File No	201192	Committee Item No.	
		Board Item No.	

COMMITTEE/BOARD OF SUPERVISORS

AGENDA PACKET CONTENTS LIST

Committee:	Budget & Finance Committee	Date_	November 18, 2020
Board of Su	pervisors Meeting	Date	
Cmte Boar	⁻ d		
	Motion Resolution Ordinance Legislative Digest Budget and Legislative Analyst Rep Youth Commission Report Introduction Form Department/Agency Cover Letter an MOU Grant Information Form Grant Budget Subcontract Budget Contract/Agreement Form 126 – Ethics Commission Award Letter Application Public Correspondence		port
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AMENDED IN COMMITTEE 11/04/2020

FILE NO. 201192

RESOLUTION NO.

1	[Contract Amendment - Color Genomics, Inc COVID-19 Testing Services - Not to Exceed \$84,382,042]
2	+ o ·, o o = , o · = j
3	Resolution approving Amendment No. 3 to the agreement between Color Genomics,
4	Inc. and the Department of Public Health, for COVID-19 testing services, to increase the
5	agreement amount by \$74,482,042 for a total not to exceed amount of \$84,382,042; and
6	to establish a specific term end date of April 5, 2021, for a total agreement term of April
7	6, 2020, through April 5, 2021.
8	
9	WHEREAS, The Department of Public Health (DPH) entered into an agreement with
10	Color Genomics, Inc. on April 6, 2020, for COVID-19 testing services for City employees only
11	at the Embarcadero testing site, in the amount of \$7,990,000 under Chapter 21.15 of the San
12	Francisco Administrative Code and the Mayor's proclamation declaring the existence of a
13	local emergency, for a term lasting through the duration of the emergency; and
14	WHEREAS, Under the same authority, on April 20, 2020, DPH subsequently amended
15	the agreement with Amendment 1, to expand testing at the Embarcadero site from only City
16	employees to all essential workers, and to add a testing site in the South of Market
17	neighborhood, increasing the amount to \$8,254,661; and
18	WHEREAS, On May 4, 2020, with Amendment No. 2, DPH mobile testing was added,
19	increasing the amount to \$9,990,000; and
20	WHEREAS, To align with the Mayor's proclamation requiring contract terms be no
21	longer than 12 months DPH wishes to amend the agreement by executing Amendment No.
22	3, to establish a specific date for the expiration of the agreement of April 5, 2021, with the
23	provision that the City may terminate the agreement earlier when a replacement agreement
24	awarded under a Request For Proposals takes its place; and
25	

1	WHEREAS, Amendment No. 3 will also add two mobile testing teams, increase
2	capacity at the Embarcadero testing site, increase City employee testing at Laguna Honda
3	Hospital and at an optional third site, and allow Color Genomics to seek reimbursement from
4	insurers; now, therefore, be it
5	RESOLVED, That the Board of Supervisors hereby authorizes the Director of Public
6	Health and the Director of the Office of Contract Administration/Purchaser, on behalf of the
7	City and County of San Francisco, to execute Amendment No. 3; and, be it
8	FURTHER RESOLVED, That the Board of Supervisors authorizes the
9	Department of Public Health to enter into any amendments or modifications to the
10	contract, prior to its final execution by all parties, that the Department determines, in
11	consultation with the City Attorney, are in the best interest of the City, do not otherwise
12	materially increase the obligations or liabilities of the City, are necessary or advisable to
13	effectuate the purposes of the contract, and are in compliance with all applicable laws;
14	and, be it
15	FURTHER RESOLVED, That within thirty (30) days of the contract being fully executed
16	by all parties, the Director of Heath and/or the Director of the Office of Contract
17	Administration/Purchaser shall provide the final contracts to the Clerk of the Board for
18	inclusion into the official File No. 201192.
19	
20	RECOMMENDED:
21	
22	
23	Director of Health
24	

25

Item 2	Department:
File 20-1192	Department of Public Health (DPH)
(Continued from 11/4 meeting)	

EXECUTIVE SUMMARY

Legislative Objectives

• The proposed resolution would approve the Third Amendment to the City's agreement with Color Genomics, increasing the amount by \$74,482,043, from \$9,900,000 to \$84,382,042. According to the proposed resolution, the end date is the earlier of (i) the award of a new agreement through a competitive Request for Proposal, or (ii) April 5, 2021.

Key Points

- The Department of Public Health (DPH) entered into the original agreement with Color Genomics in April 2020 to provide COVID-19 testing. Color Genomics opened two testing sites in the first month of the agreement in April 2020 at the Embarcadero and South of Market. Between April 2020 and October 2020, Color added three mobile testing sites and laboratory testing in support of the universal testing program at Laguna Honda Hospital.
- DPH entered into the original agreement with Color Genomics on an emergency basis under the authority of Administrative Code Section 21.15, which allows departments to enter into agreements to address a public health emergency "in the most expeditious manner." DPH has subsequently entered into agreement amendments for an amount of \$9,900,000 through July 2020.
- The proposed Third Amendment, increasing the agreement amount to \$84,382,042 and extending the agreement through March 2021, would provide for approximately 22,725 COVID tests per week at cost of \$75 per test, which according to DPH, is less than the federal benchmark of \$100 per test. The total agreement amount covers expenses invoiced by Color Genomics since July 2020 but not yet paid.

Fiscal Impact

• Of the \$74.5 million increase in the agreement, DPH expects the Federal Emergency Management Agency to pay for approximately \$49.1 million, health insurance to reimburse \$6.6 million, and the remaining \$15.8 million of contract costs to be General Fund.

Policy Consideration

 The Board of Supervisors is being asked to approve an \$84.4 million agreement, which was awarded as a sole source contract in response to an emergency. According to DPH, the Controller's Office is drafting a Request for Proposals (RFP) to solicit a new COVID testing vendor through a competitive process.

Recommendation

• Approve the proposed resolution.

MANDATE STATEMENT

City Charter Section 9.118(b) states that any contract entered into by a department, board or commission that (1) has a term of more than ten years, (2) requires expenditures of \$10 million or more, or (3) requires a modification of more than \$500,000 is subject to Board of Supervisors approval.

BACKGROUND

On April 6, 2020, the Department of Public Health entered into an agreement with Color Genomics, Inc. to provide COVID-19 testing. Currently, approximately 60 percent of City-funded COVID-19 tests are completed by Color Genomics. The remaining 40 percent of City-funded testing is conducted through the ZSFG Clinical Laboratory and the City's Public Health Lab.

The Department has entered into two prior agreement amendments in April and May 2020. Table 1 below summarizes the terms of the original agreement with Color Genomics and subsequent amendments.

Agreement Not to **Effective Date End Date** Scope **Exceed** 1 testing site for City \$7,999,702 April 6, 2020 Original Agreement essential workers Duration of the 2 testing sites, available emergency plus to essential workers Amendment 1 April 20, 2020 \$8,254,661 60 days who met DPH eligibility criteria May 4, 2020 \$9,990,000 Added a mobile unit Amendment 2

Table 1: History of Agreement with Color Genomics

Source: Agreement with Color Genomics, Inc. and Amendments 1 & 2 $\,$

Vendor Selection

According to Michelle Ruggels, Director of the Department of Public Health (DPH) Business Office, the original agreement with Color Genomics was entered into on an emergency basis under the authority of Administrative Code Section 21.15, which allows Departments to enter into agreements to address a public health emergency "in the most expeditious manner." DPH selected the vendor based on an internal review of the its qualifications and capacity for testing services. Administrative Code Section 21.15 requires Departments attempt to obtain at least three bids and to seek Board of Supervisors' approval for emergency contracts above \$100,000. According to Ms. Ruggels, DPH did not obtain three bids because of the immediate need for COVID testing services. Subsequent to entering into the original agreement with Color Genomics, on May 11, 2020 the Mayor issued the Thirteenth Supplement to her Proclamation of a Local Emergency, which waived Administrative Code requirements for solicitation and procurement for COVID-19 related agreements.

DETAILS OF PROPOSED LEGISLATION

The proposed resolution would approve the Third Amendment to the City's agreement with Color Genomics, which would increase the agreement amount by \$74,482,043, from \$9,900,000 to not-to-exceed \$84,382,042. According to the proposed resolution, the end date is the earlier of (i) the award of a new agreement through a competitive Request for Proposal, or (ii) April 5, 2021.

Services Provided

The existing agreement with Color Genomics includes COVID-19 testing, including obtaining and testing samples, site planning and rentals, and providing a scheduling platform.

Table 2: Third Amendment Provisions

Term	April 6, 2020 to March 31, 2021
Amount	\$84,382,042
Services	Collection kits (swab kits), collection paperwork, transportation of kits to Color's lab, testing results and reporting to patients and other reporting requirements established by the Health Officer, support for contact tracing, site planning, language translation (telephone), scheduling and results platform

Source: Proposed Third Amendment to Agreement with Color Genomics

Color Genomics opened two testing sites in the first month of the agreement in April 2020 at the Embarcadero and South of Market. Between April 2020 and October 2020, the agreement provided for two stationary testing sites at the Embarcadero, and South of Market, and three mobile testing sites, and laboratory testing in support of the universal testing program at Laguna Honda Hospital. DPH intends to close the SoMa testing site at 6th Street and Mission Street on November 10, 2020 and may open a new testing site near the Alemany Farmer's Market, which would start on November 17, 2020.

The total number of tests under the proposed third amendment between August 2020 and March 2021 is 772,650, shown in Table 3 below, with an average of approximately 22,725 tests per week.

Table 3: Testing Capacity for Proposed Third Amendment, Aug. 1, 2020 to March 31, 2021

Site	Tests
Embarcadero	452,200
SoMa/Alemany Farmer's Market	90,950
Mobile Testing 1	59,500
Mobile Testing 1	59,500
Mobile Testing 3	59,500
Laguna Honda (laboratory services)	51,000
Total	772,650

Source: Draft Third Amendment

According to Drew Murrell, Deputy Finance Officer for the DPH, the City's COVID Command Center, the interdepartmental task force directing the City's COVID response, determines the location of the mobile testing sites and may also change the location of testing sites based on identification of the neighborhoods in the City where testing can make the most difference. DPH reports it has determined a neighborhood-based strategy that targets geographic areas with the highest burden of disease, will improve the ability to decrease active infections within the city. Dr. Naveena Bobba, Deputy Director of DPH, advises that a new testing public webpage is under development that will provide regular updates related to positivity rates and test rates by neighborhood (though not by testing source).

According to Mr. Murrell, the turnaround time between when a patient gets tested by Color Genomics and receives their results averages less than 48 hours.

FISCAL IMPACT

The total budget for the contract is \$84,382,043.

Table 4: Agreement Budget

		Proposed 3 rd Amendment	
	April 2020 – July	Aug 2020 – Mar	
	2020	2021	Total
COVID-19 Testing	\$5,800,000	\$57,948,750	\$63,748,750
Static and Mobile Site Clinical Management (Subcontractor)	297,600	6,081,410	6,379,010
Static and Mobile Site Logistics Management (Subcontractor)	280,448	2,118,200	2,398,648
Language Capacity		13,464	13,464
Registration and Test Result Platform	90,000	340,000	430,000
Start Up and IT Costs (one time)	324,795		324,795
Mobile Platform Testing (one time)	1,667,388		1,667,388
Taxes	379,950		379,950
Contingency (12% of total)	1,059,819	7,980,219	9,040,038
Total	\$9,900,000	\$74,482,043	\$84,382,043

Source: Original and Amended Agreements

The COVID-19 testing amount of \$57,948,750 under the proposed Third Amendment is for 772,650 tests at \$75 per test. According to DPH, the \$75 cost per test included in the proposed agreement compares favorably with the national benchmark of \$100 cost per test reported by U.S. Centers for Medicare & Medicaid Services.

According to DPH, Color Genomics has invoiced approximately \$22 million through September, or approximately \$12.1 million more than the agreement amount of \$9.9 million. The proposed Third Amendment would cover expenses incurred since July 2020 through March 2021. The proposed Third Amendment contains a twelve percent contingency for an optional third site, which, as noted above, is tentatively planned to be situated near Alemany Farmer's Market.

Sources of Funding

Of the \$74.5 million increase in the Color Genomics contract, DPH expects the Federal Emergency Management Agency to pay for approximately \$49.1 million, health insurance to reimburse \$6.6 million, and the remaining \$15.8 million of contract costs to be sourced from the General Fund. Health insurance reimbursement depends on the coverage of testing patients.

POLICY CONSIDERATION

The Board of Supervisors is being asked to approve an \$84.4 million agreement, which was awarded as a sole source contract in response to an emergency. According to DPH, the Controller's Office is drafting a Request for Proposals (RFP) to solicit a new COVID testing vendor through a competitive process. At the November 4, 2020 Budget and Finance Committee meeting, the Committee Chair requested the Controller for an update on the RFP process to

ensure that a new vendor selected through a competitive process will be in place by the end date of the proposed third amendment in April 2021

RECOMMENDATION

Approve the proposed resolution.

Item 5	Department:
File 20-1192	Department of Public Health (DPH)

EXECUTIVE SUMMARY

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• The proposed resolution would approve the Third Amendment to the City's agreement with Color Genomics, increasing the amount by \$74,482,043, from \$9,900,000 to \$84,382,042. According to the proposed resolution, the end date is the earlier of (i) the award of a new agreement through a competitive Request for Proposal, or (ii) April 5, 2021.

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Recommendations

- The Board of Supervisors should request the Controller for an update on the RFP process to ensure that a new vendor selected through a competitive process will be in place by the end date of the proposed Third Amendment in April 2021.
- Amend the proposed resolution to provide for an end date of April 5, 2021, rather than March 31, 2021, as stated in the resolution.
- Approve the proposed resolution as amended.

MANDATE STATEMENT

City Charter Section 9.118(b) states that any contract entered into by a department, board or commission that (1) has a term of more than ten years, (2) requires expenditures of \$10 million or more, or (3) requires a modification of more than \$500,000 is subject to Board of Supervisors approval.

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SAN FRANCISCO BOARD OF SUPERVISORS

BUDGET AND LEGISLATIVE ANALYST

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Source: Draft Third Amendment

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Sources of Funding

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POLICY CONSIDERATION

The Board of Supervisors is being asked to approve an \$84.4 million agreement, which was awarded as a sole source contract in response to an emergency. According to DPH, the Controller's Office is drafting a Request for Proposals (RFP) to solicit a new COVID testing vendor through a competitive process. The Board of Supervisors should request the Controller for an update on the RFP process to ensure that a new vendor selected through a competitive process will be in place by the end date of the proposed third amendment in April 2021.

RECOMMENDATIONS

- Amend the proposed resolution to provide for an end date of April 5, 2021, rather than March 31, 2021, as stated in the resolution.
- The Board of Supervisors should request the Controller for an update on the RFP process to ensure that a new vendor selected through a competitive process will be in place by the end date of the proposed third amendment in April 2021.
- Approve the proposed resolution, as amended.

City and County of San Francisco Office of Contract Administration Purchasing Division

Third Amendment

THIS AMENDMENT (this "Amendment") is made as of 12th day of October 2020 in San Francisco, California, by and between Color Genomics, Inc. ("Contractor"), and the City and County of San Francisco, a municipal corporation ("City"), acting by and through its Director of the Office of Contract Administration.

Recitals

WHEREAS, City and Contractor have entered into the Agreement (as defined below); and

WHEREAS, City and Contractor desire to modify the Agreement on the terms and conditions set forth herein to expand the COVID-19 testing program; and

WHEREAS, approval for this Agreement under San Francisco Charter Section 9.118 was obtained when the Board of Supervisors approved Resolution No. on . .

NOW, THEREFORE, Contractor and the City agree as follows:

Article 1 Definitions

The following definitions shall apply to this Amendment:

- 1.1 **Agreement.** The term "Agreement" shall mean the Agreement dated April 6, 2020 between Contractor and City, Formal Modification No. 1 dated April 20, 2020, and Formal Modification No. 2 dated May 4, 2020.
- 1.2 **Other Terms.** Terms used and not defined in this Amendment shall have the meanings assigned to such terms in the Agreement.

Article 2 Modifications to the Agreement.

The Agreement is hereby modified as follows:

2.1 **Contract Documents.** The attached set of contract documents replace the original set of contract documents in their entirety.

Article 3 Effective Date

Each of the modifications set forth in Section 2 shall be effective on and after July 22, 2020.

Article 4 Legal Effect

Except as expressly modified by this Amendment, all of the terms and conditions of the Agreement shall remain unchanged and in full force and effect.

IN WITNESS WHEREOF, Contractor and City have executed this Amendment as of the date first referenced above.

CITY	1 11	CONTRACTOR				
Recommended by:		Color Genomics, Inc.				
		DocuSigned by:				
		Cardini Savello				
Grant Col	fav. MD	Caroline Savello				
Director o		Chief Commercial Officer				
	nt of Public Health	City Supplier number: 0000042840				
Departine	int of 1 done freath	City Supplier number. 0000042040				
Approved	as to Form:					
Dennis J.						
City Attor	mey					
By:						
Lo Lo	ouise S. Simpson					
	eputy City Attorney					
Approved	:					
Sailaja Ku	urella, Acting Director and Purchase	er				
By:						
Name:						
Attached	<u></u>					
City Adde						
Appendix						
A:	Scope of Services					
	Attachment 1 to Append	ix A				
	Appendix A-1 Statement	of Work				
B:	Calculation of Charges					
	Appendix B-1 Calculation	on of Charges (Budget)				
C:	Reserved					
D:	Test Authorization and Request Form, including the Order of the Health Officer C19-10					
E:	Reserved					
F:	Invoice					
G:	Local Emergency Declaration					
H:	Color Data Security/Hosting Terms					
I:	Data Flow Diagram					
J:	Reporting and Data Flow Chart					
K:	Port Operation Requirements and Site Plan					
L:	FEMA Emergency & Exigency Contracts Requirements					

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 shall expire on the earlier of (1) the effective date of any non-emergency COVID-19 testing Integrator Agreement certified by the City pursuant to the anticipated upcoming Request for Proposals ("Integrator Agreement"), or (2) April 5, 2021, 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 each party's respective 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 EIGHTY FOUR MILLION THREE HUNDRED EIGHTY TWO THOUSAND FORTY TWO DOLLARS (\$84,382,042) 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."

3.3 Payment Limited to Satisfactory Services.

Contractor is not entitled to any payments from City until Department of Public Health approves Services, including any furnished Deliverables, as satisfying all of the requirements of this Agreement. Any satisfaction requirements for Services and Deliverables shall be set forth in Exhibit A and B.

Payments to Contractor by City shall not excuse Contractor from its obligation to replace unsatisfactory Deliverables, including equipment, components, materials, or Services even if the unsatisfactory character of such Deliverables, equipment, components, materials, or Services may not have been apparent or detected at the time such payment was made. Deliverables, equipment, components, materials and Services that do not conform to the requirements of this Agreement may be rejected by City and in such case must be replaced by Contractor without delay at no cost to the City.

3.4 Withhold Payments.

If Contractor fails to provide Services in accordance with Contractor's obligations under this Agreement and City provides Contractor written notice of such failure and Contractor does not cure such failure within thirty days' thereafter, the City may withhold any and all payments covering these nonconforming services due Contractor until such failure to perform is cured, and Contractor shall not stop work as a result of City's withholding of payments as provided herein. For clarity, the City's withholding authority applies only to disputed amounts. The City has no authority to withhold undisputed amounts, which shall be subject to Section 8.3 below.

3.5 LBE Payment and Utilization Tracking System. (Reserved)

3.6 Getting paid by the City for goods and/or services.

- 3.6.1 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.
- 3.6.2 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.

