emergency throughout the City. The scientific evidence shows that at this stage of the emergency, it is essential to slow virus transmission as much as possible to protect the most vulnerable and to prevent the health care system from being overwhelmed. Accurate and precise diagnostic testing is an essential tool for combatting the spread of COVID-19. By sharing high quality test result data at scale, state and local health authorities can better track COVID-19, predict its spread, and better focus public resources to end this global pandemic.**



**City and County of  
San Francisco**

**Department of Public Health  
Order of the Health Officer**

## **ORDER OF THE HEALTH OFFICER No. C19-10**

6. This Order also is issued in light of the existence of 131 cases of COVID-19 in the City, as well as at least 1,700 confirmed cases and at least 27 deaths in California, as of 10:00 a.m. on Monday, March 23, 2020, including a significant and increasing number of suspected cases of community transmission and likely further significant increases in transmission.
7. This Order is issued in accordance with, and incorporates by reference, the March 12, 2020 Executive Order (Executive Order N-25-20) issued by Governor Gavin Newsom, the March 4, 2020 Proclamation of a State of Emergency issued by Governor Gavin Newsom, the February 25, 2020 Proclamation by the Mayor Declaring the Existence of a Local Emergency issued by Mayor London Breed, the March 6, 2020 Declaration of Local Health Emergency Regarding Novel Coronavirus 2019 (COVID-19) issued by the Health Officer, and guidance issued by the California Department of Public Health, as each of them have been and may be supplemented.
8. Pursuant to 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 any provision of this Order, including any law or regulation cited in this Order, constitutes an imminent threat and creates an immediate menace to public health and may lead to enforcement measures or referral to the relevant enforcement authorities.
9. This Order shall become effective at 12:01 a.m. on March 25, 2020 and will continue to be in effect until it is rescinded, superseded, or amended in writing by the Health Officer.
10. The City must promptly provide copies of this Order as follows: (1) by posting on the City Administrator's website ([sfgsa.org](https://www.sfgsa.org)) and the Department of Public Health website ([sfdph.org](https://www.sfdph.org)); (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. In addition, the owner, manager, or operator of any Laboratory that is likely to be impacted by this Order is strongly encouraged to post a copy of this Order onsite and to provide a copy to any member of the public asking for a copy.
11. If any provision of this Order or its application to any person or circumstance is held to be invalid, then the reminder of the Order, including the application of such part or provision to other persons or circumstances, shall not be affected and shall



**City and County of  
San Francisco**

**Department of Public Health  
Order of the Health Officer**

**ORDER OF THE HEALTH OFFICER No. C19-10**

**continue in full force and effect. To this end, the provisions of this Order are severable.**

**IT IS SO ORDERED:**

A handwritten signature in blue ink that reads "Tomás Aragón". The signature is written in a cursive style and is positioned above a horizontal line.

Tomás J. Aragón, MD, DrFH,  
Health Officer of the  
City and County of San Francisco

Dated: March 24, 2020



State of California—Health and Human Services Agency  
California Department of Public Health



GAVIN NEWSOM  
Governor

Dear Laboratory Directors and Managers,

The California Department of Public Health (CDPH) expects that CLIA-certified laboratories qualified to perform high complexity testing will soon become eligible to test for SARS-CoV-2, the virus that causes COVID-19, or novel coronavirus infection.

- On February 29, 2020, the Food and Drug Administration (FDA) issued an immediately in effect guidance with policy for diagnostic testing specific to the COVID-19 public health emergency, along with a template for Emergency Use Authorization (EUA) submissions. The guidelines and template are available on the FDA website:
  - Guidance for obtaining approval: <https://www.fda.gov/media/135659/download>.
  - Template for EUA submissions: <https://www.fda.gov/media/135658/download>.
- On March 9, 2020, the list of reportable diseases in [Title 17, California Code of Regulations \(17 CCR\) section 2500](#) was amended to include COVID-19 and Novel coronavirus infections, and [17 CCR section 2505](#) was amended to include SARS-CoV-2 and Coronavirus, novel strains, effective immediately.
  - Any laboratories approved to test for SARS-CoV-2 must report any positive test results for SARS-CoV-2 **within one hour** to the local health officer for the jurisdiction where the patient resides, by telephone and through the Electronic Laboratory Reporting system (ELR).
  - For more information about the ELR, please visit the CDPH website at <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/CalREDIE-ELR.aspx>.
  - Please use the encoding guidelines for ELR messages for SARS-CoV-2. The LOINC codes are pre-release codes, developed for special use. You can find them, and check for future updates, at <https://loinc.org/prerelease/>.
  - In addition, please use the following SNOMED codes:
 

