

STANDARD AGREEMENT - AMENDMENT

STD 213A (Rev. 4/2020)

☐ CHECK HERE IF ADDITIONAL PAGES ARE ATTACHED _____ PAGES

AGREEMENT NUMBER

21-10450

AMENDMENT NUMBER

A01

Purchasing Authority Number

1. This Agreement is entered into between the Contracting Agency and the Contractor named below:

CONTRACTING AGENCY NAME

California Department of Public Health

CONTRACTOR NAME

Color Health Inc.

2. The term of this Agreement is:

START DATE

8/13/2021

THROUGH END DATE

1/31/2022

3. The maximum amount of this Agreement after this Amendment is:

\$5,000,000.00

Five Million Dollars and Zero Cents

4. The parties mutually agree to this amendment as follows. All actions noted below are by this reference made a part of the Agreement and incorporated herein:

I. The purpose of this amendment is to add Exhibit A Attachment 2 Additional Scope of Work to the original agreement and to change Contractor name from Color Genomics, Inc. to Color Health, Inc.

II. Exhibit A Attachment 2 is hereby added to the original agreement as attached herein.

All other terms and conditions shall remain the same.

IN WITNESS WHEREOF, THIS AGREEMENT HAS BEEN EXECUTED BY THE PARTIES HERETO.

CONTRACTOR

CONTRACTOR NAME (if other than an individual, state whether a corporation, partnership, etc.)

Color Health, Inc.

CONTRACTOR BUSINESS ADDRESS

831 Mitten Rd, Suite 100

CITY

Burlingame

STATE

CA

ZIP

94010

PRINTED NAME OF PERSON SIGNING


Caroline Savello

TITLE

Chief Commercial Officer

CONTRACTOR AUTHORIZED SIGNATURE

Caroline Savello

 Digitally signed by Caroline Savello
Date: 2021.10.19 12:46:38 -07'00'

DATE SIGNED

STATE OF CALIFORNIA

CONTRACTING AGENCY NAME

California Department of Public Health

CONTRACTING AGENCY ADDRESS

1615 Capitol Ave

CITY

Sacramento

STATE

CA

ZIP

95814

PRINTED NAME OF PERSON SIGNING


Tim Bow

TITLE

Procurement Officer

CONTRACTING AGENCY AUTHORIZED SIGNATURE

Timothy Bow

 Digitally signed by Timothy Bow
Date: 2021.10.20 08:34:08 -07'00'

DATE SIGNED

CALIFORNIA DEPARTMENT OF GENERAL SERVICES APPROVAL

EXEMPTION (If Applicable)

Executive Order N-25-20-COVID19

Rapid Antigen Testing Extension

Rapid Antigen Testing Programs

Color can partner with the State/CDPH to expand access to testing for populations across California under Color's CLIA waiver.

These programs can include onsite rapid antigen testing operating under Color Health's CLIA license; PCR testing performed at CDPH's Valencia Branch Lab or another integrated lab designated by the State; and self-reported, Over-the-Counter rapid antigen testing. Any and all services can be available at a testing site, through a single program and software platform.

Color can support the use of rapid testing by providing the following software and support services, in accordance with Contract [20-10792](#):

1. Program Strategy, Management & Administration Services
2. Platform Services
 - a. Site Planning, Onboarding, and Ongoing Support
 - b. Patient Registration and Resulting Interface
 - c. Test Administration Software and Services
3. Logistics Support
 - a. Collection Site Materials and Supplies
 - b. Virtual Training for Site Staff
4. Biohazard Waste Management Services

1) Program Strategy, Management & Administration Services

- Color program manager will design testing program strategy and liaise with Site Admin and CDPH
- Support engagement with potential sites to demonstrate system capabilities and operational requirements
- Report on process and results metrics
- Share best practices, innovative solutions across system, and new opportunities for improvements to COVID-19 test collection methodologies

2a) Site Planning, Onboarding, and Ongoing Support

- Provide an online site onboarding mechanism to register organizations and sites as collection sites. Information collected will include site address, point of contact, and expected testing volumes.
- Define organizations' approaches to sample collection (e.g., frequency, timing, modalities) and logistics
- Offer logistics and infrastructure planning, documentation of equipment requirements (technology list with procurement details), and guidance on staffing to Organizations & sites
- Provide site setup best practices and materials, including QR codes for pre-registration, and signage design for testing events in multiple languages
- Provide technical support hotlines for both test collection sites and support for participants, by phone and email, for questions and concerns. Support

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hotline is available seven days per week. Training and support is available through office hours, support videos, website and robust documentation.

- Onboarding must be completed within 5 business days to ensure entities are ready to test 5 business days from day of sign-up with Color.

2b) Patient Registration and Resulting Interface (Color Participant Platform)

- **Digital data collection:** Collect individual patient PII (including demographics, insurance information, and other data needed by the State or regulatory authorities) through an online, digital registration portal. Registration and intake information will meet reporting requirements of CalREDIE, relevant regulatory bodies, and reflex testing laboratory.
- **Participant Consent and HIPAA authorization:** Collect digital consent from testing program participants and digital HIPAA authorization to enable Color to share results with authorized individuals in Organizations.
- **Resulting and reporting:** Report testing results directly to the patient, ordering provider, Collection Site, and required public health authorities. All results will be communicated electronically.
- **Program dashboards:** Provide aggregate and individual level dashboards to Collection Sites and Organizations with appropriate permissions to track test results and program metrics for their institution.
- **Results APIs:** Enable Organizations to access results for an ongoing feed of results information that can be integrated with HR and Employee Health & Safety information systems via a Color's Results API integration.