3.7 Federal and/or State Funded Contracts.

3.7.1 **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 based on their determination, not the City's determination, that Color or a Color employee failed-to comply with a law, regulation or contract term made applicable to this Agreement and such noncompliance materially affected the Services provided to the City, Color shall promptly refund the disallowed amount to City upon City's request. Such disallowance will be applied only to reduce or offset payment made to Color for Services that the State of California or United States Government disallows. In the event the State of California or United States Government disallows any reimbursement of amounts previously paid or payable to Color, City agrees to promptly notify Color of such disallowance or potential disallowance and to cooperate in good faith with Color to permit Color to dispute such disallowance or potential disallowance. At its option, City may offset such disallowed amount from any payment due or to become due to Color under this Agreement or any other agreement between Color and City.

3.7.2 Grant Terms. (Reserved)

3.8 **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.

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3.9 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.

3.10 Submitting False Claims.

The full text of San Francisco Administrative Code Chapter 21, Section 21.35, including the enforcement and penalty provisions, is incorporated into this Agreement. Pursuant to San Francisco Administrative Code §21.35, any contractor or subcontractor who submits a false claim shall be liable to the City for the statutory penalties set forth in that section. A contractor or subcontractor will be deemed to have submitted a false claim to the City if the contractor or subcontractor: (a) knowingly presents or causes to be presented to an officer or employee of the City a false claim or request for payment or approval; (b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the City; (c) conspires to defraud the City by getting a false claim allowed or paid by the City; (d) knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the City; or (e) is a beneficiary of an inadvertent submission of a false claim to the City, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the City within a reasonable time after discovery of the false claim.

3.11 Payment of Prevailing Wages (Reserved)

3.12 Scope Reduction Options

Given the local emergency, the pandemic unknowns, and the City's resulting budgetary position, and in order to preserve the Agreement and enable Contractor to continue to perform work albeit potentially on a reduced basis, the City shall have authority during the Term of the Agreement, without the execution of a Formal Amendment, to reduce scope, temporarily suspend the Agreement work, and/or convert the Term to month-to-month, upon at least thirty (30) day prior written notice and by use of a written Revision to Program Budgets, executed by the Director of Health, or his or her designee, and Contractor. Contractor understands and agrees that the City's right to effect a Revision to Program Budgets is intended to serve a public purpose and to protect the public fisc and is not intended to cause harm to or penalize Contractor. Contractor provides City with a full and final release of all claims arising from a City Revision to Program Budgets except that City agrees to reimburse Contractor for any fees Contractor incurred under the terms of this Agreement before such scope reduction or suspension. Contractor further agrees that it will not sue the City for damages arising directly or indirectly from a City Revision to Program Budgets that complies with the terms of this Section.

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 all subcontractors referenced in Appendix A and/or B, and such other subcontractors that may be mutually agreed to by the parties from time to time.

4.3 Independent Color

4.3.1 **Independent Contractor**. For the purposes of this Article 4, "Contractor" shall be deemed to include not only Contractor, but also any agent or employee of Contractor. Contractor acknowledges and agrees that at all times, Contractor or any agent or employee of Contractor shall be deemed at all times to be an independent contractor and is wholly responsible for the manner in which it performs the services and work requested by City under this Agreement. Contractor, its agents, and employees will not represent or hold themselves out to be employees of the City at any time. Contractor or any agent or employee of Contractor shall not have employee status with City, nor be entitled to participate in any plans, arrangements, or distributions by City pertaining to or in connection with any retirement, health or other benefits that City may offer its employees. Contractor or any agent or employee of Contractor is liable for the acts and omissions of itself, its employees and its agents. Contractor shall be responsible for all obligations and payments, whether imposed by federal, state or local law, including, but not limited to, FICA, income tax withholdings, unemployment compensation, insurance, and other similar responsibilities related to Contractor's performing services and work, or any agent or employee of Contractor providing same. Nothing in this Agreement shall be construed as creating an employment or agency relationship between City and Contractor or any agent or employee of Contractor. Any terms in this Agreement referring to direction from City shall be construed as providing for direction as to policy and the result of Contractor's work only, and not as to the means by which such a result is obtained. City does not retain the right to control the means or the method by which Contractor performs work under this Agreement. Contractor agrees to maintain and make available to City, upon request and during regular business hours, accurate books and accounting records demonstrating Contractor's compliance with this section. Should City determine that Contractor, or any agent or employee of Contractor, is not performing in accordance with the requirements of this Agreement, City shall provide Contractor with written notice of such failure. Within ten (10) business days of Contractor's receipt of such notice, and in accordance with Contractor policy and procedure, Contractor shall remedy the deficiency. Notwithstanding, if City believes that an action of Contractor, or any agent or employee of Contractor, warrants immediate remedial action by Contractor, City shall contact Contractor and provide Contractor in writing with the reason for requesting such immediate action.

4.3.2 **Payment of Employment Taxes and Other Expenses**. Should a relevant taxing authority such as the Internal Revenue Service or the State Employment Development Division, or both ("relevant taxing authority"), determine that Contractor is an employee of the City for purposes

of collection of any employment taxes, the amounts payable under this Agreement shall be reduced by amounts equal to both the employee and employer portions of the tax due (and offsetting any credits for amounts already paid by Contractor which can be applied against this liability). City shall then forward those employment tax amounts to the relevant taxing authority. Should a relevant taxing authority determine an employment tax liability for past services performed by Contractor for City, upon notification of such fact by City, Contractor shall promptly remit such amount due or arrange with City to have the amount due withheld from future payments to Contractor under this Agreement (again, offsetting any amounts already paid by Contractor which can be applied as a credit against such liability). A determination of employment status pursuant to this Section 4.4 shall be solely limited to the purposes of the particular tax in question, and for all other purposes of this Agreement, Contractor shall not be considered an employee of City.

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.
- b) **Commercial General Liability Insurance** with limits not less than \$5,000,000 each occurrence for Bodily Injury and Property Damage, including Contractual Liability, Personal Injury. Contractor is permitted to meet any of the insurance requirements in this section with the use of excess or umbrella coverage.
- c) Commercial Automobile Liability Insurance. Commercial Automobile Liability Insurance with limits not less than \$2,000,000 each occurrence, "Combined Single Limit" for Bodily Injury and Property Damage, including Non-Owned and Hired auto coverage, as applicable. Contractor is permitted to meet any of the insurance requirements in this section with the use of excess or umbrella coverage.

- d) Healthcare Professional and Products Liability Insurance, applicable to Color's profession, with limits not less than \$2,000,000 for each claim with respect to negligent acts, errors or omissions in connection with the Services. Contractor is permitted to meet any of the insurance requirements in this section with the use of excess or umbrella coverage.
 - e) Technology Errors and Omissions Liability coverage (Reserved)
- f) Cyber and Privacy Insurance with limits of not less than \$15,000,000 per claim and in the aggregate. 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. Contractor is permitted to meet any of the insurance requirements in this section with the use of excess or umbrella coverage.
 - 5.1.2 Commercial General Liability and Automobile 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 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.
 - 5.1.7 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.
 - 5.1.8 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.
- 5.1.9 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. Contractor shall indemnify and hold harmless City and its officers, agents and employees from, and, if requested, shall defend them from and against any and all third party claims, demands, losses, damages, costs, expenses, and liability (legal, contractual, or otherwise) to the extent arising directly or indirectly from Contractor's performance of the Agreement, except to the extent that such indemnity is void or otherwise unenforceable, and also except where such loss, damage, injury, liability or claim is the result of the negligence or willful misconduct of City (including negligence or willful misconduct of City's affiliated or contracted entities (e.g. SF DPH, security staff, greeters, etc.), and all employees, contractors, or agents thereof), in which case damages shall be apportioned pro rata under the California doctrine of comparative fault. The foregoing indemnity shall include, without limitation, reasonable fees of attorneys, consultants and experts and related costs and City's costs of investigating any claims against the City, provided that Contractor may request to control the defense and investigation of such claims from the San Francisco City Attorney's office, which request the San Francisco City Attorney's office shall not unreasonably deny.

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

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:

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- (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.

Contractor agrees that it is obligated to pay all amounts due to the City under the San Francisco Business and Tax Regulations Code during the term of this Agreement. Pursuant to Section 6.10-2 of the San Francisco Business and Tax Regulations Code, Contractor further acknowledges and agrees that City may withhold any payments due to Contractor under this Agreement if Contractor is delinquent in the payment of any amount required to be paid to the City under the San Francisco Business and Tax Regulations Code. Any payments withheld under this paragraph shall be made to Contractor, without interest, upon Contractor coming back into compliance with its obligations.

Article 8 Termination and Default

8.1 Termination for Convenience

- 8.1.1 City shall have the option, in its sole discretion, to terminate this Agreement, at any time during the term hereof, for convenience and without cause. City shall exercise this option by giving Contractor with at least 30 days' advance written notice of termination. The notice shall specify the date on which termination shall become effective after such 30 day notice period.
- 8.1.2 Upon receipt of the notice of termination Contractor shall commence and perform, with diligence, all actions necessary on the part of Contractor to effect the termination of this Agreement on the date specified by City and to minimize the liability of Contractor and City to third parties as a result of termination.

8.1.3 Within 30 days after the specified termination date, Contractor shall submit to City an invoice for all Services performed and Deliverables provided under this Agreement, including wind-down costs, provided up to the date of termination. City shall use best efforts to pay such invoice within 15 days' of receipt.

8.2 Termination for Default; Remedies.

- 8.2.1 Each of the following shall constitute an immediate event of default ("Event of Default") under this Agreement, provided City provides written notice to Contractor describing the Event of Default:
- (a) Contractor fails or refuses to perform or observe any term, covenant or condition contained in any of the following Sections of this Agreement:

3.10	Submitting False Claims.	10.8	Alcohol and Drug-Free Workplace
4.4	Assignment	10.11	Working with Minors
Article 5	Insurance and Indemnity	11.10	Compliance with Laws
Article 7	Payment of Taxes	Article 13	Data and Security

- (b) Contractor fails or refuses to materially perform or materially observe any other term, covenant or condition contained in this Agreement, including any obligation imposed by ordinance or statute and incorporated by reference herein, and such default is not cured within thirty days after written notice thereof from City to Contractor.
- (c) Contractor (i) is generally not paying its debts as they become due; (ii) files, or consents by answer or otherwise to the filing against it of an unappealable petition for relief or reorganization or arrangement or any other petition in bankruptcy or for liquidation or to take advantage of any bankruptcy, insolvency or other debtors' relief law of any jurisdiction; (iii) makes an assignment for the benefit of its creditors; (iv) consents to the appointment of a custodian, receiver, trustee or other officer with similar powers of Contractor or of any substantial part of Contractor's property; or (v) takes action for the purpose of any of the foregoing.
- (d) A court or government authority enters an order (i) appointing a custodian, receiver, trustee or other officer with similar powers with respect to Contractor or with respect to any substantial part of Contractor's property, (ii) constituting an order for relief or approving a petition for relief or reorganization or arrangement or any other petition in bankruptcy or for liquidation or to take advantage of any bankruptcy, insolvency or other debtors' relief law of any jurisdiction or (iii) ordering the dissolution, winding-up or liquidation of Contractor.
 - 8.2.2 On and after any Event of Default, City shall have the right to exercise its legal and equitable remedies, including, without limitation, the right to terminate this Agreement or to seek specific performance of all or any part of this Agreement. In addition, subject to San Francisco Administrative Code 10.27 and 21.33 and where applicable, City shall have the right (but no obligation) to offset and/or to cure (or cause to be cured) on behalf of Contractor any Event of Default; Contractor shall pay to City on demand all costs and expenses incurred by City in effecting such cure. Contractor shall have a right to a hearing by the Controller as set forth in San Francisco Administrative Code 10.27-7.

- 8.2.3 All remedies provided for in this Agreement may be exercised individually or in combination with any other remedy available hereunder or under applicable laws, rules and regulations. The exercise of any remedy shall not preclude or in any way be deemed to waive any other remedy. Nothing in this Agreement shall constitute a waiver or limitation of any rights that City may have under applicable law.
- 8.2.4 Any notice of default must be sent by registered mail to the address set forth in Article 11.

8.3 Contractor's Right to Suspend.

In the event that Contractor determines that the City has placed a Participant at risk, is in violation of law, or has not paid undisputed amounts within the payment term indicated, Contractor shall immediately notify the City in writing and provide the City with a fifteen (15) day opportunity to cure. In the event that the City fails to achieve a timely cure, Contractor may immediately suspend services with the understanding that Contractor will reasonably cooperate with the City's cure efforts, and such suspension shall not be deemed a breach of this Agreement. Once the City achieves the cure, Contractor shall immediately resume services, with the understanding that some suspended services may take time to wind down and/or re-implement.

8.4 Non-Waiver of Rights.

The omission by either party at any time to enforce any default or right reserved to it, or to require performance of any of the terms, covenants, or provisions hereof by the other party at the time designated, shall not be a waiver of any such default or right to which the party is entitled, nor shall it in any way affect the right of the party to enforce such provisions thereafter.

8.5 Rights and Duties upon Termination or Expiration.

8.5.1 This Section and the following Sections of this Agreement listed below, shall survive termination or expiration of this Agreement:

3.3	Payment Limited to Satisfactory		
	Services		
3.7.1	Federal and/or State Funded		
	Contracts - Disallowance		
3.9	Audit and Inspection of Records	11.6	Dispute Resolution Procedure
3.10	Submitting False Claims	11.7	Agreement Made in California;
			Venue
Article 5	Insurance and Indemnity	11.8	Construction
Article 6	Liability of the Parties	11.9	Entire Agreement
		11.10	Compliance with Laws
Article 7	Payment of Taxes	11.11	Severability
8.1.3	Payment Obligation	Article 13	Data and Security

Subject to the survival of the Sections identified in Section 8.5.1, above, if this Agreement is terminated prior to expiration of the term specified in Article 2, this Agreement shall be

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of no further force or effect. Contractor shall transfer title to City, and deliver in the manner, at the times, and to the extent, if any, directed by City, any work in progress, completed work, supplies, equipment, and other materials produced as a part of, or acquired in connection with the performance of this Agreement as specified in Exhibit B, and any completed or partially completed work which, if this Agreement had been completed, would have been required to be furnished to City as specified in Exhibit B.

Article 9 Rights In Deliverables (Reserved)

Article 10 Additional Requirements to the Extent Applicable and 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/. For clarity, to the extent that the provisions set forth in this Article 10 are new to this Modification No. 3 and were not drafted in the original Agreement or Modification No. 1 and No. 2, their applicability is not retroactive.

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. Section 3.7.1 shall apply in the event of a breach of this Section 10.2.

10.3 Prohibition on Use of Public Funds for Political Activity.

In performing the Services, Contractor shall comply with San Francisco Administrative Code Chapter 12G, which prohibits funds appropriated by the City for this Agreement from being expended to participate in, support, or attempt to influence any political campaign for a candidate or for a ballot measure. Contractor is subject to the enforcement and penalty provisions in Chapter 12G.

10.4 Nondiscrimination Requirements

10.4.1 **Non Discrimination in Contracts**. Contractor shall comply with the provisions of Chapters 12B and 12C of the San Francisco Administrative Code. Contractor shall incorporate by reference in all subcontracts the provisions of Sections 12B.2(a), 12B.2(c)-(k), and 12C.3 of the San Francisco Administrative Code and shall require all subcontractors to comply with such provisions. Contractor is subject to the enforcement and penalty provisions in Chapters 12B and 12C.

10.4.2 **Nondiscrimination in the Provision of Employee Benefits**. San Francisco Administrative Code 12B.2. Contractor does not as of the date of this Agreement, and will not during the term of this Agreement, in any of its operations in San Francisco, on real property owned by San Francisco, or where work is being performed for the City elsewhere in the United States, discriminate in the provision of employee benefits between employees with domestic partners and employees with

spouses and/or between the domestic partners and spouses of such employees, subject to the conditions set forth in San Francisco Administrative Code Section12B.2.

10.4.3 Local Business Enterprise and Non-Discrimination in Contracting

Ordinance. Contractor shall comply with all applicable provisions of Chapter 14B ("LBE Ordinance"). Contractor is subject to the enforcement and penalty provisions in Chapter 14B.

10.5 Minimum Compensation Ordinance.

If Administrative Code Chapter 12P applies to this contract, Contractor shall pay covered employees no less than the minimum compensation required by San Francisco Administrative Code Chapter 12P, including a minimum hourly gross compensation, compensated time off, and uncompensated time off. Contractor is subject to the enforcement and penalty provisions in Chapter 12P. Information about and the text of the Chapter 12P is available on the web at http://sfgov.org/olse/mco. Contractor is required to comply with all of the applicable provisions of 12P, irrespective of the listing of obligations in this Section. By signing and executing this Agreement, Contractor certifies that it complies with Chapter 12P.

10.6 Health Care Accountability Ordinance.

If Administrative Code Chapter 12Q applies to this contract, Contractor shall comply with the requirements of Chapter 12Q. For each Covered Employee, Contractor shall provide the appropriate health benefit set forth in Section 12Q.3 of the HCAO. If Contractor chooses to offer the health plan option, such health plan shall meet the minimum standards set forth by the San Francisco Health Commission. Information about and the text of the Chapter 12Q, as well as the Health Commission's minimum standards, is available on the web at http://sfgov.org/olse/hcao. Contractor is subject to the enforcement and penalty provisions in Chapter 12Q. Any Subcontract entered into by Contractor shall require any Subcontractor with 20 or more employees to comply with the requirements of the HCAO and shall contain contractual obligations substantially the same as those set forth in this Section.

10.7 First Source Hiring Program.

If Administrative Code Chapter 83 applies to this contract, Contractor must comply with all of the provisions of the First Source Hiring Program, Chapter 83 of the San Francisco Administrative Code, that apply to this Agreement, and Contractor is subject to the enforcement and penalty provisions in Chapter 83.

10.8 Alcohol and Drug-Free Workplace.

City reserves the right to deny access to, or require Contractor to remove from, City facilities personnel of any Contractor 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.

10.9 Limitations on Contributions.

By executing this Agreement, Contractor acknowledges its obligations under section 1.126 of the City's Campaign and Governmental Conduct Code, which prohibits any person who contracts with, or is seeking a contract with, any department of the City for the rendition of personal services, for the furnishing of any material, supplies or equipment, for the sale or lease of any land or building, for a grant, loan or loan guarantee, or for a development agreement, from making any campaign contribution to (i) a City elected official if the contract must be approved by that official, a board on which that official serves, or the board of a state agency on which an appointee of that official serves, (ii) a candidate for that City elective office, or (iii) a committee controlled by such elected official or a candidate for that office, at any time from the submission of a proposal for the contract until the later of either the termination of negotiations for such contract or twelve months after the date the City approves the contract. The prohibition on contributions applies to each prospective party to the contract; each member of Contractor's board of directors; Contractor's chairperson, chief executive officer, chief financial officer and chief operating officer; any person with an ownership interest of more than 10% in Contractor; any subcontractor listed in the bid or contract; and any committee that is sponsored or controlled by Contractor. Contractor certifies that it has informed each such person of the limitation on contributions imposed by Section 1.126 by the time it submitted a proposal for the contract, and has provided the names of the persons required to be informed to the City department with whom it is contracting.

10.10 Reserved. Slavery Era Disclosure.

10.11 Working with Minors.

In accordance with California Public Resources Code Section 5164, if Contractor, or any subcontractor, is providing services at a City park, playground, recreational center or beach, Contractor shall not hire, and shall prevent its subcontractors from hiring, any person for employment or a volunteer position in a position having supervisory or disciplinary authority over a minor if that person has been convicted of any offense listed in Public Resources Code Section 5164. In addition, if Contractor, or any subcontractor, is providing services to the City involving the supervision or discipline of minors or where Contractor, or any subcontractor, will be working with minors in an unaccompanied setting on more than an incidental or occasional basis, Contractor and any subcontractor shall comply with any and all applicable requirements under federal or state law mandating criminal history screening for such positions and/or prohibiting employment of certain persons including but not limited to California Penal Code Section 290.95. In the event of a conflict between this section and Section 10.14, "Consideration of Criminal History in Hiring and Employment Decisions," of this Agreement, this section shall control.