• 260373001	Detected		• 260415000	Not detected
• 419984006	Inconclusive		• 125154007	Specimen unsatisfactory
- Please note that any California laboratory performing testing under the provisions of the EUA must hold a valid California clinical laboratory license pursuant to [Business and Professions Code \(BPC\) section 1265](#), and testing personnel must be authorized to perform testing classified as high complexity under CLIA, as specified in [BPC section 1206.5 \(c\)](#).
  - If a California laboratory sends biological specimens originating in California to a laboratory outside the state for testing, [BPC section 1241](#) requires the out-of-state laboratory to hold a valid California clinical laboratory license.
- CDPH requests that any laboratory applying for an EUA please copy Laboratory Field Services (LFSCovid@cdph.ca.gov) on the email submitting the completed EUA request to the FDA.

Please contact Laboratory Field Services at [LFSCovid@cdph.ca.gov](mailto:LFSCovid@cdph.ca.gov) if you have questions.

Robert J. Thomas, Branch Chief



**Title 17, California Code of Regulations (CCR), Section 2505****REPORTABLE CONDITIONS: NOTIFICATION BY LABORATORIES**

Effective March 9, 2020

California Code of Regulations, Title 17, Section 2505 requires laboratories to report laboratory testing results, including molecular and pathologic results, suggestive of diseases of public health importance to the local health department. Laboratories must report any initial findings as well as any subsequent findings. In addition, laboratories must report negative test results or findings when requested by the Department or a local health officer. The diseases included are:

**Subsection (e)(1) List**

- **Anthrax**, animal (*B. anthracis*)
- **Anthrax**, human (*B. anthracis*)
- **Botulism**
- **Brucellosis**, human (all *Brucella* spp.)
- **Burkholderia pseudomallei** (detection or isolation from a clinical specimen)
- **Burkholderia mallei** (detection or isolation from a clinical specimen)
- **Coronavirus**, novel strains
- **Influenza**, novel strains (human)
- **Plague**, animal (*Y. pestis*)
- **Plague**, human (*Y. pestis*)
- **Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)**
- **Smallpox** (*Variola*)
- **Tularemia**, human (*F. tularensis*)
- **Viral hemorrhagic Fever** agents, animal (VHF), (e.g., Crimean-Congo, Ebola, Lassa and Marburg viruses)
- **Viral Hemorrhagic Fever** agents, human (VHF), (e.g., Crimean-Congo, Ebola, Lassa and Marburg viruses)

**Subsection (e)(2) List**

- **Acid-fast bacillus** (AFB)
- **Anaplasmosis**
- **Babesiosis**
- **Bordetella pertussis** acute infection, by culture or molecular identification
- **Borrelia burgdorferi** infection
- **Brucellosis**, animal (*Brucella* spp. except *Brucella canis*)
- **Campylobacteriosis** (*Campylobacter* spp.) (detection or isolation from a clinical specimen)
- **Chancroid** (*Haemophilus ducreyi*)
- **Chikungunya Virus** infection
- **Chlamydia trachomatis** infection, including lymphogranuloma venereum
- **Carbapenem-resistant Enterobacteriaceae (Carbapenemase-producing)**
- **Coccidioidomycosis**
- **Cryptosporidiosis**
- **Cyclosporiasis** (*Cyclospora cayetanensis*)
- **Dengue virus** infection
- **Diphtheria**
- **Ehrlichiosis**
- **Encephalitis**, arboviral
- **Escherichia coli** infection: shiga toxin producing (STEC) including *E. coli* O157