10.12 Consideration of Criminal History in Hiring and Employment Decisions)

10.12.1If San Francisco Administrative Code Chapter 12T applies to this Agreement, Contractor agrees to comply fully with and be bound by all of the provisions of Chapter 12T, "City Contractor/Subcontractor Consideration of Criminal History in Hiring and Employment Decisions," of the San Francisco Administrative Code ("Chapter 12T"), including the remedies provided, and implementing regulations, as may be amended from time to time, The provisions of Chapter 12T are incorporated by reference and made a part of this Agreement as though fully set forth herein. The text of the Chapter 12T is available on the web at http://sfgov.org/olse/fco. Contractor is required to comply with all of the applicable provisions of 12T, irrespective of the listing of obligations in this Section. Capitalized terms used in this Section and not defined in this Agreement shall have the meanings assigned to such terms in Chapter 12T.

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10.12.2 The requirements of Chapter 12T shall only apply to a Contractor's or Subcontractor's operations to the extent those operations are in furtherance of the performance of this Agreement, shall apply only to applicants and employees who would be or are performing work in furtherance of this Agreement, and shall apply when the physical location of the employment or prospective employment of an individual is wholly or substantially within the City of San Francisco. Chapter 12T shall not apply when the application in a particular context would conflict with federal or state law or with a requirement of a government agency implementing federal or state law.

10.13 Reserved. (Public Access to Nonprofit Records and Meetings.).

10.14 Food Service Waste Reduction Requirements.

Contractor shall comply with the Food Service Waste Reduction Ordinance, as set forth in San Francisco Environment Code Chapter 16, including but not limited to the remedies for noncompliance provided therein.

10.15 Distribution of Beverages and Water.

10.15.1Sugar-Sweetened Beverage Prohibition. Contractor agrees that it shall not sell, provide, or otherwise distribute Sugar-Sweetened Beverages, as defined by San Francisco Administrative Code Chapter 101, as part of its performance of this Agreement.

10.15.2**Packaged Water Prohibition.** Contractor agrees that it shall not sell, provide, or otherwise distribute Packaged Water, as defined by San Francisco Environment Code Chapter 24, as part of its performance of this Agreement.

10.16 Tropical Hardwood and Virgin Redwood Ban.

Pursuant to San Francisco Environment Code Section 804(b), the City urges Contractor not to import, purchase, obtain, or use for any purpose, any tropical hardwood, tropical hardwood wood product, virgin redwood or virgin redwood wood product.

10.17 Preservative Treated Wood Products. (Reserved)

Article 11 General Provisions

11.1 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 Philip, MD

If to: Color Genomics, Inc.

831 Mitten Road, Suite 100 Burlingame CA 94010 Attn: Caroline Savello

11.2 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.

11.3 Incorporation of Recitals. (Reserved)

11.4 Sunshine Ordinance.

- 11.4.1 **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.
- 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 requestor and 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 or initiates action to seek 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.
- 11.4.3 **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.

11.5 Modification of this Agreement.

This Agreement may not be modified, nor may compliance with any of its terms be waived, except by written instrument executed and approved in the same manner as this Agreement.

11.6 Dispute Resolution Procedure. (Reserved)

11.6.1 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.

11.6.2 Health and Human Service Dispute Resolution Procedure. (Reserved)

11.7 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.

11.8 Construction.

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

11.9 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."

11.10 Compliance with Laws. (Reserved)

11.11 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.

11.12 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.

11.13 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.

11.14 Notification of Legal Requests.

To the extent permitted by applicable law, regulation, or rule, Contractor shall promptly notify City upon receipt of any subpoenas, service of process, litigation holds, discovery requests and other legal requests ("Legal Requests") related to all data given to Contractor by City in the performance of this Agreement ("City Data" or "Data"), or which in any way might reasonably require access to City's Data, and in no event later than 72 hours after it receives the request. Unless otherwise required by applicable law, regulation, or rule, or Contractor's obligations as a Covered Entity thereunder, Contractor shall not respond to Legal Requests related to City without first notifying City other than to notify the requestor that the information sought is potentially covered under a non-disclosure agreement. Contractor shall retain and preserve City Data in accordance with the City's instruction and requests, including, without limitation, any retention schedules and/or litigation hold orders provided by the City to Contractor, independent of where the City Data is stored; subject to Contractor's obligations under applicable law, regulation, rule, licensure requirement, or patient instructions.

Article 12 Department Specific Terms

12.1 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.

12.2 Federal and State Financial Participation

- 12.2.1 Contractor acknowledges that some or all of the items, products, or services that Contractor furnishes to City under this Agreement may be included, directly or indirectly, in whole or in part, in claims submitted by City to Federal or State health care programs. By executing this Agreement Contractor certifies that it is not currently, and shall not during the term of this Agreement become, excluded, directed to be excluded, suspended, ineligible or otherwise sanctioned from participation in any Federal or State assistance programs. Contractor shall notify City, as provided in Section 11.1, within thirty (30) days of any such exclusion, suspension, ineligibility, or other sanction. This is a material term of this Agreement.
- 12.2.2 Contractor agrees to indemnify and hold harmless City and City's officers, directors, employees, agents, successors and permitted assigns from and against any and all (including but not limited to Federal, State, or third party) civil monetary penalties, assessments, repayment obligations, losses, damages, settlement agreements and expenses (including reasonable attorneys' fees) arising from the exclusion, suspension, ineligibility, or other sanction of Contractor and/or Contractor's workforce (including those who oversee Contractor's workforce, supervisors and governing body members) from participation in any Federal or State assistance program.

Article 13 Data and Security

13.1 Nondisclosure of Private, Proprietary or Confidential Information.

- 13.1.1 **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.
- 13.1.2 **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.
 - 13.2 Payment Card Industry ("PCI") Requirements. (Reserved)
 - 13.3 **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.

13.4 Management of City Data and Confidential Information

13.4.1 Access to City Data. City shall at all times have access to and control of all data given to Contractor by City in the performance of this Agreement ("City Data" or "Data"), and shall be able to retrieve it in a readable format, in electronic form and/or print, at any time, at no additional cost.

13.4.2 **Use of City Data and Confidential Information.** Contractor agrees to hold City's Confidential Information received from or created on behalf of the City in strictest confidence. Contractor shall not use or disclose City's Data or Confidential Information except as permitted or required by the Agreement, including the Definitions section of Appendix A-1, applicable law, and/or or as otherwise authorized in writing by the City.

13.5 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 by Color or its subcontractors or agents, 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 14 MacBride And Signature

The provisions of San Francisco Administrative Code §12F are incorporated herein by this reference and made part of this Agreement. By signing this Agreement, Contractor confirms that Contractor has read and understood that the City urges companies doing business in Northern Ireland to resolve employment inequities and to abide by the MacBride Principles, and urges San Francisco companies to do business with corporations that abide by the MacBride Principles.

Article 15 Official Actions Relating to the Emergency; FEMA Assistance

15.1 Orders of Local, State or Federal Officials.

City and Contractor mutually acknowledge that local, state, or federal authorities may issue official orders related to the COVID-19 epidemic, or take other official actions, subsequent to the execution of this Agreement that Parties to this Agreement cannot presently predict. City and Contractor mutually acknowledge and agree that this Agreement shall be subject to the provisions of any such official action or order ("Official Actions"), as they may be revised and updated. If the provisions of any such Official Actions materially impact the terms of this Agreement, the provisions of those Official Actions shall govern without rendering invalid the remaining terms and provisions or affecting the validity of any other terms or provisions in this agreement. Contractor shall stay updated on the status of the City Health Officer orders by checking the Department of Public Health website (sfdph.org) regularly.

15.2 FEMA Assistance.

This is an acknowledgement that FEMA financial assistance will be requested by City and if provided will be used to fund all or a portion of this Agreement. Contractor shall comply with all applicable Federal law, regulations, executive orders, FEMA policies, procedures, and directives, including the FEMA Emergency & Exigency Contracts Requirements attached hereto as Appendix D and incorporated herein by reference.

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

City Addendum

Appendix

A: Scope of Services

Attachment 1 to Appendix A Appendix A-1 Statement of Work

B: Calculation of Charges

Appendix B-1 Calculation of Charges (Budget)

- C: Reserved
- D: Test Authorization and Request Form, including the Order of the Health Officer C19-10
- E: Reserved
- F: Invoice
- G: Local Emergency Declaration
- H: Color Data Security/Hosting Terms
- I: Data Flow Diagram
- J: Reporting and Data Flow Chart
- K: Port Operation Requirements and Site Plan
- L: FEMA Emergency & Exigency Contracts Requirements

Appendix A Scope of Services

A. Contract Administrator:

In performing the Services hereunder, Color shall report to **Susan Philip, 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

<u>AIM</u>: All services provided through contractual agreement are provided safely and effectively for patient care and support services, annually.

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

Appendix A-1

Statement of Work

Color will provide the following COVID-19 Services:

Definitions:

- a. "City Data" means all data transmitted to and/or collected, used, maintained, processed, stored, or generated by Color under this Agreement. To the extent that Color may seek to use and/or retain City Data for regulatory and licensure requirement compliance or de-identified City Data for quality assurance, laboratory validation, or necessary laboratory testing improvements for Covid-19 testing purposes, DPH provides Color the express right to do so. The City does not grant Color authority to attribute any deidentified data or any aspect of its use to the City.
- b. "Participant" means an individual tested by Color.
- 1. COVID-19 TESTING (\$75/test): Including:
 - a. Collection kits (swab kits)
 - b. collection paperwork (barcodes, instructions, order forms)
 - c. Transport of sample collection kits: Batch drop-off of kits, 1x-2x/day sample pickup and courier to Color's lab
 - 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. Regular reporting of results to CalREDIE and San Francisco DPH
 - g. Positive patient routing (e.g., support for contact tracing)
 - h. Color is providing COVID-19 Testing at Pier 30/32 in San Francisco (the "SF Pier Site #1"), SOMA (the "SOMA Site #2"), across 3 mobile testing sites, and for Laguna Honda Hospital, as directed by SF DPH. Estimated daily testing volume across all locations is 3,500 tests/day.
 - i. [Optional]: SF DPH and Color may mutually agree to add a third high-throughput testing site with a volume of roughly 500 tests/day.
 - j. Take-home collateral in priority languages, including translated FAQs
- 2. STATIC AND MOBILE TEST SITE MANGEMENT AND SAMPLE COLLECTION SERVICES
 (estimated \$241,165/week): Including: Onsite translation support through translated signage in priority languages, specific to each site (e.g., onsite welcome and traffic signs; flipcards in multiple languages for instructions and clinical team communications onsite, etc.). Use of translated signs to guide test takers through the site to educate on the process of testing and support communication with onsite staff.

 Translations available in Spanish, Arabic, Armenian, Chinese, Vietnamese, Farsi, Korean, and Tagalog (as appropriate to different communities). Staffing where possible to reflect cultural and language needs of the community

For each of the following types of sites

- a. Full site operations for Pier 30/32 in San Francisco (the "SF Pier Site #1"), including:
 - i. Clinical sample collection through Color's sub-contractor
 - ii. Site planning, infrastructure, and rentals (including tents) through Color's sub-contractor

- iii. Site operations
- b. Mobile COVID-19 Services ("the Mobile Testing Platform") for residents who cannot travel to static testing sites or community-based pop-up testing needs, including:
 - i. Priority congregate settings as directed by the SFDPH, including:
 - 1. Clinical sample collection through Color's sub-contractor
 - 2. Onsite operations & site setup
 - ii. Other Mobile/community testing sites to be agreed to by the parties, including:
 - 1. Clinical sample collection through Color's sub-contractor
 - 2. Site operations
 - iii. SFDPH will identify and prioritize locations for administering the Mobile Testing Platform sites.
- c. For all testing sites, including SOMA Site #2, Color shall provide the testing infrastructure (testing & workflows)
 - i. Courier costs / sample shipping
 - ii. Tablets
 - iii. WiFi hot spots
 - iv. Signage
 - v. Sample collection supplies
 - vi. Ice chest/refrigeration for collected specimens (where required)
- 3. <u>LANGUAGE CAPACITY</u> (estimated \$1,300/month for phone-based language line at pass-through cost to City of \$1.65/min): To the extent that language support is required not mentioned elsewhere in this scope, Color shall provide phone-based customer support for onsite questions from participants with multi-language support via language line translation service provided by Color.
- 4. <u>REGISTRATION AND TEST RESULTING PLATFORM (FOR ALL TESTING)</u>: (\$10,000/week through Oct. 3, 2020 for ongoing configuration, custom reporting, translation for Spanish language, and maintenance; beginning on Oct 4, 2020, any custom work to the platform (i.e., any non-routine updates, changes, or other customization to the platform) requested by City shall be charged at a rate of \$175.00/hour as set forth in Section 4(m) below)
 - a. **Website and Hosting**: Color will use its front-end registration, eligibility, and scheduling website and hosting platform for all sites
 - b. **HIPAA compliance**: Registration platform and hosting architecture is HIPAA-compliant. Color's hosting terms are attached hereto as Appendix H.
 - c. **User experience**: After entering all required information, the user will be able to select an appointment slot at a testing site and book that appointment. The user will get a confirmation email or text with the time and place of their appointment and instructions for the appointment.
 - d. **Browsers and devices**: The Registration Platform will work in a range of browsers, including Safari, Firefox, Chrome and Explorer, and will work on a range of devices including phones, tablets and desktop computers.
 - e. **Maintenance**: Color will maintain and support the Registration Platform, providing patches, updates and fixes as needed. Any material changes to content or form fields on the front end will be signed off by SFDPH before being deployed. If needed, Color can ask for support with copy

- changes from Digital Services, or the wider CityTestSF team, to ensure that copy is written to align with the City's content style guide;
- f. **Data collection configuration & customization:** Customizations to required patient intake questions as requested through Oct 3, 2020, at the direction of SF DPH, including updates to questionnaire. Any such customization on or after Oct 4, 2020 shall be subject to Section 4(m) below.
- g. **Spanish language translation:** Color will translate its registration and test resulting platform into Spanish language by Oct. 3, 2020, including Spanish-language reports. Any such translation services on or after Oct 4, 2020 shall be subject to Section 4(m) below.
- h. **Service level**: If bugs or system errors in the Registration Platform occur, the City will report these to Color's technical lead, and Color will investigate the issue within a reasonable time frame. If the issue is found to be a bug or technical issue (as opposed to user error) Color will give an estimated time frame for resolution that is proportional to the scale of the issue. Issues that prevent people registering and/or booking are considered urgent.
- i. **Help desk**: The following Color email address (support@color.com) may be used for reporting technical issues that occur on the site, however Color will not be required to provide support directly to users to help them use the site. This function will be fulfilled by City staff and their non-profit partners.
- j. **Registration shutdown**: The City will communicate when the testing program is over and appointments should stop. Color will have four weeks (or such other time frame that is mutually agreed by the parties) to close down its instance of the registration and booking system and transfer all Participant data to the City, to a point of contact at DPH, as permitted by applicable laws.
- k. **Scheduling configuration**: Color will adjust scheduling upon mutual agreement with DPH to reflect urgent needs and to prioritize scheduling for medical staff, first responders, and essential workers. Including:
 - i. **DSW**: At a frequency as mutually agreed upon in writing (email is sufficient) by the parties, DPH shall identify the number of DSW tests slots anticipated to be required. Color shall reserve those reasonable number of DSW slots as requested by DPH for DSW dedicated testing. The initial "hold" for DSW slots shall be 100 at the Embarcadero site, to be adjusted up or down as mutually agreed in writing (email is sufficient) by the parties. The parties shall meet and confer periodically to review the appropriateness of reserved DSW slots. Color shall expand this functionality beyond the Embarcadero site as mutually agreed in writing (email is sufficient).
 - ii. **Contact Tracing**: At a frequency as mutually agreed upon in writing (email is sufficient) by the parties, DPH shall identify the number of tests slots anticipated to be required for individuals identified by DPH contract tracing and/or case management as being exposed. Color shall reserve those reasonable number of slots for exposed individuals as requested by DPH for dedicated testing. The initial "hold" for contact tracing slots shall be 100 at the Embarcadero site, to be adjusted up or down as mutually agreed in writing (email is sufficient) by the parties. The parties shall meet and confer periodically to review the appropriateness of reserved slots. Color shall expand this functionality beyond the Embarcadero site as mutually agreed in writing (email is sufficient).
- 1. **Reporting and Data Analytics**: Color will provide the test result reporting, in accordance with the "Reporting and Data Flow" chart, attached hereto. The Reporting and Data Flow chart reflects the current mutually agreed upon (1) fields required to be included in Color's

Registration Platform, and (2) reporting streams. Reporting includes, but is not limited to the following:

- i. **State CalREDIE (California Reportable Disease Information Exchange)**: Color will handle CalREDIE reporting for all Participants whom it tests under this Agreement as required by applicable regulations or health orders and that fully complies with adding data as requested by DPH (in compliance with applicable regulations or health orders) into CalREDIE.
- ii. **Participants tested**: Participants may access their own test results after receiving a text and/or email alert from Color that they are available, by viewing them in Color's HIPAA-compliant website.
- iii. **Ordering physician**: Color will report all results to the ordering physician of the program.
- iv. **Health care providers**: If requested by Participants, Color will notify the healthcare providers of the Participants, subject to Color receiving contact information for such healthcare providers. Participants may identify their own health care providers when registering for the test, and City employees may also have their health plan information (Kaiser, Blue Shield, etc.) in the master eligibility file record provided to Color.
- v. City Department of HR for City employees: Periodically, as mutually agreed upon by the parties, Color shall transmit a dataset to the City Department of Human Resources ("DHR") through a Secure File Transfer Protocol ("SFTP") as necessary to support DPH treatment, billing and/or healthcare operations, including but not limited to reporting for epidemiology, contact tracing, and/or billing for services provided to City employees. The dataset includes test results and no-show appointments for City employees from the inception of the CityTestSF project at each site through the current business day.
- vi. **SF DPH for All Participants**: Color will provide mutually agreed upon reporting to DPH regarding all Participants, at a frequency mutually agreed upon by both parties, as necessary to support DPH treatment, billing and/or healthcare operations.
- vii. <u>Aggregate program reporting for DPH leadership</u>: Aggregate, de-identified program statistics for designated DPH leadership, including appointment utilization at sites, aggregate testing statistics (e.g. % positive rate), testing statistics by testing site location, and breakdown of testing statistics by relevant demographics.
- viii. Custom reporting, analytics, and data feeds as requested: Through Oct. 3, 2020, providing custom reporting, dashboards, analytics, and data feeds as reasonably requested by the City. Any such customization on or after Oct 4, 2020 shall be subject to Section 4(m) below.
- m. Ad Hoc Customization and Custom Reporting (beginning Oct. 4, 2020): At mutual agreement of Color and SF DPH, Color can support ad hoc platform customizations at an hourly engineering rate of \$175/engineering hour.

n. Data security:

- i. **Purpose**. The City provides Color with access to City Data provided by City solely for the purposes detailed in this LOU. Any use outside of the scope detailed in this LOU shall constitute a material breach of this Agreement.
- ii. **Secure File Transfer**. The City will share City Data provided by City with the Color Site Administrator via a secure file transfer.

- iii. **Qualified Personnel**. Color shall allow only qualified personnel under Color's direct supervision to access shared City Data.
- iv. **Safeguards**. Color shall safeguard the confidentiality of all shared City Data at all times.
- v. **No Re-Disclosure or Reporting**. Color may not re-disclose or otherwise prepare reports (in electronic or hard-copy format) regarding or containing City Data for transmission to any other individuals, agencies, or organizations except as permitted under applicable law, rule, regulation, licensure requirement, or health order, or with prior written City approval or the consent of the applicable Participant.
- vi. **Data Transmission**. Color must ensure that all electronic transmission or exchange of City Data is encrypted according to current industry standard(s), as determined in its sole discretion by Color. City and Color must also ensure that all City Data is used solely for the purposes enumerated in the Agreement.
- vii. Compliance with Law. Color shall comply with all applicable federal and state laws regarding the transmission, storage and protection of all City Data. Color agrees that any failure of Color to comply with the applicable requirements of federal and/or state and/or local privacy laws shall be a material breach of the Agreement, subject to the general equitable indemnity clause set forth in Section 5.2.1 of the City Addendum, as applicable.
- viii. **Disposition of Data**. Except as otherwise required by law, rule, regulation, or Color's licensure requirements, at the termination or expiration of this Agreement, or upon written request of the City, Color shall return all City Data (hardcopy and electronic in a useable machine readable format) to the City. After the City confirms receipt, Color shall destroy all remaining City Data in Color's possession and/or control, except as required by law, rule, regulation, or Color's licensure requirements.
- 5. <u>INSURANCE BILLING</u> (7%/per dollar received via insurance reimbursement): To the extent permitted by applicable federal and state insurance laws and regulations, Color shall make a good faith effort where operationally feasible for Color, in Color's discretion, to seek payment from third party, private insurers of individuals who receive Covid-19 Testing provided by Color pursuant to this Agreement, as follows:
 - i. Color may attempt to collect insurance information from individuals who receive Covid-19 Testing hereunder by requesting individuals' insurance information either in person at the time of Sample collection or earlier should the individual use Color's online portal to schedule testing. For the avoidance of doubt, nothing herein shall require Color to follow up with individuals who fail or refuse to provide their insurance information when requested/prompted by Color or its subcontractor(s).
 - ii. When an individual does provide Color with their insurance information pursuant to the process above, Color may attempt to bill the individual's private insurance carrier for the Color Covid-19 Test. For the avoidance of doubt, Color shall in no event bill insurance for any other expenses related to Covid-19 Testing (e.g., test collection fees).
 - iii. For clarity, Color will bill the City upfront for all testing fees as set forth in the budget, and following Color's receipt from City of payment for such testing fees, Color will then credit the City for amounts actually received directly from insurance carriers, subject to audit, if and after Color receives reimbursement from insurance carriers for testing expenses. Color's costs for billing, collection, and appealing claims ("Expenses") shall be deducted from any such credit, which as of the Effective Date of this Second Revised LOU, includes a 7% charge on all insurance reimbursements collected. If Color is unable to obtain insurance reimbursement for any individual's Covid-19 Test covered by the parties' Agreement within 30 days of Color

submitting claims for reimbursement, the parties agree that such insurance reimbursement shall be deemed uncollectable, and Color shall have no obligation or liability to credit City for any such amounts so deemed uncollectable; provided, however, that upon conclusion or termination of this Agreement, Color agrees to promptly conduct a final accounting of all insurance amounts actually received as of the date of termination or expiration, and within 60 days after termination or expiration of the Agreement, to provide City with reimbursement for any amounts not already credited to the City but only to the extent that Color has received payment from City for such testing prior to such final accounting.

iv. City shall provide Color with any additional information Color requires to submit claims for reimbursement, for example, ordering physician NPI number, proper diagnosis codes, etc.

Appendix B Calculation of Charges

1. Method of Payment

A. Color shall submit semi-monthly invoices by the fifteenth (15th) and thirtieth (30th) 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 semi-monthly pay period. 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) for each pay period. City shall pay all invoices within fifteen (15) days' of receipt, unless otherwise indicated in Appendix B-1. In the event invoices are not paid within fifteen (15) days' of receipt, Section 8.3 shall apply.

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, \$7,980,218 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.

Calculation of Charges Budget

COVID-19 Testing Services

-	Da	r	F
_	-		

Contract Budget Summary

Line#	Transaction		Bu	dgeted Amount
1	Original Contract		\$	7,134,555.00
2	Amendment # 1		\$	235,679.00
3	Amendment # 2		\$	1,469,947.00
4		Sub Total Original + Amendments 1 & 2	\$	8,840,181.00
5		Contingency	\$	1,059,819.00
6		Contract Amount	\$	9,900,000.00
7	Amendment # 3		\$	66,501,824.00
9		Contingency 12 % of Amendment # 3	\$	7,980,218.00
10		New Not to Exceed Amount (as amended)	\$	84,382,042.00

Part II

Estimated Recovery from 3rd Parties

Line #		Estir	nated Recovery
2 Th	nird Party Recovery	\$	10,778,468.00

Total Estimated Recovery from 3rd Parties \$ 10,778,468.00

Part III

Projected Total Expenditures (Including Recovery)

	Total Estimated Expenditures for COVID-19 Testing (April	
1	2020 - March 2021)	\$ 73,603,574.00

Services are rendered as needed. Subcontractor costs shall be passed through. Services will be invoiced according to invoicing terms of the Agreement. In no event may the scope of services or the not-to-exceed amount of the Agreement be increased without a formal modification of this Agreement. Should costs increase based on an increased testing volume, the City and Color will meet promptly to revise the Budget and payments herein before Services can continue, subject to approval of the San Francisco Board of Supervisors acting in its sole discretion.

Calculation of Charges Budget COVID-19 Testing Services

COVID-19 Testing Budget effective 07/22/2020

		W	eekly Budgeted
Item#	Item		Amount
1	COVID-19 Testing (\$75 / Test)		
	Rate: \$75 / test inclusive of all items listed in Item 1 of Appendix A-1	\$	1,704,375.00
2	Static and Mobile Test Site Management		
	Clinical Partner Rate: \$/ week Inclusive of all applicable items listed		
	in Item 2 of Appendix A-1	\$	178,865.00
	Logistics Partner Rate: \$/ week Inclusive of all applicable items		
	listed in Item 2 of Appendix A-1	\$	62,300.00
3	Language Capacity		
	To include all items listed in Item 3 of Appendix A-1	\$	396.00
4	Registration Platform		
	Rate: \$10,000 / week through Oct. 3, 2020 includes all items listed		
	in Item 4 of Appendix A-1	\$	10,000.00
	Subtotal for Services	\$	1,955,936.00

5 Insurance Platform

On a monthly basis Contractor shall report to the City the amount of tests that were submitted to third party payors for reimbursement and the amount received. Contractor shall then deduct the billing admin fee listed in item 2 below from the amount listed in item 1 below. The remaining amount shall be listed in item 3 "Service Credit to the City" shall be applied to the next billing cycle. Any remaining credit or reimbusment from a third party payor received after the contract has finished shall be paid directly to the City via a separate check.

Amount Collected From Third Party Payors	\$ 340,875.00
2) Less Contractor Admin Fee (7%)	\$ 23,861.25
3) Service Credit to the City	\$ 317.013.75

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

\$75

COVID-19 Testing Budget effective 07/22/2020

Page 3

Item # Item

1 COVID-19 Testing (\$75 / Test) Price/test

Rate: \$75 / test inclusive of all items listed in Item 1 of

Appendix A-1

		Days/w	Weekly
Site	Volume	eek	volume
Embarcadero	1900	7	13300
SOMA	535	5	2675
Mobile 1	250	7	1750
Mobile 2	250	7	1750
Mobile 3 (community)	250	7	1750
Laguna Honda	300	5	1500
Total	3485	n/a	22725
Total Weekly Budget	\$1,704,375.00		
Optional			
Additional 3rd site	535	5	2675

2 Static and Mobile Test Site Management

Clinical Partner Rate: \$/ week Inclusive of all applicable

items listed in Item 2 of Appendix A-1

Embarcadero staffing, excluding PPE \$ 110,365.00 \$ Mobile units staffing, excluding PPE \$ 68,500.00

Logistics Partner Rate: \$/ week Inclusive of all applicable

items listed in Item 2 of Appendix A-1

Weekly rentals: Embarcadero \$ 57,700.00

Weekly logistics: Mobile units \$ 4,600.00

Optional

Additional 3rd site clinical staffing \$ 33,958.00 Additional 3rd site weekly rentals \$ 30,219.00

3 Language Capacity

To include all items listed in Item 3 of Appendix A-1	\$ 396.00
Language line per minute	\$ 1.65
Estimated minutes of usage per week (based on historical	
call-in rates)	240

Page 4

4 Registration Platform

Rate: \$10,000 / week includes all items listed in Item 4 of

Appendix A-1 \$ 10,000.00

Subtotal for Services

5 Insurance Platform

On a monthly basis Contractor shall report to the City the amount of tests that were submitted to third party payors for reimbursement and the amount received. Contractor shall then deduct the billing admin fee listed in item 2 below from the amount listed in item 1 below. The remaining amount shall be listed in item 3 "Service Credit to the City" shall be applied to the next billing cycle. Any remaining credit or reimbusment from a third party payor received after the contract has finished shall be paid directly to the City via a separate check.

Tests run/week	22725
% reimbursed	15%
Reimbursement rate	\$ 100.00
Total tests reimbursed	3408.75
Total \$ reimbursed	\$ 340,875.00
7% collections processing fee	\$ 23,861.25
Total credit to City	\$ 317,013.75

Appendix C Reserved



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 ("Citv") EMPLOYEES AND GENERAL PUBLIC PATIENTS (collectively, "Patients")

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. City Employee Patients: City authorizes testing of City employees identified by City. In order to receive testing. City employees must register for a testing appointment by going to https://sf.gov/citytestsf and completing the registration process. Color will confirm registered City employees against the City-provided list.
- B. Non-City Employee Patients: City also authorizes testing for non-City employees and the general public. In order to receive testing, non-City employees must register for a testing appointment with the assistance of a City, Color, Carbon Health, or One Medical staffer at the applicable site or by registering for a test at https://sf.gov/citytestsf.
- C. Patient Consent: Each 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.

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

Color (either itself or through its subcontractor(s)) hereby agrees to inform all 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, written or electronic 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) or otherwise by law and to report the COVID-19 Test result directly to the Patient and/or a Color or a Patient specified clinical service for follow-up consultation.

Approved:

Susan Philips, MD

Deputy Health Officer

Department of Public Health



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.

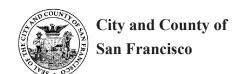
DATE OF ORDER: March 24, 2020

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:



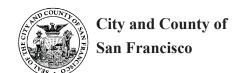
ORDER OF THE HEALTH OFFICER No. C19-10

- 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 <u>positive</u>, <u>negative</u>, <u>and inconclusive</u> 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.sfcdcp.org/wp-



ORDER OF THE HEALTH OFFICER No. C19-10

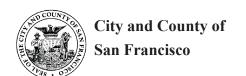
content/uploads/2018/01/Reportable-Diseases-List-CMR-SFDPH-EFF-10.2019-UPDATED-12.2019.pdf;

- 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.



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) and the Department of Public Health website (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



ORDER OF THE HEALTH OFFICER No. C19-10

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

Dated: March 24, 2020

IT IS SO ORDERED:

Tomás J. Aragón, MD, DrFH

Health Officer of the

City and County of San Francisco

5



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



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.
 - o Template for EUA submissions: https://www.fda.gov/media/135658/download.
- On March 9, 2020, the list of reportable diseases in <u>Title 17, California Code of Regulations (17 CCR)</u>
 section 2500 was amended to include COVID-19 and Novel coronavirus infections, and <u>17 CCR section</u>
 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 <u>Business and Professions Code (BPC)</u> <u>section 1265</u>, and testing personnel must be authorized to perform testing classified as high complexity under CLIA, as specified in <u>BPC section 1206.5 (c)</u>.
 - If a California laboratory sends biological specimens originating in California to a laboratory outside the state for testing, <u>BPC section 1241</u> 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 if you have questions.

Robert J. Thomas, Branch Chief

Robert J. Thomas



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

- 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 (Richettsia 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

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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 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 formatofreports, can be found on the <u>CalREDIE ELRwebpage</u> (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 forinstruction.

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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

OFFICE OF THE MAYOR SAN FRANCISCO



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

OFFICE OF THE MAYOR 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

Appendix H

Color Genomics, Inc.

How is our customer data protected?

We use Amazon Web Service's S3 and RDS services to store our data. See <u>AWS's security whitepaper</u> and <u>more detailed security whitepapers</u>. At a high level, all such data uses anonymized identifiers, and is encrypted at rest using AES-256, and in transit using TLS 1.2 with a modern cipher suite, so this data is only readable by Color. All data access is done using unique identifiers, is logged for auditability, and is restricted to only those employees who need access to perform their job duties.

Our security practices have been validated by an independent HIPAA-compliance audit, and an independent technical security penetration test.

Internal application access and application logs are audited regularly to ensure that only employees that need access to sensitive internal systems have access. When employees change roles or leave the company, their access is removed immediately.

What are the levels of access or authentication controls?

Only employees involved in the treatment of an individual patient have access to PHI. Those individuals involved in payment or operations have access to the minimum amount of PHI necessary to complete their job. All other access to PHI requires patient authorization.

- Regular employee: has no access to PII.
- Support staff: can access PII related to the patient's account, in order to resolve account-related issues. Cannot access PHI.
- Medical staff / clinical services: can access PHI, as needed to sign out reports and conduct any necessary outreach to patients.

What is our information security / access policy?

Our Security Policy follows the provisions of the Security Rule of HIPAA: we encrypt all data at rest and in transit, we only allow employees to access the minimum level of PHI needed to perform their job duties and log all access, and we conduct penetration testing of our software on an annual basis. We also sign Business Associate Agreements to extend this protection to all vendors we work with. Our service is wholly hosted on Amazon Web Service's cloud, which has been certified to several security standards, including HIPAA, HITRUST, and FedRAMP.

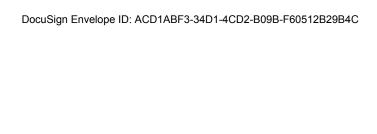
Per our responsibilities as a HIPAA covered entity, we have a designated Security and Privacy Officer, as well as a documented process for responding to security incidents.

Appendix I

Reserved

Appendix J

	DATA COLLECTION AND REPORTING												
ID NO.	Field	Need	User type		Source					Shared with			
							Cal-REDIE	Patient	PCP	On-site team	SF DPH (x = daily reporting) (x return data)	SF DHR For City Employees Only	Color
	eni rernirin	1111	Α	inp r							X		Х
	p nir i n	LLII	Α	inp r			Х		Х		Х		Х
	ir n e	lden i e e	Α	inp r			Х		Х	Х	Х	Х	Х
	n e	lden i e e	Α	inp r			Х		X	Х	Х	Х	Х
	Midd e ini i	n r in	Α	inp r	end	r D R	Х			Х	Х		Х
	D	1111	i	inp r							X	Х	Х
	P ne	P re n	Α	inp r			Х		X		X		X
	i	P re n	Α	inp r			Х		Х		X		X
	ree ddre	n r in	Α	inp r	end	r D R	Х		X		Х		Х
	i e	pide i	Α	r ip de			Х		Х		Χ		X
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	e in rneID	i in	Α	inp r							Χ		X
	e in rner pID	i in	Α	inp r							X		X
	Prir der e in rne	i in	Α	inp r							X		X
	irne pri r der e in rne	i in	Α	inp r							Х		X
	n e pri r der e in rne	i in	Α	inp r							X		X
	Prir repiinir priei e	P re n	Α	inp r							Х		X
	n en re	P re n	Α	inp r							X		X
	n en rDR re i i e p ee depr en	per i n	i	inp r	end	r D R					X	х	х
	ex ir	re ire en	Α	inp r	end	r D R	Х		Х		X		X
	D e ir	re ire en Iden i e	Α	inp r	end	r D R	X		X	X	X	X	X
	p er	i i i i i in	en i	inp r							X		X
	d repred r	n r in	i en i	inp r							X		X
	r in	n r in	en i	inp r							X		X
	R e nii	pide i	Α	inp r	end	r D R	X		X		X		X
	App in en i e	per i n	Α	inp r				X		Х	X		X
	App in en end n e	per i n	A	n ie e						X	X	X	X
	pe einie	In ern	Α	n ie e							X		Х
	pe einie	In ern	Α	inp r							X		Х
	Dri in in	per i n	Α	inp r						Х	X		Х
	pe r de	In ern	Α	n ie e				X		Х	X		Х
	peien pe P Pe	re ire en	Α	n ie e			Х		Х		X		Х
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	rderin Pr ider		Α	n e rder			X				Х		Х
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Appendix K Port Operation Requirements and Site Plan

OPERATIONAL REQUIREMENTS

This plan documents what activities will occur on site and what standards will apply to these activities.

1.0 KEY STAFF

In the event of an emergency, the following key staff are responsible.

TABLE 1: Key Staff

NAME	TITLE	PHONE	EMAIL
Crezia Tano-	Project Manager	(415)215-8903	Crezia.tano-lee@sfport.com
Lee	(PRT)		
Matthias	Site Operations	(415)218-0465	Matthias.giezendanner@sfport.com
Giezendanner	Manager (PRT)		
Fatima Sabar	Operations, Color	(314) 644-	Fatima@color.com
		8557	
Caroline	Partnerships, Color	(650) 714-	caroline@color.com
Savello		6621	

2.0 GOOD NEIGHBOR POLICY

Good Neighbor Policies are commonly included in City contracts in order to support productive and communicative relationships between service organizations and the communities/neighborhoods in which they are located. Organizations who wish to operate the contracted services or facilities, agree to follow all provisions of the policy outlined below.

- A. Minimize the impact on the neighborhood of CityTestSF guests entering, exiting, or waiting for services.
- B. Implement management practices necessary to ensure that staff and clients do not block driveways of neighboring businesses.
- C. The Embarcadero Promenade (Herb Caen Way) is a public access area. The SFDPH agrees to have its security direct traffic in and out of the Valley gate so as not to adversely affect public access on the Promenade. This is a requirement of Bay Conservation Development Commission (BCDC) Permit M1996.013 section b.
- D. Sufficient toilet facilities shall be made accessible to patrons within the Premises, and toilet facilities shall be made accessible to prospective patrons who may be lined up waiting to enter the Premises.

- E. The SFDPH or its agents shall not load-in/load out or build out the tent structures between the hours of 11:00 pm to 7:00am.
- F. There shall be no noise audible outside the Premises during hours that violate Section 49 or Article 29 of the San Francisco Police Code. Further, absolutely no sound from the Premises shall be audible inside any surrounding residences or businesses that violate Article 29 of the San Francisco Police Code.

3.0 USE OF PORT FACILITIES - PROTECTING THE BAY

Most Port piers and the structures on them drain to the San Francisco Bay. Therefore, materials that are released on pier aprons and inside pier sheds could ultimately be released into the Bay. Materials can also be conveyed to the Bay by stormwater or wind. Even materials that are spilled in the dry summer months can be washed into the Bay with the winter rains.

TABLE 3a: Pollutants and Activities of Concern

POLLUTANTS	ACTIVITIES OF CONCERN
Trash / Debris	Waste Management
Vehicle Fluids	Parking, Deliveries/Provisioning,
Equipment Fluids	Operation of plant equipment

TABLE 3b: Port Facilities and Environmental Risks

PORT FACILITY	ENVIRONMENTAL RISKS
TYPE	
Pier Aprons, Decks, and	Discharge via sheet flow or storm drains to SF Bay
Open Land	Wind carries debris into SF Bay and neighboring
	communities

The two most important Best Management Practice (BMP) when using Port facilities are:

- 1) Be aware of the potential to pollute the Bay.
- 2) Train staff to protect the Bay.

The following Best Management Practices (BMPs) shall be used at all times.

BMPs– General Use of Port Facilities

- **BE AWARE**: Be aware of the potential to pollute the Bay.
- TRAIN STAFF: Train staff to be partners in protecting the Bay.
- **DEBRIS MANAGEMENT**: Place trash and debris in the proper containers.

- END OF DAY CLEAN-UP: At the end of the day or when activities are over, conduct a general clean-up to remove debris, trash, and inspect for spills.
- **SWEEP**: Use dry cleaning methods rather than pressure washing surfaces.
- CLEAN SPILLS IMMEDIATELY: Keep equipment clean. Avoid excessive build-up of oil and grease.