- **Flavivirus** infection of undetermined species
- **Giardiasis** (*Giardia lamblia*, *intestinalis*, or *duodenalis*)
- **Gonorrhea**
- **Haemophilus influenzae** infection, all types (detection or isolation from a sterile site in a person less than five years of age)
- **Hantavirus** infection
- **Hepatitis A**, acute infection
- **Hepatitis B**, acute or chronic infection (specify gender)
- **Hepatitis C**, acute or chronic infection
- **Hepatitis D** (Delta), acute or chronic infection
- **Hepatitis E**, acute infection (detection of hepatitis E virus RNA from a clinical specimen or positive serology)
- **Human Immunodeficiency Virus (HIV)**, acute infection
- **Influenza**
- **Legionellosis** (*Legionella* spp.) (antigen or culture)
- **Leprosy** (Hansen Disease) (*Mycobacterium leprae*)
- **Leptospirosis** (*Leptospira* spp.)
- **Listeriosis** (*Listeria*)
- **Malaria** (*Plasmodium* spp.)
- **Measles** (Rubeola), acute infection
- **Middle East Respiratory Syndrome Coronavirus (MERS-CoV)**, infection
- **Mumps** (mumps virus), acute infection
- **Neisseria meningitidis** (sterile site isolate or eye specimen) infection
- **Poliovirus** infection
- **Psittacosis** (*Chlamydophila psittaci*)
- **Q Fever** (*Coxiella burnetii*)
- **Rabies**, animal or human
- **Relapsing Fever** (*Borrelia* spp.) (identification of *Borrelia* spp. spirochetes on peripheral blood smear)
- **Rickettsia**, any species, acute infection (detection from a clinical specimen or positive serology)
- **Rocky Mountain Spotted Fever** (*Rickettsia rickettsii*)
- **Rubella**, acute infection
- **Salmonellosis** (*Salmonella* spp.)
- **Shiga toxin** (detected in feces)
- **Shigellosis** (*Shigella* spp.)
- **Syphilis**
- **Trichinosis** (*Trichinella*)
- **Tuberculosis**, including *Mycobacterium tuberculosis* complex
- **Latent Tuberculosis Infection identified by a positive laboratory test** (includes interferon gamma release assays)
- **Tularemia**, animal (*F. tularensis*)
- **Typhoid**
- **Vibrio species** infection
- **West Nile virus** infection
- **Yellow Fever** (yellow fever virus)
- **Yersiniosis** (*Yersinia* spp., non-pestis) (isolation from a clinical specimen)
- **Zika virus** infection



Reportable laboratory findings for these diseases are those specified in 17 CCR Section 2505 or that satisfy the most recent [communicable disease surveillance case definitions](https://wwwn.cdc.gov/nndss/conditions/search/) published by the Centers for Disease Control and Prevention (<https://wwwn.cdc.gov/nndss/conditions/search/>). **All laboratory reports to public health agencies are treated as confidential.**

### **WHEN TO REPORT (ALL DISEASES EXCEPT HIV ACUTE INFECTION)**

These laboratory findings are reportable to the local health officer of the health jurisdiction where the patient resides by telephone within one (1) hour (List (e)(1) diseases) or within one (1) working day (List (e)(2) diseases) from the time that the laboratory notifies the health care provider or other person authorized to receive the report. If the laboratory that makes the positive finding received the specimen from another laboratory, the laboratory making the positive finding shall notify the local health officer of the jurisdiction in which the patient resides within the time specified above from the time the laboratory notifies the referring laboratory that submitted the specimen. If the laboratory is an out-of-state laboratory, the California laboratory that receives a report of such findings shall notify the local health officer in the same way as if the finding had been made by the California laboratory.