4.0 OPERATIONAL BASICS / PRIMARY ACTIVITIES

BASICS

- Monday through Friday, 8:00 am to 6:00 pm
- Approx. 22-30 Employees on Site; Intake 1; Collections 3-6; Operations 15
 Site Plan (refer to Exhibit A)

DESCRIBE ACTIVITES

Drive through testing of symptomatic essential workers for COVID19. Clients will be greeted at entrance of the site. They will be asked if they have an appointment and if they do, they will proceed to Station 1. At Station 1, they will keep their windows rolled up and hold their ID against the window for the staff member at Station 1 to confirm their appointment and check them in. They will then proceed to Station 2, where they will get their testing done. Samples are batched and transported to the lab for processing daily.

TABLE 2: Materials Inventory

TABLE 2. Matthals inventory		
TYPES OF MATERIALS*	QUANTITY	STORAGE**
	(MAXIMUM)	
Surgical Gowns	10,000	Locked Freight Container
Surgical Shoe Coverings	5,000	Locked Freight Container
N95 Masks	1,000	Locked Freight Container
Surgical Masks	5,000	Locked Freight Container
Face Shields	50	Locked Freight Container
Cleaing Wipe Cannisters (i.e. Clorox	100	Locked Freight Container
wipes)		_
Industrial Nitrile Gloves	30,000	Locked Freight Container
Coveralls	5,000	Locked Freight Container
Goggles	100	Locked Freight Container
Tables & Chairs	20	In Tents

^{*} Materials – (e.g., compressed gas cylinders of O2, or 55-gallon drums of motor oil, or wood products)

SITE PLAN (Map)

Provide a site plan showing the location of all activities including storage.

^{**} Storage – (e.g., on secondary containment pallets, or in flammable cabinet)

BEST MANAGEMENT PRACTICES (BMPs)

Identify Best Management Practices (BMPs)

A janitorial cleaning contractor has been engaged to provide hospital-grade cleaning of tents, tables, and equipment. The team will arrive one hour prior to the scheduled hours of operation and remains onsite throughout the day to provide ongoing cleaning of the facilities. Once the testing site has been closed to visitors and clinical staff has completed their work, the entire site will undergo a through cleaning.

Portable toilets with hot water are provided for staff use only. Visitors are not provided access to the toilets. An ADA compliant portable toilet is available for staff. Toilets and sinks are cleaned hourly by assigned janitorial staff.

Clinical waste and hazardous materials will be disposed of in clearly demarcated hazardous waste bins which are emptied each day into hazardous waste pickup containers. These containers are stored in a designated and clearly marked locked hazardous waste flamable storage container. The testing site operations manager and clinical operations manager will be the only two onsite staff with access to this container. Hazardous waste is retrieved and disposed of three times per week by Stericycle, a designated hazardouse waste removal company.

Persona Protective Equipment (PPE) is stored in two locked shipping containers. Inventory of PPE is conducted twice weekly by the onsite operations manager and clinical operations manager. Inventory supply is uploaded to a spreadsheet for ongoing tracking and burn rate. The clinical team monitors their daily PPE usage on this spreadsheet and records use of key items including N95 masks and gowns.

Security onsite is provided twenty four hours per day seven days per week. While staff is onsite, three security guards are located at the facility. One guard patrols the facility while two gates are manned by additional guards. When not in operation, entry gates are locked and one security guard patrols the facility.

Visitors are guided through a driving pathway demarcated clearly through orange traffic cones. Staff greeters are assigned to three different locations along this drivepath to direct visitors through the route in and out of the facilty. Signage instructs patients to keep their windows rolled up . Staff provides communication visually. Additionally, a phone is manned by greeter staff to answer in depth questions and provide further information pertaining to site operations if necessary for visitors.

SPILL RESPONSE

The testing site will not utilize industrial oils or fuel for operations. Construction is limited to free-standing tents supported by concrete ballasts. Waste is limited to staff refuse, waste generated by cleaning staff, and clinical operations.

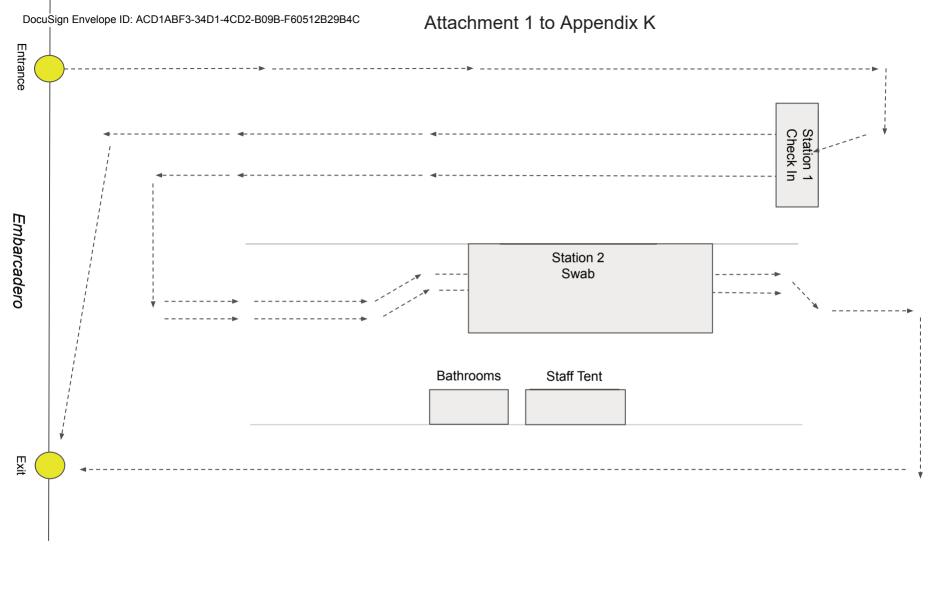
REGULATORY AGENCIES / PERMITS / PROFESSIONAL STANDARDS

Port Building Permits # B-2020-0070 and B-2020-0068 have been issued. SF Planning Department permit 2010.0493E and BCDC permit M1996.013 have been issued.

5.0 APPENDIX A - PERMITTED & REGULATED ACTIVITY - SUMMARY TABLE

CITY & COUNTY OF S	AN FRANCISCO			
AGENCY	REGULATED ACTIVITY	REQUIREMENT	APPLIES	PERMIT NO.
Port of San Francisco	- Post-Construction Stormwater	Stormwater Control Plan	YES/NO	B-2020-0070 B-2020-0068
SF Department of Public Health – Hazardous Materials Unified Program Agency	- Hazardous Materials Storage - Hazardous Waste	Hazardous Materials Business Plan	YES/NO	
(HMUPA)		Review/Approval of Proposal	YES/NO	
SF PUC	Industrial WastewaterFats, Oils, Grease ControlChemical toilets, etc.	Industrial Discharge Permit FOG Control Compliance	YES/NO	
SF Fire Department	Flammable MaterialsCompressed GasesOpen Flame Devices		YES/NO	
SF Planning Department	- Project subject to CEQA	CEQA conditions	YES/NO	2010.0493E
STATE OF CALIFORN	IA			
AGENCY	ACTIVITY	REQUIREMENT	APPLIES	PERMIT NO.
DTSC	Hazardous Waste Generation	EPA ID Numbers	YES/NO	
CA PUC	- Carry Passengers - Issuance of Livery Plates			

	- Certain Transit Routes			
	- Reviews Passenger Rates			
Cal-OSHA	- Employee Health and		YES	
	Safety			
BCDC			Yes	M1996.013
FEDERAL				
AGENCY	ACTIVITY	REQUIREMENT	APPLIES	PERMIT
				NO.
DOT				



Appendix L FEMA Emergency & Exigency Contracts Requirements

1. Precedence of FEMA Requirements. This contract may be eligible for FEMA funding. FEMA requires inclusion of the following contract provisions for procurement under exigent or emergency circumstances. In the event of a conflict between this appendix and other provisions of the Agreement that address the same or a similar requirement, the provisions that are stricter and impose the greater duties upon Contractor shall apply.

2. Work Hours and Safety Standards. Contractor agrees as follows:

- A. **Overtime requirements.** No contractor or subcontractor contracting for any part of the contract work which may require or involve the employment of laborers or mechanics shall require or permit any such laborer or mechanic in any workweek in which he or she is employed on such work to work in excess of forty hours in such workweek unless such laborer or mechanic receives compensation at a rate not less than one and one-half times the basic rate of pay for all hours worked in excess of forty hours in such workweek.
- B. Violation; liability for unpaid wages; liquidated damages. In the event of any violation of the clause set forth in paragraph (A) of this section Contractor and any subcontractor responsible therefor shall be liable for the unpaid wages. In addition, Contractor and subcontractor(s) shall be liable to the United States for liquidated damages. Such liquidated damages shall be computed with respect to each individual laborer or mechanic, including watchmen and guards, employed in violation of the clause set forth in paragraph (A) of this section, in the sum of \$26 for each calendar day on which such individual was required or permitted to work in excess of the standard workweek of forty hours without payment of the overtime wages required by the clause set forth in paragraph (A) of this section.
- C. Withholding for unpaid wages and liquidated damages. The City shall upon its own action or upon written request of an authorized representative of the Department of Labor withhold or cause to be withheld, from any moneys payable on account of work performed by Contractor or subcontractor under any such contract or any other Federal contract with the same prime contractor, or any other federally-assisted contract subject to the Contract Work Hours and Safety Standards Act, which is held by the same prime contractor, such sums as may be determined to be necessary to satisfy any liabilities of such contractor or subcontractor for unpaid wages and liquidated damages as provided in the clause set forth in paragraph (B) of this section.
- D. **Subcontracts.** As appropriate and/or to the extent feasible, Contractor or subcontractor shall insert in any subcontracts the clauses set forth in paragraphs (A) through (D) of this section and also a clause requiring the subcontractors to include these clauses in any lower tier subcontracts. Contractor shall be responsible for compliance by any subcontractor or lower tier subcontractor with the clauses set forth in paragraphs (A) through (D) of this section. The City understands the difficulty presented by this requirement for subcontracts already in place and further understands that it may not be appropriate or feasible to effect all subcontract amendments.
- E. **Exceptions.** This Section 5 does not apply to the purchase of supplies or materials or articles ordinarily available on the open market, or contracts for transportation or transmission of intelligence

1

3. Clean Air Act. Contractor agrees as follows:

- A. Contractor agrees to comply with all applicable standards, orders or regulations issued pursuant to the Clean Air Act, as amended, 42 U.S.C. § 7401 et seq.
- B. Contractor agrees to report each violation to the City and understands and agrees that the City will, in turn, report each violation as required to assure notification to the Federal Emergency Management Agency, and the appropriate Environmental Protection Agency Regional Office.
- C. Subject to the limitations stated herein and understood and agreed to by the City (including, without limitation, Section 2(D) above), Contractor agrees to include these requirements in each subcontract exceeding \$150,000 financed in whole or in part with Federal assistance provided by FEMA.

4. Federal Water Pollution Act. Contractor agrees as follows:

- A. Contractor agrees to comply with all applicable standards, orders, or regulations issued pursuant to the Federal Water Pollution Control Act, as amended, 33 U.S.C. 1251 et seq.
- B. Contractor agrees to report each violation to the City and understands and agrees that the City will, in turn, report each violation as required to assure notification to the Federal Emergency Management Agency, and the appropriate Environmental Protection Agency Regional Office.
- C. Subject to the limitations stated herein and understood and agreed to by the City (including, without limitation, Section 2(D) above), Contractor agrees to include these requirements in each subcontract exceeding \$150,000 financed in whole or in part with Federal assistance provided by FEMA.

5. Debarment and Suspension. Contractor agrees as follows:

- A. To the extent this contract is a covered transaction for purposes of 2 C.F.R. pt. 180 and 2 C.F.R. pt. 3000, Contractor is required to verify that none of Contractor's principals (defined at 2 C.F.R. § 180.995) or its affiliates (defined at 2 C.F.R. § 180.905) are excluded (defined at 2 C.F.R. § 180.940) or disqualified (defined at 2 C.F.R. § 180.935).
- B. Subject to the limitations stated herein and understood and agreed to by the City (including, without limitation, Section 2(D) above), to the extent this contract is a covered transaction, Contractor must comply with 2 C.F.R. pt. 180, subpart C and 2 C.F.R. pt. 3000, subpart C, and must include a requirement to comply with these regulations in any lower tier covered transaction it enters into.
- C. This certification is a material representation of fact relied upon by the City. If it is later determined that Contractor did not comply with 2 C.F.R. pt. 180, subpart C and 2 C.F.R. pt. 3000, subpart C, in addition to remedies available to the City, the Federal Government may pursue available remedies, including but not limited to suspension and/or debarment.
- D. Contractor agrees to comply with the requirements of 2 C.F.R. pt. 180, subpart C and 2 C.F.R. pt. 3000, subpart C throughout the period of any contract that may arise from this offer. Subject to the limitations stated herein and understood and agreed to by the City (including, without limitation, Section 2(D) above), Contractor further agrees to include a provision requiring such compliance in its lower tier covered transactions.

6. Procurement of Recovered Materials

- A. In the performance of this contract, Contractor shall make maximum use of products containing recovered materials that are EPA-designated items unless the product cannot be acquired:
 - i. Competitively within a timeframe providing for compliance with the contract performance schedule;
 - ii. Meeting contract performance requirements; or
 - iii. At a reasonable price.
- B. Information about this requirement, along with the list of EPA-designated items, is available at EPA's Comprehensive Procurement Guidelines web site, https://www.epa.gov/smm/comprehensive-procurement-guideline-cpg-program.
- C. Contractor also agrees to comply with all other applicable requirements of Section 6002 of the Solid Waste Disposal Act.
- 7. **Department of Homeland Security Seal, Logo, and Flags.** Contractor shall not use the DHS seal(s), logos, crests, or reproductions of flags or likenesses of DHS agency officials without specific FEMA pre-approval.
- **8.** Compliance with Federal Law, Regulations, and Executive Orders. This is an acknowledgement that FEMA financial assistance will be used to fund all or a portion of the contract. Contractor will comply with all applicable Federal law, regulations, executive orders, FEMA policies, procedures, and directives.
- 9. No Obligation by Federal Government. The Federal Government is not a party to this contract and is not subject to any obligations or liabilities to the City, Contractor, or any other party pertaining to any matter resulting from the contract.
- 10. Program Fraud and False or Fraudulent Statements or Related Acts. Contractor acknowledges that 31 U.S.C. Chap. 38 (Administrative Remedies for False Claims and Statements) applies to the Contractor's actions pertaining to this contract.

11. Byrd Anti-Lobbying Certification.

- A. Contractors who apply or bid for an award of \$100,000 or more shall file the required certification pursuant to the Byrd Anti-Lobbying Amendment, 31 U.S.C. §1352, as amended. Each tier certifies to the tier above that it will not and has not used Federal appropriated funds to pay any person or organization for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, officer or employee of Congress, or an employee of a Member of Congress in connection with obtaining any Federal contract, grant, or any other award covered by 31 U.S.C. § 1352. Each tier shall also disclose any lobbying with non-Federal funds that takes place in connection with obtaining any Federal award. Such disclosures are forwarded from tier to tier up to the recipient who in turn will forward the certification(s) to the awarding agency.
- B. Subject to the limitations stated herein and understood and agreed to by the City (including, without limitation, Section 2(D) above), if this contract is for a price of \$100,000 or more, Contractor, and its lower tiers, must sign and submit to the City the following certification:

<u>APPENDIX A, 44 C.F.R. PART 18 – CERTIFICATION REGARDING LOBBYING</u>

Certification for Contracts, Grants, Loans, and Cooperative Agreements

The undersigned certifies, to the best of his or her knowledge and belief, that:

- (1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.
- (2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.
- (3) Subject to the limitations stated herein and understood and agreed to by the City (including, without limitation, Section 2(D) above), the undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

Contractor certifies or affirms the truthfulness and accuracy of each statement of its certification and disclosure, if any. In addition, Contractor understands and agrees that the provisions of 31 U.S.C. Chap. 38, Administrative Remedies for False Claims and Statements, apply to this certification and disclosure, if any. — Docusigned by:

any. — DocuSigned by:	
any. Docusigned by: Cardens Sacro C40516314A7A4B7	lle
Signature of Contrac	tor's Authorized Official
Caroline Savello)
Name and Title of Co	ontractor's Authorized Official
10/18/2020 12:5	55 PM PDT
Date	



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.

CONTRACTOR

DocuSigned by:

Caroline Savello

Chief Commercial Officer Supplier ID: 0000042840

Color Genomics, Inc.

CITY
Recommended by:
DocuSigned by: Gry Wagner 28527524752949F
Grant Colfax, MD Director of Health Department of Public Health
Approved as to Form: Dennis J. Herrera
City Attorney
By: Simpson, buse S BD54168AAC3BA52. Louise S. Simpson Deputy City Attorney
Approved:
Docusigned by: Linda Repola 42E00F6456504C0 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.

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/

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.
- 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.

P-250 (EMERGENCY;4-19; DPH 4-18; 3-2020) C: 2233

Attachment 1 to Appendix A

PERFORMANCE IMPROVEMENT PLAN AND PERFORMANCE MEASURE GRID

Contract Services

<u>AIM</u>: All services provided through contractual agreement are provided safely and effectively for patient care and support services, annually.

Contract Name	Services Provided	Measure Name	Metric (What data is being collected?)
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

COVID-19 Test	Price
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)	\$75 / test
Subcontractor Cost: Clinical partner 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.	\$18,600 per 5 day week, based on estimate of 200 tests/day (to be revised in the event of volume increase)
Subcontractor Cost: Logistics partner 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.	\$17,528 per 5 day week, based on current site design
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.	\$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

Charge Item	Estimated
	Budgeted Amount
1 Completed Test = 1 Unit of Service	
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
Total not to Exceed Amount of the Contract	\$7,990,702

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

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

DocuSign Envelope ID: FD7811E8-5C4D-4B15-BF3A-59F70B1C8D9F

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Caroline Savello
Chief Commercial Officer
caroline@color.com
(650) 714-6621



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:

Susan Philips, MD

Deputy Health Officer

Department of Public Health



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.

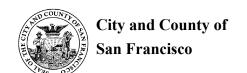
DATE OF ORDER: March 24, 2020

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:



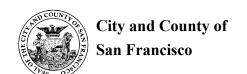
ORDER OF THE HEALTH OFFICER No. C19-10

- 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 <u>positive</u>, <u>negative</u>, <u>and inconclusive</u> 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.sfcdcp.org/wp-



ORDER OF THE HEALTH OFFICER No. C19-10

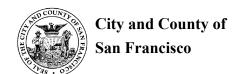
content/uploads/2018/01/Reportable-Diseases-List-CMR-SFDPH-EFF-10.2019-UPDATED-12.2019.pdf;

- 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.



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) and the Department of Public Health website (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



ORDER OF THE HEALTH OFFICER No. C19-10

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

Dated: March 24, 2020

IT IS SO ORDERED:

Tomás J. Aragón, MD, Dri H

Health Officer of the

City and County of San Francisco

5



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



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.
 - o Template for EUA submissions: https://www.fda.gov/media/135658/download.
- On March 9, 2020, the list of reportable diseases in <u>Title 17, California Code of Regulations (17 CCR)</u>
 <u>section 2500</u> was amended to include COVID-19 and Novel coronavirus infections, and <u>17 CCR section</u>
 <u>2505</u> 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 <u>Business and Professions Code (BPC)</u> <u>section 1265</u>, and testing personnel must be authorized to perform testing classified as high complexity under CLIA, as specified in <u>BPC section 1206.5 (c)</u>.
 - If a California laboratory sends biological specimens originating in California to a laboratory outside the state for testing, <u>BPC section 1241</u> 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 if you have questions.

Robert J. Thomas, Branch Chief

Robert J. Thomas



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

- 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 (Richettsia 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 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 formatofreports, can be found on the <u>CalREDIE ELRwebpage</u> (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 forinstruction.

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TUBERCULÓSIS (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.

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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

OFFICE OF THE MAYOR SAN FRANCISCO



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

Office of the Mayor 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

City and County of San Francisco Office of Contract Administration Purchasing Division

First Amendment

THIS AMENDMENT (this "Amendment") is made as of **20**th **day of April, 2020** in San Francisco, California, by and between **Color Genomics, Inc.** ("Contractor"), and the City and County of San Francisco, a municipal corporation ("City"), acting by and through its Director of the Office of Contract Administration.

Recitals

WHEREAS, City and Contractor have entered into the Agreement (as defined below); and

WHEREAS, City and Contractor desire to modify the Agreement on the terms and conditions set forth herein to expand the COVID-19 testing program and add FEMA requirements to the contract; and

NOW, THEREFORE, Contractor and the City agree as follows:

Article 1 Definitions

The following definitions shall apply to this Amendment:

- 1.1 **Agreement.** The term "Agreement" shall mean the Agreement dated April 6, 2020 between Contractor and City.
- 1.2 **Other Terms.** Terms used and not defined in this Amendment shall have the meanings assigned to such terms in the Agreement.

Article 2 Modifications to the Agreement.

The Agreement is hereby modified as follows:

2.1 **Contract Documents.** The attached set of contract documents replace the original set of contract documents in their entirety.

Article 3 Effective Date

Each of the modifications set forth in Section 2 shall be effective on and after April 6, 2020.

Article 4 Legal Effect

Except as expressly modified by this Amendment, all of the terms and conditions of the Agreement shall remain unchanged and in full force and effect.

IN WITNESS WHEREOF, Contractor and City have executed this Amendment as of the date first referenced above. **CITY** Recommended by: CONTRACTOR Color Genomics, Inc. Grant Colfax, MD Director of Health Caroline Savello Department of Public Health City Supplier number: 0000042840 Approved as to Form: Dennis J. Herrera City Attorney By: Louise S. Simpson Deputy City Attorney Approved: Alaric Degrafinried Director of the Office of Contract Administration, and Purchaser Name: **Attached Contract Documents** 1) Letter of Understanding 2) City Addendum and 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
- H: Color Data Security/Hosting Terms
- I: Reserved
- J: Reporting and Data Flow Chart
- K: Port Operation Requirements and Site Plan
- L: FEMA Emergency & Exigency Contracts Requirements



This Revised Letter of Understanding is made effective as of April [29], 2020 (the "Effective Date") by and between Color Genomics, Inc. ("Color"), a Delaware corporation, and the City of San Francisco ("City") (each a "Party" and collectively, the "Parties"). This Revised Letter of Understanding (the "Agreement") hereby supersedes and replaces in its entirety the Letter of Understanding between the Parties dated April 6, 2020.

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. **DEFINITIONS**:

- a. "City Data" means all data transmitted to and/or collected, used, maintained, processed, stored, or generated by Color under this Agreement. To the extent that Color may seek to use and/or retain deidentified City Data for commercial, regulatory, or any other purposes, DPH provides Color the express right to do so. The City does not grant Color authority to attribute any deidentified data or any aspect of its use to the City.
- b. **Color Program Administrator** means Caroline Savello, who can receive City Data at the following email address: caroline@color.com. Color may change such Color Program Administrator and the email address by providing notice to City.
- c. **DHR Program Administrator** means Micki Callahan, or designee, who can receive City Data at the following email address: <u>micki.callahan@sfgov.org</u>.
- d. **DPH Program Administrator** means Susan Philip, or designee, who can receive City Data at the following email address: susan.philip@sfdph.org.
- e. Executive Sponsor of the CityTestSF means Susan Philip, or designee, at susan.philip@sfdph.org.
- 2. <u>TESTING:</u> 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.
- 3. **REPORTING:** Color will provide the test result reporting, in accordance with the "Reporting and Data Flow" chart, attached hereto. The Reporting and Data Flow chart reflects the current mutually agreed upon (1) fields required to be included in Color's Registration Platform, and (2) reporting streams. Appendix XX is subject to modification as mutually agreed by Color and DPH. Reporting includes, but is not limited to the following:
 - a. **State CalREDIE** (California Reportable Disease Information Exchange): Color will handle CalREDIE reporting for all those whom it tests under this Agreement as required by applicable regulations or health orders and that fully complies with adding data as requested by DPH (in compliance with applicable regulations or health orders) into CalREDIE.
 - b. **Persons tested**: Individuals may access their own test results after receiving a text and/or email alert from Color that they are available.
 - c. **Health care providers**: If requested by persons tested, Color will notify the healthcare providers of the persons tested, subject to Color receiving contact information for such healthcare providers. Persons tested may identify their own health care providers when registering for the test, and City employees may also have their health plan information (Kaiser, Blue Shield, etc.) in the master eligibility file record provided to Color.



- d. City employees: Each business day (or such other frequency mutually agreed upon by the Parties), Color shall transmit a dataset to the City Department of Human Resources ("DHR") through a Secure File Transfer Protocol ("SFTP"). The dataset includes test results and no-show appointments for City employees from the inception of the CityTestSF project at each site through the current business day.
- e. **All Patients:** Color will provide mutually agreed upon reporting to DPH regarding all patients, at a frequency mutually agreed upon by both parties, as necessary to support DPH treatment, billing and/or healthcare operations, including but not limited to reporting for epidemiology, contact tracing, and/or billing for services provided to non-City employees.
- 4. **ELIGIBLE CITY EMPLOYEES**: DHR will periodically send to Color a comprehensive list of eligible City employees with appropriate confidential identifying information, including DSW numbers. In order to receive testing, City employees must register for a testing appointment by going to https://sf.gov/citytestsf and completing the registration process. Color will confirm registered City employees against the City-provided list.
- 5. ELIGIBLE NON-CITY EMPLOYEES: In order to receive testing, eligible non-City employees, whose employer has a payment contract with the City ("Paid Program"), may register for a testing appointment by going to https://sf.gov/citytestsf and completing the registration process, including the provision of insurance information (if available) and employer identification. DPH will send and periodically update Color with a list of non-City employees eligible for testing under the Paid Program. DPH represents and warrants that such all such employees on such list shall be part of a Paid Program. Color will confirm registered employees against the City-provided list.
- 6. **GENERAL PUBLIC**: All other persons eligible for testing consistent with Public Health Orders issues by the San Francisco Department of Public Health may register for a testing appoint with the assistance of a City, Color, Carbon Health, or One Medical staffer at the applicable site or by registering for a test at https://sf.gov/citytestsf.
- 7. <u>SITE MANAGEMENT</u>: Color understands and agrees to the site management/operational guidelines and site plan attached hereto as Appendix K.
- 8. **DATA SECURITY**: Color understands and agrees to the following data security terms:
 - a. **Purpose**. The City provides Color with access to City Data provided by City solely for the purposes detailed in this LOU. Any use outside of the scope detailed in this LOU shall constitute a material breach of this Agreement.
 - b. **Secure File Transfer**. The City will share City Data provided by City with the Color Site Administrator via a secure file transfer.
 - c. **Qualified Personnel**. Color shall allow only qualified personnel under Color's direct supervision to access shared City Data.
 - d. Safeguards. Color shall safeguard the confidentiality of all shared City Data at all times.
 - e. **No Re-Disclosure or Reporting**. Color may not re-disclose or otherwise prepare reports (in electronic or hard-copy format) regarding or containing City Data for transmission to any other individuals, agencies, or organizations except as permitted under applicable law, rule, regulation, licensure requirement, or health order, or with prior written City approval or the consent of the applicable individual.
 - f. **Data Transmission**. Color must ensure that all electronic transmission or exchange of City Data is encrypted according to current industry standard(s), as determined in its sole discretion by Color. City and Color must also ensure that all City Data is used solely for the purposes enumerated in the Agreement.



- g. **Compliance with Law**. Color shall comply with all applicable federal and state laws regarding the transmission, storage and protection of all City Data. Color agrees that any failure of Color to comply with the applicable requirements of federal and/or state and/or local privacy laws shall be a material breach of the Agreement, subject to the general equitable indemnity clause set forth in Section 5.2.1 of the City Addendum, as applicable.
- h. **Disposition of Data**. Except as otherwise required by law, rule, regulation, or Color's licensure requirements, at the termination or expiration of this Agreement, or upon written request of the City, Color shall return all City Data (hardcopy and electronic in a useable machine readable format) to the City. After the City confirms receipt, Color shall destroy all remaining City Data in Color's possession and/or control, except as required by law, rule, regulation, or Color's licensure requirements.
- 9. <u>COST BREAKDOWN</u>: Color will provide the COVID-19 Testing Platform to San Francisco at a cost of \$75 per test completed, including:
 - a. <u>TEST SITES</u>: Managing two (2) testing sites: (i) Pier 30/32 in San Francisco (the "SF Pier Site #1"), and (ii) [SOMA] (the "SOMA Site #2"). For both testing sites, Color shall provide the testing infrastructure (testing & workflows)
 - b. <u>SUPPLIES AND SERVICES AT TEST SITES</u>: Color provided (either itself or through its subcontractors) test site supplies and services include;
 - i. Sample collection kits (swab kits)
 - ii. Sample collection paperwork (barcodes, instructions, order forms)
 - iii. Transport of sample collection kits: Daily drop-off of kits, 1x-2x/day sample pickup from facilities
 - iv. Clinical support (bulk ordering authorization flow, results dashboard)
 - v. Clinical testing results & reporting to patients (negatives & positives) by HIPAA secure method. Results ready notifications by text/phone/email
 - vi. Daily reporting of results to CalREDIE and San Francisco DPH
 - vii. Positive patient routing (e.g., return of results to authorized providers identified by patients)
 - a. **REGISTRATION PLATFORM**: Color will build a front-end registration, eligibility, and scheduling website and hosting platform for both sites using Color's HIPAA-compliant framework and hosting architecture. Color's hosting terms are attached hereto as Appendix H. The Registration Platform may include dashboards reflecting test volume per day and overall.
 - b. **SCHEDULING**: Color will adjust scheduling upon mutual agreement with DPH to reflect urgent needs and to prioritize scheduling for medical staff, first responders, and essential workers.
 - **c.** <u>USER EXPERIENCE</u>: After entering all required information, the user/patient will be able to select an appointment slot at either testing site (Embarcadero or SOMA), and book that appointment. The user/patient will get a confirmation email or text with the time and place of their appointment and instructions for the appointment.
 - **d. BROWSERS AND DEVICES**: No more than two weeks after go-live, the Registration Platform will work in a range of browsers, including Safari, Firefox, Chrome and Explorer, and will work on a range of devices including phones, tablets and desktop computers.



- **e. PATTERN LIBRARY:** The Registration Platform interface will integrate the City's pattern library in agreement with Digital Services to the extent possible in the timeframe and will make the cobranding relationships clear and transparent for users.
- f. MAINTENANCE: Color will maintain and support the Registration Platform, providing patches, updates and fixes as needed. Any material changes to content or form fields on the front end will be signed off by the Executive Sponsor of the CityTestSF project before being deployed. If needed, Color can ask for support with copy changes from Digital Services, or the wider CityTestSF team, to ensure that copy is written to align with the City's content style guide.
- g. <u>SERVICE LEVEL</u>: If bugs or system errors in the Registration Platform occur, the City will report these to Color's technical lead, and Color will investigate the issue within a reasonable time frame. If the issue is found to be a bug or technical issue (as opposed to user error) Color will give an estimated time frame for resolution that is proportional to the scale of the issue. Issues that prevent people registering and/or booking are considered urgent.
- **h. HELP DESK**: The following Color email address (support@color,com) may be used for reporting technical issues that occur on the site, however Color will not be required to provide support directly to users to help them use the site. This function will be fulfilled by City staff and their non-profit partners.
- i. <u>REGISTRATION SHUTDOWN</u>: The City will communicate when the testing program is over and appointments should stop. Color will have four weeks (or such other time frame that is mutually agreed by the parties) to close down the registration and booking system and transfer all data to the City, to a point of contact at DPH.
- 10. <u>SUBCONTRACTS</u>: 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. At time of signing, Color is sub-contracting clinical staffing, onsite logistics, and site collection logistics and operations for SF Pier 30/32 Site #1 only.
- 11. <u>LAUNCH</u>: The parties intend to launch the COVID-19 Testing Platform at the SF Pier Site #1 on April 6, 2020. The parties intend to launch the COVID-19 Testing Platform at the SOMA Site #2 on April 27, 2020.



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

CITY	CONTRACTOR
Recommended by:	Color Genomics, Inc.
Court Calfor, MD	Caroline Savello
Grant Colfax, MD Director of Health	Chief Commercial Officer
Department of Public Health	Supplier ID: 0000042840
Approved as to Form:	
Dennis J. Herrera	
City Attorney	
By:	
Louise S. Simpson	
Deputy City Attorney	
Approved:	
11pp10 red.	
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 EIGHT MILLION TWO HUNDRED FIFTY FOUR THOUSAND SIX HUNDRED SIXTY ONE DOLLARS (\$8,254,661), 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.

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

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provision shall be null and void. For clarity, the City has approved in writing certain subcontracting services and costs in the Letter of Understanding (paragraph 5).

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 \$15,000,000 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. Contractor is permitted to meet any of the insurance requirements in this section with the use of excess or umbrella coverage.

- 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/

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 P-250 (EMERGENCY;4-19; DPH 4-18; 3-2020) 6 Contract ID # 1000017632 C: 2233

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.
- 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
- H: Color Data Security/Hosting Terms
- I: Reserved
- J: Reporting and Data Flow Chart
- K: Port Operation Requirements and Site Plan
- L: FEMA Emergency & Exigency Contracts
 - Requirements

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

<u>AIM</u>: All services provided through contractual agreement are provided safely and effectively for patient care and support services, annually.

Contract Name	Services Provided	Measure Name	Metric (What data is being collected?)
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, \$884,427 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

COVID-19 Test	Price
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)	\$75 / test
Subcontractor Cost: Clinical partner 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.	\$18,600 per 5 day week, based on estimate of 200 tests/day (to be revised in the event of volume increase)
Subcontractor Cost: Logistics partner 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.	\$17,528 per 5 day week, based on current site design
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.	\$214,795.49

Rebuild and expansion of Color's HIPAA-compliant digital platform and web application for the appointment registration, appointment scheduling, clinical test results, follow up and required reporting, per specification of the City. Application specifications are contained in the Letter of Understanding between the parties which this City Addendum is attached. One-time fee inclusive of all expenses required for the rebuild and expansion of the Color digital platform and web clinical application.	\$110,000
Application maintenance and hosting: Weekly fee is inclusive of all data transfer to and from the Contractor and the City and all system maintenance per the specifications contained in the Letter of Understanding between the parties which this City Addendum is attached. Weekly fee is inclusive of all expense required for application maintenance and hosting.	\$10,000 / weekly

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

Charge Item	Estimated Budgeted Amount
1 Completed Test - 1 Unit of Service	Duugeteu Amount
1 Completed Test = 1 Unit of Service	
1 Completed Startup task = 1 Unit of Service 1 Week of Maintenance = 1 Unit of Service	
	¢£ 000 000
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
One time charge for rebuild and expansion of digital	\$110,000
platform and web application.	
Weekly maintenance fee (\$10,000 / week)	\$90,000
Subtotal	\$6,792,843
Estimated Taxes	\$577,391
Subtotal Including Estimated Taxes	\$7,370,234
Contingency 12%	\$884,427
Total not to Exceed Amount of the Contract	\$8,254,661

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

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
(650) 714-6621





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 ("Citv") EMPLOYEES AND GENERAL PUBLIC PATIENTS (collectively, "Patients")

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. City Employee Patients: City authorizes testing of City employees identified by City. In order to receive testing, City employees must register for a testing appointment by going to https://sf.gov/citytestsf and completing the registration process. Color will confirm registered City employees against the City-provided list.
- B. Non-City Employee Patients: City also authorizes testing for non-City employees and the general public. In order to receive testing, non-City employees must register for a testing appointment with the assistance of a City, Color, Carbon Health, or One Medical staffer at the applicable site or by registering for a test at https://sf.gov/citytestsf.
- C. Patient Consent: Each 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.

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

Color (either itself or through its subcontractor(s)) hereby agrees to inform all 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, written or electronic 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) or otherwise by law and to report the COVID-19 Test result directly to the Patient and/or a Color or a Patient specified clinical service for follow-up consultation.

Approved:	
Susan Philips, MD	
Deputy Health Officer	
Department of Public Health	



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:



- 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. <u>Definitions.</u>

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

- a. "Reporting Requirements" means:
 - i. Reporting all <u>positive</u>, <u>negative</u>, <u>and inconclusive</u> 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.sfcdcp.org/wp-

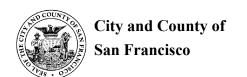


content/uploads/2018/01/Reportable-Diseases-List-CMR-SFDPH-EFF-10.2019-UPDATED-12.2019.pdf;

- 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.



- 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) and the Department of Public Health website (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



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

Dated: March 24, 2020

IT IS SO ORDERED:

Tomás J. Aragón, MD, Orl H,

Health Officer of the

City and County of San Francisco

5



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



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.
 - o Template for EUA submissions: https://www.fda.gov/media/135658/download.
- On March 9, 2020, the list of reportable diseases in <u>Title 17, California Code of Regulations (17 CCR)</u>
 <u>section 2500</u> was amended to include COVID-19 and Novel coronavirus infections, and <u>17 CCR section</u>
 <u>2505</u> 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 <u>Business and Professions Code (BPC)</u> <u>section 1265</u>, and testing personnel must be authorized to perform testing classified as high complexity under CLIA, as specified in <u>BPC section 1206.5 (c)</u>.
 - If a California laboratory sends biological specimens originating in California to a laboratory outside the state for testing, <u>BPC section 1241</u> 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 if you have questions.

Robert J. Thomas, Branch Chief

Robert J. Thomas



EXHIBIT B

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 (Richettsia 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 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 formatofreports, can be found on the <u>CalREDIE ELRwebpage</u> (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 forinstruction.

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.



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



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



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

Appendix H

Color Genomics, Inc.

How is our customer data protected?

We use Amazon Web Service's S3 and RDS services to store our data. See <u>AWS's security whitepaper</u> and <u>more detailed security whitepapers</u>. At a high level, all such data uses anonymized identifiers, and is encrypted at rest using AES-256, and in transit using TLS 1.2 with a modern cipher suite, so this data is only readable by Color. All data access is done using unique identifiers, is logged for auditability, and is restricted to only those employees who need access to perform their job duties.

Our security practices have been validated by an independent HIPAA-compliance audit, and an independent technical security penetration test.

Internal application access and application logs are audited regularly to ensure that only employees that need access to sensitive internal systems have access. When employees change roles or leave the company, their access is removed immediately.

What are the levels of access or authentication controls?

Only employees involved in the treatment of an individual patient have access to PHI. Those individuals involved in payment or operations have access to the minimum amount of PHI necessary to complete their job. All other access to PHI requires patient authorization.

- Regular employee: has no access to PII.
- Support staff: can access PII related to the patient's account, in order to resolve account-related issues. Cannot access PHI.
- Medical staff / clinical services: can access PHI, as needed to sign out reports and conduct any necessary outreach to patients.

What is our information security / access policy?

Our Security Policy follows the provisions of the Security Rule of HIPAA: we encrypt all data at rest and in transit, we only allow employees to access the minimum level of PHI needed to perform their job duties and log all access, and we conduct penetration testing of our software on an annual basis. We also sign Business Associate Agreements to extend this protection to all vendors we work with. Our service is wholly hosted on Amazon Web Service's cloud, which has been certified to several security standards, including HIPAA, HITRUST, and FedRAMP.

Per our responsibilities as a HIPAA covered entity, we have a designated Security and Privacy Officer, as well as a documented process for responding to security incidents.