### **HOW TO REPORT (ALL DISEASES EXCEPT HIV ACUTE INFECTION)**

Laboratories must report results via electronic laboratory reporting (ELR) to the California Reportable Disease Information Exchange (CalREDIE). Laboratories unable to submit reports electronically may temporarily report on paper to the local health department; reporting on paper must be approved by the local health department. Additional information, including instructions for format of reports, can be found on the [CalREDIE ELR webpage](https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/CalREDIE-ELR.aspx) (<https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/CalREDIE-ELR.aspx>).

Reporting requirements for diseases and agents listed in Subsection (e)(1):

- Make initial report to the local health officer via telephone **within one hour**, and
- Report result(s) to CalREDIE **within one working day** of identification.

Reporting requirements for diseases and agents listed in Subsection (e)(2):

- Report result(s) to CalREDIE within **one working day** of identification.

All reports to the local health officer must include the following: 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.

### **HIV ACUTE INFECTION REPORTING REQUIREMENTS**

In addition to routine reporting requirements set forth in section 2643.10, for acute HIV infection reporting, laboratories shall report all cases within one business day to the local health officer of the jurisdiction in which the patient resides by telephone. If the patient residence is unknown, the laboratory shall notify the health officer of the jurisdiction in which the health care provider is located. If evidence of acute HIV infection is based on presence of HIV p24 antigen, laboratories shall not wait until HIV-1 RNA is detected before reporting to the local health officer.

### **ADDITIONAL REPORTING REQUIREMENTS**

#### **ANTHRAX, BOTULISM, BRUCELLOSIS, GLANDERS, INFLUENZA (NOVEL STRAINS), MELIOIDOSIS, PLAGUE, SMALLPOX, TULAREMIA, and VIRAL HEMORRHAGIC FEVERS**

Whenever a laboratory **receives a specimen** for the laboratory diagnosis of a suspected human case of one of these diseases, such laboratory shall **communicate immediately by telephone** with the Infectious Disease Laboratory Branch of the Department of Public Health for instruction.

**TUBERCULOSIS (Section 2505 Subsections (f) and (g))**

Any laboratory that isolates *Mycobacterium tuberculosis* complex or identifies *Mycobacterium tuberculosis* complex by molecular testing from a patient specimen must submit a culture to the local public health laboratory for the local health jurisdiction in which the patient resides as soon as available from the primary isolate on which a diagnosis of tuberculosis was established. If *Mycobacterium tuberculosis* complex is identified by molecular testing but no culture isolate is available, a specimen available to the laboratory must be submitted instead.

The information listed under “HOW TO REPORT” above must be submitted with the culture.

Unless drug susceptibility testing has been performed by the clinical laboratory on a strain obtained from the same patient within the previous three months or the health care provider who submitted the specimen for laboratory examination informs the laboratory that such drug susceptibility testing has been performed by another laboratory on a culture obtained from that patient within the previous three months, the clinical laboratory must do the following:

- Perform or refer for drug susceptibility testing on at least one isolate from each patient from whom *Mycobacterium tuberculosis* complex was isolated,
- Report the results of drug susceptibility testing, including molecular assays for drug resistance if performed, to the local health officer of the city or county where the patient resides within **one (1) working day** from the time the health care provider or other authorized person who submitted the specimen is notified, and
- If the drug susceptibility testing determines the culture to be resistant to at least isoniazid and rifampin, in addition, submit one culture or subculture from each patient from whom multidrug-resistant *Mycobacterium tuberculosis* complex was isolated to the local public health laboratory (as described above) as soon as available.

Whenever a clinical laboratory finds that a specimen from a patient with known or suspected tuberculosis tests positive for acid fast bacillus (AFB) staining and the patient has not had a culture which identifies that acid fast organism within the past 30 days, the clinical laboratory shall culture and identify the acid fast bacteria or refer a subculture to another laboratory for those purposes.

**MALARIA (Section 2505 Subsection (h))**

Any clinical laboratory that makes a finding of malaria parasites in the blood film of a patient shall immediately submit one or more such blood film slides for confirmation to the local public health laboratory for the local health jurisdiction where the patient resides. When requested, all blood films will be returned to the submitter.