Appendix I

Reserved

Appendix J

	DATA COLLECTION AND REPORTING										
ID NO.	Field	Need	User type	Source				Shared with			
			,		Cal-REDIE	Patient	PCP	On-site team	SF DPH (x = daily reporting) (x return data)	SF DHR For City Employees Only	Color
1	Essential worker confirmation	Eligibility	All	Signup Form					Х		Х
2	Symptoms confirmation	Eligibility	All	Signup Form	Х		X		Х		Х
3	First name	Identify test subject	All	Signup Form	Х		Х	Х	X	Х	Х
4	Last name	Identify test subject	All	Signup Form	Х		Х	Х	X	Х	Х
5	Middle initial	Contact tracing	All	Signup Form; back end match from DHR	Х			Х	X		Х
6	DSW#	Eligibility	City	Signup Form					Х	Х	Х
7	Phone	Post-results contact	All	Signup Form	Х		X		Х		Х
8	Email	Post-results contact	All	Signup Form	Х		Х		Х		Х
9	Street address	Contact tracing	All	Signup Form; back end match from DHR	Х		Х		X		Х
10	City/State	Epidemiology	All	Form, Zipcode	Х		Х		X		Х
11	Zipcode	Epidemiology	All	Signup Form; back end match from DHR	Х		Х		X		Х
12	Insurance provider	Billing	All	Signup Form; back end match from DHR					X		Х
13	Kaiser Medical Record Number	Billing/Post-results contact	All	Signup Form					X		Х
14	Health insurance ID #	Billing	All	Signup Form					X		Х
15	Health insurance group ID #	Billing	All	Signup Form					X		Х
16	Primary holder of health insurance	Billing	All	Signup Form					Х		Х
17	First name of primary holder of health insurance	Billing	All	Signup Form					Х		Х
18	Last name of primary holder of health insurance	Billing	All	Signup Form					Χ		Х
19	Primary care physician (first, last, practice, city, state)	Post-results contact	All	Signup Form					Х		Х
20	Consent to share	Post-results contact	All	Signup Form					Χ		Х
21	Consent for DHR to share with City employee department	Operational	City	Signup Form; back end match from DHR					Х	х	х
22	Sex at birth	Lab requirement	All	Signup Form; back end match from DHR	Х		Х		Х		Х
23	Date of birth	Lab requirement; Identify te	All	Signup Form; back end match from DHR	Х		X	Х	Х	Х	Х
24	Employer	Eligibility; billing	Essential	Signup Form					Х		Х
25	Last day reported to work	Contact tracing	City, Essential	Signup Form					Х		Х
26	Work location	Contact tracing	Essential	Signup Form					Х		Х
27	Race/Ethnicity	Epidemiology	All	Signup Form; back end match from DHR	Х		X		Х		Х
28	Appointment time	Operational	All	Signup Form		Х		Х	Х		Х
29	Appointment attendance	Operational	All	On-site team				Х	X	Х	Х
30	Sample collection time	Internal	All	On-site team					X		Х
31	Sample collection site	Internal	All	Signup Form					X		Х
32	Driving / walking	Operational	All	Signup Form				Х	Х		Х
33	Sample Barcode	Internal	All	On-site team		Х		Х	Х		Х
34	Specimen type (NP, OP, etc.)	Lab requirement	All	On-site team	Х		Х		Х		Х
35	Test results	Lab requirement	All	Color Lab	Х	Х	Х		Х	Х	Х
36	Test results release time	Internal	All	Color Lab					Х	Х	Х
37	Ordering Provider		All	Blanket Order	Х	_			Х		Х
38	Ordering Provider NPI		All	Blanket Order	Х				Х		Х

Appendix K Port Operation Requirements and Site Plan

OPERATIONAL REQUIREMENTS

This plan documents what activities will occur on site and what standards will apply to these activities.

1.0 KEY STAFF

In the event of an emergency, the following key staff are responsible.

TABLE 1: Kev Staff

NAME	TITLE	PHONE	EMAIL
Crezia Tano-	Project Manager	(415)215-8903	Crezia.tano-lee@sfport.com
Lee	(PRT)		
Matthias	Site Operations	(415)218-0465	Matthias.giezendanner@sfport.com
Giezendanner	Manager (PRT)		
Fatima Sabar	Operations, Color	(314) 644-	Fatima@color.com
		8557	
Caroline	Partnerships, Color	(650) 714-	caroline@color.com
Savello		6621	

2.0 GOOD NEIGHBOR POLICY

Good Neighbor Policies are commonly included in City contracts in order to support productive and communicative relationships between service organizations and the communities/neighborhoods in which they are located. Organizations who wish to operate the contracted services or facilities, agree to follow all provisions of the policy outlined below.

- A. Minimize the impact on the neighborhood of CityTestSF guests entering, exiting, or waiting for services.
- B. Implement management practices necessary to ensure that staff and clients do not block driveways of neighboring businesses.
- C. The Embarcadero Promenade (Herb Caen Way) is a public access area. The SFDPH agrees to have its security direct traffic in and out of the Valley gate so as not to adversely affect public access on the Promenade. This is a requirement of Bay Conservation Development Commission (BCDC) Permit M1996.013 section b.
- D. Sufficient toilet facilities shall be made accessible to patrons within the Premises, and toilet facilities shall be made accessible to prospective patrons who may be lined up waiting to enter the Premises.

- E. The SFDPH or its agents shall not load-in/load out or build out the tent structures between the hours of 11:00 pm to 7:00am.
- F. There shall be no noise audible outside the Premises during hours that violate Section 49 or Article 29 of the San Francisco Police Code. Further, absolutely no sound from the Premises shall be audible inside any surrounding residences or businesses that violate Article 29 of the San Francisco Police Code.

3.0 USE OF PORT FACILITIES – PROTECTING THE BAY

Most Port piers and the structures on them drain to the San Francisco Bay. Therefore, materials that are released on pier aprons and inside pier sheds could ultimately be released into the Bay. Materials can also be conveyed to the Bay by stormwater or wind. Even materials that are spilled in the dry summer months can be washed into the Bay with the winter rains.

TABLE 3a: Pollutants and Activities of Concern

POLLUTANTS	ACTIVITIES OF CONCERN
Trash / Debris	Waste Management
Vehicle Fluids	Parking, Deliveries/Provisioning,
Equipment Fluids	Operation of plant equipment

TABLE 3b: Port Facilities and Environmental Risks

PORT FACILITY	ENVIRONMENTAL RISKS
TYPE	
Pier Aprons, Decks, and	Discharge via sheet flow or storm drains to SF Bay
Open Land	Wind carries debris into SF Bay and neighboring
	communities

The two most important Best Management Practice (BMP) when using Port facilities are:

- 1) Be aware of the potential to pollute the Bay.
- 2) Train staff to protect the Bay.

The following Best Management Practices (BMPs) shall be used at all times.

BMPs– General Use of Port Facilities

- **BE AWARE**: Be aware of the potential to pollute the Bay.
- TRAIN STAFF: Train staff to be partners in protecting the Bay.
- **DEBRIS MANAGEMENT**: Place trash and debris in the proper containers.

- END OF DAY CLEAN-UP: At the end of the day or when activities are over, conduct a general clean-up to remove debris, trash, and inspect for spills.
- **SWEEP**: Use dry cleaning methods rather than pressure washing surfaces.
- CLEAN SPILLS IMMEDIATELY: Keep equipment clean. Avoid excessive build-up of oil and grease.

4.0 OPERATIONAL BASICS / PRIMARY ACTIVITIES

BASICS

- Monday through Friday, 8:00 am to 6:00 pm
- Approx. 22-30 Employees on Site; Intake 1; Collections 3-6; Operations 15
 Site Plan (refer to Exhibit A)

DESCRIBE ACTIVITES

Drive through testing of symptomatic essential workers for COVID19. Clients will be greeted at entrance of the site. They will be asked if they have an appointment and if they do, they will proceed to Station 1. At Station 1, they will keep their windows rolled up and hold their ID against the window for the staff member at Station 1 to confirm their appointment and check them in. They will then proceed to Station 2, where they will get their testing done. Samples are batched and transported to the lab for processing daily.

TABLE 2: Materials Inventory

TABLE 2. Waterials inventory					
QUANTITY	STORAGE**				
(MAXIMUM)					
10,000	Locked Freight Container				
5,000	Locked Freight Container				
1,000	Locked Freight Container				
5,000	Locked Freight Container				
50	Locked Freight Container				
100	Locked Freight Container				
	_				
30,000	Locked Freight Container				
5,000	Locked Freight Container				
100	Locked Freight Container				
20	In Tents				
	(MAXIMUM) 10,000 5,000 1,000 5,000 50 100 30,000 5,000 100				

^{*} Materials – (e.g., compressed gas cylinders of O2, or 55-gallon drums of motor oil, or wood products)

SITE PLAN (Map)

Provide a site plan showing the location of all activities including storage.

^{**} Storage – (e.g., on secondary containment pallets, or in flammable cabinet)

BEST MANAGEMENT PRACTICES (BMPs)

Identify Best Management Practices (BMPs)

A janitorial cleaning contractor has been engaged to provide hospital-grade cleaning of tents, tables, and equipment. The team will arrive one hour prior to the scheduled hours of operation and remains onsite throughout the day to provide ongoing cleaning of the facilities. Once the testing site has been closed to visitors and clinical staff has completed their work, the entire site will undergo a through cleaning.

Portable toilets with hot water are provided for staff use only. Visitors are not provided access to the toilets. An ADA compliant portable toilet is available for staff. Toilets and sinks are cleaned hourly by assigned janitorial staff.

Clinical waste and hazardous materials will be disposed of in clearly demarcated hazardous waste bins which are emptied each day into hazardous waste pickup containers. These containers are stored in a designated and clearly marked locked hazardous waste flamable storage container. The testing site operations manager and clinical operations manager will be the only two onsite staff with access to this container. Hazardous waste is retrieved and disposed of three times per week by Stericycle, a designated hazardouse waste removal company.

Persona Protective Equipment (PPE) is stored in two locked shipping containers. Inventory of PPE is conducted twice weekly by the onsite operations manager and clinical operations manager. Inventory supply is uploaded to a spreadsheet for ongoing tracking and burn rate. The clinical team monitors their daily PPE usage on this spreadsheet and records use of key items including N95 masks and gowns.

Security onsite is provided twenty four hours per day seven days per week. While staff is onsite, three security guards are located at the facility. One guard patrols the facility while two gates are manned by additional guards. When not in operation, entry gates are locked and one security guard patrols the facility.

Visitors are guided through a driving pathway demarcated clearly through orange traffic cones. Staff greeters are assigned to three different locations along this drivepath to direct visitors through the route in and out of the facilty. Signage instructs patients to keep their windows rolled up. Staff provides communication visually. Additionally, a phone is manned by greeter staff to answer in depth questions and provide further information pertaining to site operations if necessary for visitors.

SPILL RESPONSE

The testing site will not utilize industrial oils or fuel for operations. Construction is limited to free-standing tents supported by concrete ballasts. Waste is limited to staff refuse, waste generated by cleaning staff, and clinical operations.

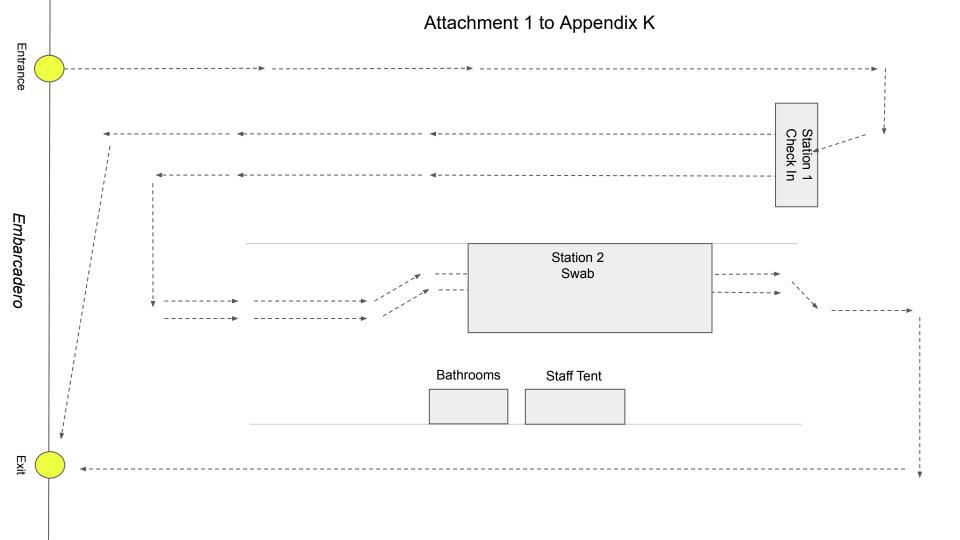
REGULATORY AGENCIES / PERMITS / PROFESSIONAL STANDARDS

Port Building Permits # B-2020-0070 and B-2020-0068 have been issued. SF Planning Department permit 2010.0493E and BCDC permit M1996.013 have been issued.

5.0 APPENDIX A - PERMITTED & REGULATED ACTIVITY - SUMMARY TABLE

CITY & COUNTY OF S	AN FRANCISCO			
AGENCY	REGULATED ACTIVITY	REQUIREMENT	APPLIES	PERMIT NO.
Port of San Francisco	- Post-Construction Stormwater	Stormwater Control Plan	YES/NO	B-2020-0070 B-2020-0068
SF Department of Public	- Hazardous Materials	Hazardous Materials	YES/NO	
Health – Hazardous	Storage	Business Plan		
Materials Unified	- Hazardous Waste			
Program Agency				
(HMUPA)		Review/Approval of	YES/NO	
		Proposal		
SF PUC	- Industrial Wastewater	Industrial Discharge Permit	YES/NO	
	- Fats, Oils, Grease Control	FOG Control Compliance		
	- Chemical toilets, etc.			
SF Fire Department	- Flammable Materials		YES/NO	
	- Compressed Gases			
	- Open Flame Devices			
SF Planning Department	- Project subject to CEQA	CEQA conditions	YES/NO	2010.0493E
STATE OF CALIFORN	IA			
AGENCY	ACTIVITY	REQUIREMENT	APPLIES	PERMIT NO.
DTSC	Hazardous Waste	EPA ID Numbers	YES/NO	
	Generation			
CA PUC	- Carry Passengers			
	- Issuance of Livery Plates			

	- Certain Transit Routes			
	- Reviews Passenger Rates			
Cal-OSHA	- Employee Health and		YES	
	Safety			
BCDC			Yes	M1996.013
FEDERAL				
AGENCY	ACTIVITY	REQUIREMENT	APPLIES	PERMIT
				NO.
DOT				



Appendix L FEMA Emergency & Exigency Contracts Requirements

1. Precedence of FEMA Requirements. This contract may be eligible for FEMA funding. FEMA requires inclusion of the following contract provisions for procurement under exigent or emergency circumstances. In the event of a conflict between this appendix and other provisions of the Agreement that address the same or a similar requirement, the provisions that are stricter and impose the greater duties upon Contractor shall apply.

2. Work Hours and Safety Standards. Contractor agrees as follows:

- A. **Overtime requirements.** No contractor or subcontractor contracting for any part of the contract work which may require or involve the employment of laborers or mechanics shall require or permit any such laborer or mechanic in any workweek in which he or she is employed on such work to work in excess of forty hours in such workweek unless such laborer or mechanic receives compensation at a rate not less than one and one-half times the basic rate of pay for all hours worked in excess of forty hours in such workweek.
- B. Violation; liability for unpaid wages; liquidated damages. In the event of any violation of the clause set forth in paragraph (A) of this section Contractor and any subcontractor responsible therefor shall be liable for the unpaid wages. In addition, Contractor and subcontractor(s) shall be liable to the United States for liquidated damages. Such liquidated damages shall be computed with respect to each individual laborer or mechanic, including watchmen and guards, employed in violation of the clause set forth in paragraph (A) of this section, in the sum of \$26 for each calendar day on which such individual was required or permitted to work in excess of the standard workweek of forty hours without payment of the overtime wages required by the clause set forth in paragraph (A) of this section.
- C. Withholding for unpaid wages and liquidated damages. The City shall upon its own action or upon written request of an authorized representative of the Department of Labor withhold or cause to be withheld, from any moneys payable on account of work performed by Contractor or subcontractor under any such contract or any other Federal contract with the same prime contractor, or any other federally-assisted contract subject to the Contract Work Hours and Safety Standards Act, which is held by the same prime contractor, such sums as may be determined to be necessary to satisfy any liabilities of such contractor or subcontractor for unpaid wages and liquidated damages as provided in the clause set forth in paragraph (B) of this section.
- D. **Subcontracts.** As appropriate and/or to the extent feasible, Contractor or subcontractor shall insert in any subcontracts the clauses set forth in paragraphs (A) through (D) of this section and also a clause requiring the subcontractors to include these clauses in any lower tier subcontracts. Contractor shall be responsible for compliance by any subcontractor or lower tier subcontractor with the clauses set forth in paragraphs (A) through (D) of this section. The City understands the difficulty presented by this requirement for subcontracts already in place and further understands that it may not be appropriate or feasible to effect all subcontract amendments.
- E. **Exceptions.** This Section 5 does not apply to the purchase of supplies or materials or articles ordinarily available on the open market, or contracts for transportation or transmission of intelligence

1 Appendix L

3. Clean Air Act. Contractor agrees as follows:

- A. Contractor agrees to comply with all applicable standards, orders or regulations issued pursuant to the Clean Air Act, as amended, 42 U.S.C. § 7401 et seq.
- B. Contractor agrees to report each violation to the City and understands and agrees that the City will, in turn, report each violation as required to assure notification to the Federal Emergency Management Agency, and the appropriate Environmental Protection Agency Regional Office.
- C. Subject to the limitations stated herein and understood and agreed to by the City (including, without limitation, Section 2(D) above), Contractor agrees to include these requirements in each subcontract exceeding \$150,000 financed in whole or in part with Federal assistance provided by FEMA.

4. Federal Water Pollution Act. Contractor agrees as follows:

- A. Contractor agrees to comply with all applicable standards, orders, or regulations issued pursuant to the Federal Water Pollution Control Act, as amended, 33 U.S.C. 1251 et seq.
- B. Contractor agrees to report each violation to the City and understands and agrees that the City will, in turn, report each violation as required to assure notification to the Federal Emergency Management Agency, and the appropriate Environmental Protection Agency Regional Office.
- C. Subject to the limitations stated herein and understood and agreed to by the City (including, without limitation, Section 2(D) above), Contractor agrees to include these requirements in each subcontract exceeding \$150,000 financed in whole or in part with Federal assistance provided by FEMA.

5. Debarment and Suspension. Contractor agrees as follows:

- A. To the extent this contract is a covered transaction for purposes of 2 C.F.R. pt. 180 and 2 C.F.R. pt. 3000, Contractor is required to verify that none of Contractor's principals (defined at 2 C.F.R. § 180.995) or its affiliates (defined at 2 C.F.R. § 180.905) are excluded (defined at 2 C.F.R. § 180.940) or disqualified (defined at 2 C.F.R. § 180.935).
- B. Subject to the limitations stated herein and understood and agreed to by the City (including, without limitation, Section 2(D) above), to the extent this contract is a covered transaction, Contractor must comply with 2 C.F.R. pt. 180, subpart C and 2 C.F.R. pt. 3000, subpart C, and must include a requirement to comply with these regulations in any lower tier covered transaction it enters into.
- C. This certification is a material representation of fact relied upon by the City. If it is later determined that Contractor did not comply with 2 C.F.R. pt. 180, subpart C and 2 C.F.R. pt. 3000, subpart C, in addition to remedies available to the City, the Federal Government may pursue available remedies, including but not limited to suspension and/or debarment.
- D. Contractor agrees to comply with the requirements of 2 C.F.R. pt. 180, subpart C and 2 C.F.R. pt. 3000, subpart C throughout the period of any contract that may arise from this offer. Subject to the limitations stated herein and understood and agreed to by the City (including, without limitation, Section 2(D) above), Contractor further agrees to include a provision requiring such compliance in its lower tier covered transactions.

2 Appendix L

6. Procurement of Recovered Materials

- A. In the performance of this contract, Contractor shall make maximum use of products containing recovered materials that are EPA-designated items unless the product cannot be acquired:
 - i. Competitively within a timeframe providing for compliance with the contract performance schedule;
 - ii. Meeting contract performance requirements; or
 - iii. At a reasonable price.
- B. Information about this requirement, along with the list of EPA-designated items, is available at EPA's Comprehensive Procurement Guidelines web site, https://www.epa.gov/smm/comprehensive-procurement-guideline-cpg-program.
- C. Contractor also agrees to comply with all other applicable requirements of Section 6002 of the Solid Waste Disposal Act.
- 7. **Department of Homeland Security Seal, Logo, and Flags.** Contractor shall not use the DHS seal(s), logos, crests, or reproductions of flags or likenesses of DHS agency officials without specific FEMA pre-approval.
- **8.** Compliance with Federal Law, Regulations, and Executive Orders. This is an acknowledgement that FEMA financial assistance will be used to fund all or a portion of the contract. Contractor will comply with all applicable Federal law, regulations, executive orders, FEMA policies, procedures, and directives.
- 9. No Obligation by Federal Government. The Federal Government is not a party to this contract and is not subject to any obligations or liabilities to the City, Contractor, or any other party pertaining to any matter resulting from the contract.
- 10. Program Fraud and False or Fraudulent Statements or Related Acts. Contractor acknowledges that 31 U.S.C. Chap. 38 (Administrative Remedies for False Claims and Statements) applies to the Contractor's actions pertaining to this contract.

11. Byrd Anti-Lobbying Certification.

- A. Contractors who apply or bid for an award of \$100,000 or more shall file the required certification pursuant to the Byrd Anti-Lobbying Amendment, 31 U.S.C. §1352, as amended. Each tier certifies to the tier above that it will not and has not used Federal appropriated funds to pay any person or organization for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, officer or employee of Congress, or an employee of a Member of Congress in connection with obtaining any Federal contract, grant, or any other award covered by 31 U.S.C. § 1352. Each tier shall also disclose any lobbying with non-Federal funds that takes place in connection with obtaining any Federal award. Such disclosures are forwarded from tier to tier up to the recipient who in turn will forward the certification(s) to the awarding agency.
- B. Subject to the limitations stated herein and understood and agreed to by the City (including, without limitation, Section 2(D) above), if this contract is for a price of \$100,000 or more, Contractor, and its lower tiers, must sign and submit to the City the following certification:

3 Appendix L

APPENDIX A, 44 C.F.R. PART 18 - CERTIFICATION REGARDING LOBBYING

Certification for Contracts, Grants, Loans, and Cooperative Agreements

The undersigned certifies, to the best of his or her knowledge and belief, that:

- (1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.
- (2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.
- (3) Subject to the limitations stated herein and understood and agreed to by the City (including, without limitation, Section 2(D) above), the undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

Contractor certifies or affirms the truthfulness and accuracy of each statement of its certification and disclosure, if any. In addition, Contractor understands and agrees that the provisions of 31 U.S.C. Chap. 38, Administrative Remedies for False Claims and Statements, apply to this certification and disclosure, if any.

4

Signature of Contractor's Authorized Official
Name and Title of Contractor's Authorized Official
Date

Appendix L

City and County of San Francisco Office of Contract Administration Purchasing Division

Second Amendment

THIS AMENDMENT (this "Amendment") is made as of **4**th **day of May** in San Francisco, California, by and between **Color Genomics, Inc.** ("Contractor"), and the City and County of San Francisco, a municipal corporation ("City"), acting by and through its Director of the Office of Contract Administration.

Recitals

WHEREAS, City and Contractor have entered into the Agreement (as defined below); and

WHEREAS, City and Contractor desire to modify the Agreement on the terms and conditions set forth herein to expand the COVID-19 testing program; and

NOW, THEREFORE, Contractor and the City agree as follows:

Article 1 Definitions

The following definitions shall apply to this Amendment:

- 1.1 **Agreement.** The term "Agreement" shall mean the Agreement dated April 6, 2020 between Contractor and City and Formal Modification No. 1 dated April 20, 2020;
- 1.2 **Other Terms.** Terms used and not defined in this Amendment shall have the meanings assigned to such terms in the Agreement.

Article 2 Modifications to the Agreement.

The Agreement is hereby modified as follows:

2.1 **LOU, Section 10 (SUBCONTRACTS)** currently reads as follows at the last sentence: "At time of signing, Color is sub-contracting clinical staffing, onsite logistics, and site collection logistics and operations for SF Pier 30/32 Site #1 only." Section 10, last sentence, is revised in its entirety as follows:

Section 10 (SUBCONTRACTS), last sentence: At time of signing, Color is sub-contracting clinical staffing, onsite logistics, mobile testing, and site collection logistics and operations for SF Pier 30/32 Site #1 only.

- 2.2 **LOU, Section 11 (LAUNCH)** currently reads as follows: The parties intend to launch the COVID-19 Testing Platform at the SF Pier Site #1 on April 6, 2020. The parties intend to launch the COVID-19 Testing Platform at the SOMA Site #2 on April 27, 2020. Section 11 is revised in its entirety as follows:
 - **Section 11 (LAUNCH).** The parties intend to launch the COVID-19 Testing Platform at the SF Pier Site #1 on April 6, 2020. The parties intend to launch the COVID-19 Testing Platform at the SOMA Site #2 on April 27, 2020. The parties intend to launch the COVID-19 Mobile Testing Platform on May 4, 2020 as described in Attachment 2 to Appendix A.
- 2.3 **City Addendum, Article 3, Section 3.2 (Guaranteed Maximum Costs)** currently reads as follows: The City's payment obligation to Color cannot at any time exceed EIGHT MISSION TWO HUNDRED FIFTY FOUR THOUSAND SIX HUNDRED SIXTY ONE DOLLARS (\$8,254,661), certified by the City's controller for the purpose and period stated in such certification. . . . Section 3.2 is revised in part as follows:

- **Section 3.2 (Guaranteed Maximum Costs).** The City's payment obligation to Color cannot at any time exceed NINE MILLION NINE HUNDRED THOUSAND DOLLARS (\$9,900,000), certified by the City's controller for the purpose and period stated in such certification. . . .
- 2.4 **City Addendum, Article 4, Section 4.2 (Subcontracting)** currently reads as follows at the last sentence: "For clarity, the City has approved in writing certain subcontracting services and costs in the Letter of Understanding (paragraph 5)." Section 4.2 is revised in part as follows:
 - **Section 4.2 (Subcontracting).** ... For clarity, the City has approved in writing certain subcontracting services and costs in the Letter of Understanding (paragraph 10).
- 2.5 City Addendum, Article 5 (Insurance and Indemnity), Section 5.1 (Insurance), Part 5.1.1.1.c. currently reads as follows: Commercial Automobile Liability Insurance (Reserved). Part 5.1.1.1.c. is revised in its entirety as follows:
 - 5.1.1.1.c. Commercial Automobile Liability Insurance Color and/or its subcontractor shall carry Commercial Automobile Liability Insurance with limits not less than \$1,000,000 each occurrence, "Combined Single Limit" for Bodily Injury and Property Damage, including Owned, Non-Owned and Hired auto coverage, as applicable. The Commercial Automobile Liability Insurance policy must be endorsed to name as Additional Insured the City and County of San Francisco, its Officers, Agents, and Employees. The Commercial Automobile Liability Insurance policies shall provide that such policy is 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. Before commencing any Services under this Modification No. 2, Color shall furnish to City certificates of insurance and additional insured policy endorsements with insurers with ratings comparable to A-, VIII 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.
- 2.6 **City Addendum, Appendix B.** Appendix B is hereby replaced in its entirety by Appendix B, dated May 4, 2020 attached to this Amendment and fully incorporated within the Agreement.
- 2.7 **City Addendum, Appendix B-1.** Appendix B-1 is hereby replaced in its entirety by Appendix B-1, dated May 4, 2020 attached to this Amendment and fully incorporated within the Agreement.

Article 3 Effective Date

Each of the modifications set forth in Section 2 shall be effective on and after May 4, 2020.

Article 4 Legal Effect

Except as expressly modified by this Amendment, all of the terms and conditions of the Agreement shall remain unchanged and in full force and effect.

IN WITNESS WHEREOF, Contractor and City have executed this Amendment as of the date first referenced above.

CITY Recommended by: DocuSigned by: Greg Wagner Grant Colfax, MD Director of Health Department of Public Health Approved as to Form: Dennis J. Herrera City Attorney DocuSigned by: ouise S. Simpson -BD54168A4C3B452... Louise S. Simpson Deputy City Attorney Approved: Alaric Degrafinried Director of the Office of Contract Administration, and Purchaser DocuSianed by: linda Repola 2E99F6456504C9 Linda Repola Name: **Attached Contract Documents** Attachment 2 to Appendix A

Appendix B
Appendix B-1

CONTRACTOR
Color Genomics, Inc.

Caroline Savello

City Supplier number: 0000042840

DocuSign Envelope ID: 6B6E3026-AE95-4CD8-BAFB-E073CEC60476

Attachment 2 to Appendix A - Modification No. 2 Mobile Testing Platform May 4,2020

Color will extend its Services to the City as set forth below, subject to the terms and conditions of the Agreement.

1. Expansion for Skilled Nursing and Mobile COVID-19 Testing Platform Services: Color will expand its scope from the "SF Pier Site #1" and the "SOMA Site #2" to provide mobile COVID-19 Services (collectively, "Mobile Testing Platform") for residents who cannot travel to existing testing sites. The Mobile Testing Platform will provide access for Skilled Nursing Facilities (SNF), congregate settings, and communities with difficulty accessing physical test sites as identified and prioritized by SFDPH. SFDPH will identify and prioritize locations for administering the Mobile Testing Platform.

2. Summary of Added Mobile Testing Platform Services:

- a. Testing
 - i. Collect test samples
 - ii. Process COVID-19 samples submitted from Mobile Testing Platform
 - iii. Deliver test samples to Color lab daily
- b. Testing Reporting and Data Sharing
 - i. Provide Reporting and Data Sharing as specified in the existing Agreement.
- c. Mobile Site Logistics
 - i. Manage design, supply, and operations of Mobile Testing Platform
 - **ii.** Provide clinical staffing and logistics support, including pop-up tenting or mobile units, based on the specifics of the prioritization of sites identified by DPH
 - iii. Manage supply of the clinical staffing support for Mobile Testing Platform

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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, \$1,059,819 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.

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

COVID-19 Test	Price
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)	\$75 / test
Subcontractor Cost: Clinical partner 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.	\$18,600 per 5 day week, based on estimate of 200 tests/day (to be revised in the event of volume increase)
Subcontractor Cost: Logistics partner 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.	\$17,528 per 5 day week, based on current site design
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.	\$214,795.49
Rebuild and expansion of Color's HIPAA-compliant digital platform and web application for the appointment registration, appointment scheduling, clinical test resu follow up and required reporting, per specification of the City. Application specification	

are contained in the Letter of Understanding between the parties which this City Addendum is attached. One-time fee inclusive of all expenses required for the rebuild and expansion of the Color digital platform and web clinical application.	
Application maintenance and hosting: Weekly fee is inclusive of all data transfer to and from the Contractor and the City and all system maintenance per the specifications contained in the Letter of Understanding between the parties which this City Addendum is attached. Weekly fee is inclusive of all expense required for application maintenance and hosting.	\$10,000 / weekly
Budget for Attachment 2 to Appendix A1 - Modification No. 2 Mobile Testing Platform May 4,2020	Price
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)	\$75 / test
Subcontractor Cost: Subcontractor shall provide Healthcare worker staffing at the testing site and pop-up site logistics support, and shall be responsible for all Personal Protect Equipment for its staff. Estimated budget includes clinical staffing, medical assistant, and daily PPE	100/day volume, 7 days/week: \$20,720 / week 200/day volume, 7 days/week: \$38,115 / week 400/day volume, 7 days/week: \$76,230 / week 600/day volume, 7 days/week: \$114,345 / week 800/day volume, 7 days/week: \$152,460 / week

Services are rendered as needed. Subcontractor costs shall be passed through. Services will be invoiced according to invoicing terms of the Agreement. In no event may the scope of services or the not-to-exceed amount of the Agreement be increased without a formal modification of this Agreement. Should costs increase

based on an increased testing volume, the City and Color will meet promptly to revise the Budget and payments herein before Services can continue.

Budget Summary

Charge Item	Estimated Budgeted Amount
1 Completed Test = 1 Unit of Service	
1 Completed Startup task = 1 Unit of Service	
1 Week of Maintenance = 1 Unit of Service	
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
One time charge for rebuild and expansion of digital platform and web application.	\$110,000
Weekly maintenance fee (\$10,000 / week)	\$90,000
Budget for Attachment 2 to Appendix A1 - Modification No. 2 Mobile Testing Platform May 4,2020	
Amount allocated for Mobile Testing Platform	\$1,667,388
Subtotal	\$8,460,231
Estimated Taxes	\$379,950
Subtotal Including Estimated Taxes	\$8,840,181
Contingency 12%	\$1,059,819
Total not to Exceed Amount of the Contract	\$9,900,000

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San Francisco Ethics Commission

25 Van Ness Avenue, Suite 220, San Francisco, CA 94102 Phone: 415.252.3100 . Fax: 415.252.3112 ethics.commission@sfgov.org . www.sfethics.org

Received On:

File #: 201192

Bid/RFP #:

1

Notification of Contract Approval

SFEC Form 126(f)4
(S.F. Campaign and Governmental Conduct Code § 1.126(f)4)

A Public Document

Each City elective officer who approves a contract that has a total anticipated or actual value of \$100,000 or more must file this form with the Ethics Commission within five business days of approval by: (a) the City elective officer, (b) any board on which the City elective officer serves, or (c) the board of any state agency on which an appointee of the City elective officer serves. For more information, see: https://sfethics.org/compliance/city-officers/contract-approval-city-officers

<u> </u>	
1. FILING INFORMATION	
TYPE OF FILING	DATE OF ORIGINAL FILING (for amendment only)
	40
Original	0,,
AMENDMENT DESCRIPTION – Explain reason for amendment	***
	10
	X.

2. CITY ELECTIVE OFFICE OR BOARD		
OFFICE OR BOARD NAME OF CITY ELECTIVE OFFICER		
Board of Supervisors	Members	

3. FILER'S CONTACT	
NAME OF FILER'S CONTACT	TELEPHONE NUMBER
Angela Calvillo	415-554-5184
FULL DEPARTMENT NAME	EMAIL
Office of the Clerk of the Board	Board.of.Supervisors@sfgov.org

4. CONTRACTING DEPARTMENT CONTACT			
NAME OF DEPARTMENTAL CONTACT		DEPARTMENT CONTACT TELEPHONE NUMBER	
Jacquie Hale		(415) 255-3508	
FULL DEPARTMENT NAME		DEPARTMENT CONTACT EMAIL	
DPH	Department of Public Health	Jacquie.Hale@SFDPH.org	

5. CONTRACTOR	
NAME OF CONTRACTOR	TELEPHONE NUMBER
Color Genomics, Inc.	(650) 714-6621
STREET ADDRESS (including City, State and Zip Code)	EMAIL
831 Mitten Road, Suite 100, Burlingame, CA 94010	Caroline@Color.com

6. C	ONTRACT			
DAT	CONTRACT WAS APPROVED BY THE CITY	ELECTIVE OFFICER(S)	ORIGINAL BID/RFP NUMBER	FILE NUMBER (If applicable)
		\$		201192
DESC	CRIPTION OF AMOUNT OF CONTRACT			
\$8	4,382,042	'0',		
NAT	URE OF THE CONTRACT (Please describe)			
cc	VID-19 Testing		9	
			S. S	
			2	to a
7. C	DMMENTS			
8. C	ONTRACT APPROVAL			
	contract was approved by:			
	THE CITY ELECTIVE OFFICER(S) IDENTIFIED	D ON THIS FORM		
	A BOARD ON WHICH THE CITY ELECTIVE	OFFICER(S) SERVES		
X	Board of Supervisors	`,		
	Board of Supervisors			
	THE BOARD OF A STATE AGENCY ON WH	ICH AN APPOINTEE OF	THE CITY ELECTIVE OFFICER(S)	DENTIFIED ON THIS FORM SITS
1				

2

9. AFFILIATES AND SUBCONTRACTORS

List the names of (A) members of the contractor's board of directors; (B) the contractor's principal officers, including chief executive officer, chief financial officer, chief operating officer, or other persons with similar titles; (C) any individual or entity who has an ownership interest of 10 percent or more in the contractor; and (D) any subcontractor listed in the bid or contract.

cont	contract.				
#	LAST NAME/ENTITY/SUBCONTRACTOR	FIRST NAME	ТҮРЕ		
1	Wagner	Sue	Board of Directors		
2	Taneja	Hemant	Board of Directors		
3	Gil	Elad	Board of Directors		
4	Gil	Elad	Shareholder		
5	Laraki	Othman	Board of Directors		
6	Laraki	Othman	CEO		
7	Laraki	Othman	Shareholder		
8	Savello	Caroline	Other Principal Officer		
9	Chen	Sherwin	Other Principal Officer		
10	Zhou	Alicia	Other Principal Officer		
11	Carbon Health		Subcontractor		
12	Czarnowski Event Services		Subcontractor		
13					
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19					

9. AFFILIATES AND SUBCONTRACTORS

List the names of (A) members of the contractor's board of directors; (B) the contractor's principal officers, including chief executive officer, chief financial officer, chief operating officer, or other persons with similar titles; (C) any individual or entity who has an ownership interest of 10 percent or more in the contractor; and (D) any subcontractor listed in the bid or contract.

contract.				
#	LAST NAME/ENTITY/SUBCONTRACTOR	FIRST NAME	ТУРЕ	
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9. AFFILIATES AND SUBCONTRACTORS List the names of (A) members of the contractor's board of directors; (B) the contractor's principal officers, including chief executive officer, chief financial officer, chief operating officer, or other persons with similar titles; (C) any individual or entity who has an ownership interest of 10 percent or more in the contractor; and (D) any subcontractor listed in the bid or contract. LAST NAME/ENTITY/SUBCONTRACTOR **FIRST NAME** TYPE 39 40 41 42 43 44 45 46 47 48 49 50 Check this box if you need to include additional names. Please submit a separate form with complete information. Select "Supplemental" for filing type.

10. VERIFICATION	
I have used all reasonable diligence in preparing this statement. I have reviewed this statement and to the best of my knowledge the information I have provided here is true and complete.	
and the age the amortinate provided here is true and complete.	
I certify under penalty of perjury under the laws of the State of California that the foregoing is true and correct.	
SIGNATURE OF CITY ELECTIVE OFFICER OR BOARD SECRETARY OR CLERK	DATE SIGNED
BOS Clerk of the Board	

From: Peacock, Rebecca (MYR)
To: BOS Legislation, (BOS)

Cc: Kittler, Sophia (MYR); Hale, Jacquie (DPH); Murrell, Drew (DPH); Ruggels, Michelle (DPH); Patil, Sneha (DPH)

Subject: Mayor -- [Resolution] -- [Contract Amendment - Color Genomics, Inc. - COVID-19 Testing Services - Not to

Exceed \$84,382,042]

Date: Tuesday, October 20, 2020 4:15:42 PM
Attachments: (2) Reso DPH Color Genomics Amendment.zip

Attached for introduction to the Board of Supervisors is a resolution approving Amendment No. 3 to the agreement between Color Genomics, Inc. and the Department of Public Health for COVID-19 testing services, to increase the agreement amount by \$74,482,042, for an amount not to exceed \$84,382,042; and to establish a specific term end date of March 31, 2021, for a total agreement term of April 6, 2020, through March 31, 2021.

Please let me know if you have any questions.

Rebecca Peacock (<u>they/she</u>)

(415) 554-6982 | Rebecca.Peacock@sfgov.org Office of Mayor London N. Breed City & County of San Francisco