**SALMONELLA (Section 2612)**

California Code of Regulations, Title 17, Section 2612 requires that a culture of the organisms on which a diagnosis of salmonellosis is established must be submitted to the local public health laboratory and then to the State’s Microbial Diseases Laboratory for definitive identification.

**Additional Specimens or Isolates to be Submitted to Public Health (Section 2505 Subsection (m)(1) and (m)(2) Lists)**

The following specimens or isolates must be submitted as soon as available to the local or state public health laboratory:

(m)(1) Specimens:

- Malaria positive blood film slides (see (h) for additional reporting requirements)
- *Neisseria meningitidis* eye specimens
- Shiga toxin-positive fecal broths
- Zika virus immunoglobulin M (IgM)-positive sera

(m)(2) Isolates:

- Drug resistant *Neisseria gonorrhoeae* isolates (cephalosporin or azithromycin only)
- *Listeria monocytogenes* isolates
- *Mycobacterium tuberculosis* isolates (see (f) for additional reporting requirements)
- *Neisseria meningitidis* isolates from sterile sites
- *Salmonella* isolates (see section 2612 for additional reporting requirements)
- Shiga toxin-producing *Escherichia coli* (STEC) isolates, including O157 and non-O157 strains
- *Shigella* isolates

**Additional Instructions for (m)(2) Isolates (Section 2505 Subsection (m)(3)):**

If a laboratory test result indicates infection with any one of the pathogens listed in (m)(2), then the testing laboratory must attempt to obtain a bacterial culture isolate for submission to a public health laboratory in accordance with (m)(2). This requirement includes identification of Shiga toxin in a clinical specimen. If latent tuberculosis infection is identified, an attempt to obtain a bacterial culture isolate is not required. The testing laboratory shall take steps necessary to obtain an isolate, including requesting that additional specimens be collected and sending specimens to a laboratory able to carry out bacterial culture as soon as possible.

**Additional Instructions for HIV-1/2 Specimens (Section 2500 Subsection (n)):**

Upon written request and submission instructions by the Department, a laboratory that receives a specimen reactive for HIV-1/2 antigen or antibody shall submit the specimen to either the local public health laboratory for the jurisdiction in which the patient resides, the State Public Health Laboratory, or their designee. The specimen submission shall include the information identified in subdivision (m) and the Clinical Laboratory Improvement Amendments number.



## **Appendix E**

**Reserved.**



**Appendix F**  
**Invoice**

**Contractor shall submit invoices in a form mutually acceptable to the Contract Administrator and Contractor and invoices shall contain all required information as requested by the City.**





OFFICE OF THE MAYOR  
SAN FRANCISCO



LONDON N. BREED  
MAYOR

## **PROCLAMATION BY THE MAYOR DECLARING THE EXISTENCE OF A LOCAL EMERGENCY**

**WHEREAS**, California Government Code Sections 8550 et seq., San Francisco Charter Section 3.100(13) and Chapter 7 of the San Francisco Administrative Code empower the Mayor to proclaim the existence of a local emergency, subject to concurrence by the Board of Supervisors as provided in the Charter, in the case of an emergency threatening the lives, property or welfare of the City and County or its citizens; and

**WHEREAS**, The United States has confirmed cases of individuals who have a severe acute respiratory illness caused by a novel (new) coronavirus ("COVID-19" or "the virus") first detected in Wuhan, Hubei Province, People's Republic of China ("China"). The virus was first reported in China on December 31, 2019. As of February 24, 2020, the World Health Organization ("WHO") has reported approximately 77,262 confirmed cases of COVID-19 in China, more than the number of confirmed cases of Severe Acute Respiratory Syndrome (SARS) during its 2003 outbreak. An additional 2,069 cases have been confirmed across 29 other countries; in many of these cases, the infected individuals had not visited China. More than 2,500 people have died from the virus, including 23 outside of China. The number of confirmed cases has continued to escalate dramatically over a short period of time; and

**WHEREAS**, WHO officials now report that sustained human-to-human transmission of the virus is occurring. Transmission from an asymptomatic individual has been documented. Although the majority of individuals infected with COVID-19 recover from the disease without special treatment, approximately 1 in 6 may become seriously ill. Manifestations of severe disease have included severe pneumonia, acute respiratory distress syndrome, septic shock, and multi-organ failure. Approximately 2% of the people confirmed infected with COVID-19 have died; and

**WHEREAS**, On January 30, 2020, WHO declared the COVID-19 outbreak a public health emergency of international concern, and on January 31, 2020, the U.S. Department of Health and Human Services declared a Public Health Emergency for the United States; and

**WHEREAS**, The Centers for Disease Control and Prevention ("CDC") has determined that the virus presents a serious public health threat, requiring coordination among state

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LONDON N. BREED  
MAYOR

and local health departments to ensure readiness for potential health threats associated with the virus; and

**WHEREAS**, The CDC has issued guidance to local and State health departments, including San Francisco's Department of Public Health ("DPH"), concerning risk assessment and public health management of persons with potential exposure to COVID-19. These guidelines require DPH to make extraordinary efforts to monitor ongoing communicable disease threats and prepare for management of individuals who may have been exposed to COVID-19; and

**WHEREAS**, DPH, the Department of Emergency Management, and other City partners have been working successfully and diligently to implement CDC guidelines, but now require additional tools and resources to protect the public health given the current state of the epidemic and the need for a sustained response; and

**WHEREAS**, The City's Director of Public Health has determined that DPH cannot comply with the CDC's guidance without immediate action beyond the City's ordinary response capabilities, including directing personnel and resources from other City departments to assist with the ongoing and developing threat of COVID-19; and

**WHEREAS**, Conditions of extreme peril to the safety of persons and property have arisen; and

**WHEREAS**, The Mayor does hereby proclaim that the aforesaid conditions of extreme peril warrant and necessitate the proclamation of the existence of a local emergency,

**NOW, THEREFORE,**

I, London N. Breed, Mayor of the City and County of San Francisco, proclaim the existence, effective immediately on February 25, 2020, of an emergency within the City and County threatening the lives, property or welfare of the City and County and its citizens;

**It is further ordered that:**

(1) All City and County officers and employees take all steps requested by the Director of Public Health to prevent the spread of COVID-19 and to prevent or alleviate illness or death due to the virus; and

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SAN FRANCISCO



LONDON N. BREED  
MAYOR

(2) All City and County officers and employees take all steps requested by the Director of Public Health to qualify the City for reimbursement from the Federal Emergency Management Agency and for other state and federal relief as may be available to reimburse the City for the expenses it incurs in addressing this emergency; and

**I further proclaim and order that:**

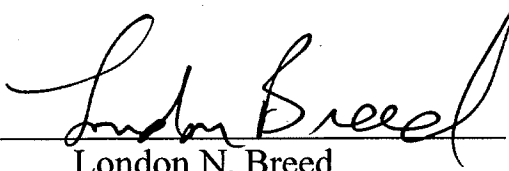
By the terms of this emergency declaration the government of the City and County of San Francisco is organized under the provisions of the Incident Command System (ICS), which system forms an essential part of the City's Emergency Operations Plan. The head of each City department and agency shall observe his or her proper relationship in the command structure outlined by the system and shall respond to the orders and requests of the Lead Department designated to exercise supervision over his or her department during the course of this emergency;

Because of the extreme peril to its residents and visitors, the Governor of the State of California is hereby requested to include the area of the City and County of San Francisco in any emergency declaration by the State, and is further requested to ensure that the City and County is included in any emergency declaration that may be issued by the President of the United States.

**And I further proclaim and order that:**

This declaration of a local emergency shall continue to exist until it is terminated by the Mayor or the Board of Supervisors. All departments of the City and County of San Francisco are strictly ordered to cooperate with the requests for material and personnel resources that may emanate from the Incident Command Staff of the City and County which is located in the Emergency Command Center of the City and County of San Francisco.

DATED: 2/25/2020

  
London N. Breed  
Mayor of San Francisco