2c) Test Administration Software & Services (Color Intake Platform)

- **Rx rapid antigen administration support:** Provide test administration software & training for Rx rapid antigen testing. Trained, authorized individuals who are Organization employees will check in registered individuals, administer a sample collection event, and record results of the rapid antigen testing in Color's platform.
- **CDPH Obligations:** CDPH's obligations with respect to rapid test administration include the following:
 - (1) Tests will be administered pursuant to Color's CLIA License #05D2081492 and CDPH will act in accordance with all requirements as determined by Color Health in its sole discretion.
 - (2) Color will interface directly with relevant Organizations in providing services under this Agreement. CDPH will ensure that such organizations and all collection site staff follow the protocols, instructions, and training provided by Color's clinical laboratory staff regarding administration of CLIA-waived tests. Color may discontinue

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testing at any collection site if site staff do not follow Color's protocols, instructions, and training until staff comply appropriately.

- (3) Collection site staff will, at all times comply with Color's instructions, including CLIA protocols, in administering CLIA-waived tests. If Organizations do not ensure compliance for each collection site Color may suspend testing at such site until the site complies. CDPH will ensure each Organization complies.
- (4) The relevant Organizations will identify to Color in writing all collection sites administering CLIA-waived tests pursuant to Color's CLIA licensure.
- (5) Color is not responsible for supervising collection site staff or for staff's actions or omissions.
- (6) Each relevant Organization will designate a single point of contact responsible for CLIA compliance at each collection site and provide that information to Color. CDPH will ensure each Organization complies with this requirement.
- (7) All site collection staff shall be duly authorized under BPC 1206.5(a)(1)-(14) to administer the test. If Organizations do not so certify for each collection site Color may suspend testing at such site until the site complies. CDPH will ensure each Organization complies.
- (8) CDPH will reasonably cooperate with Color with regards to any inspections, investigations, inquiries, or other proceedings regarding its CLIA license and any other state or federal licensures or any accreditations which arise from or relate to this agreement.

Any breach of the obligations at (1)-(8) above will constitute a material breach of this agreement.

- **Self-reported rapid testing administration support:** Provide test administration software & training for individuals to self-report their own results from Over-the-Counter rapid antigen tests. Individuals in the testing program will self-administer a sample and record the test result into Color's platform.

3a) Virtual Training for Site Staff

- Provide a robust, digital training program to support Organizations and their testing sites with their program launch.
 - The training program includes modules on HIPAA, site operations, performing the antigen test, and using the Color software, and includes some competency quizzes and hands-on exercises.

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- For sites running Rx rapid antigen tests administered under Color's CLIA waiver, training and documentation of accurate administration is required for all personnel administering testing.
- For each testing site, the state is responsible for identifying sufficient employees to act as "site leads" and as "site staff".

3b) Collection Site Materials and Supplies (Optional)

At a site's request, provide sites with materials and supplies needed to operate a testing site. Materials and Supplies will include both initial Site Set-up Materials (e.g., tables) and Consumable Materials (e.g., PPE) for ongoing operations. Site staff are solely responsible for assembling, placing, and using site set-up materials.

For each testing site, a Site Set-up Package is provided. This package includes:

- Signage, Posters, and A-Frame Sign Holders (6)
- Tablet, case, and charger (4)
- Mirror (2)
- Barcode scanner (2)
- Power Strip and Extension Cords (3)
- Timer/stopwatch (10)
- Large digital clock (1)
- Sharpies (6)

A Site Consumables kit is sent to each site every month the site is operational. The site consumables kit includes:

- WiFi LTE Plan for iPads
- PPE (enough for 4 staff operating for 20 days)
- Disinfectant materials (facial tissues, disinfectant spray, disinfectant wipes, hand sanitizer)
- Paper towels

Note: For large collection sites requiring more than four staff to be present on testing days, Color will ship additional Site Consumables kits each month to provide adequate supplies for ongoing operations.

4) Biohazard Waste Management Services

- Provide biohazard waste management services to sites to ensure proper disposal of any biohazard waste, including:
 - 5 gallon biohazard collection tub (2 each month per site of 4 staff members / 150 tests/day)
 - Regulated medical waste mailback system, including pre-paid postage, instructions, and return packaging
 - Training and instructions

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Note: **Biohazard waste only includes positive rapid antigen test cards**; PPE and negative antigen test cards do not need to be discarded as biohazard waste.

Terms

Service	Fee
Program Administration & Management	
Rapid, Onsite Testing Program Administration & Management	\$35,000/month
Virtual Training for Site Staff	\$150/site one-time
Platform Services	
CLIA-waived rapid antigen tests	\$3.85/test reported
Self-reported OTC antigen tests	\$3.45/test reported
PCR Reflex Testing	Per sample collection fees as reflected in contract 20-10792 ¹
Logistics Support	
Site Set-up Materials (Optional - upon request by CDPH)	\$5,050/site
Site Consumable Materials (Optional - upon request by CDPH)	\$2,620/month/site (1 unit per site)
Biohazard waste and trash removal	\$1,180/month/site (1 unit per site)
CLIA Waiver & Documentation Setup Fee ²	\$350/antigen testing site registered (one-time pass-through of LFS CLIA waiver application fee)
CLIA Training Administration	\$250/site
Optional: Unmonitored / At-Home PCR Test Collection³	
Unmonitored Ship-from-Home Collection Kit	\$6.40/kit

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Color Lab Processing Fee (per test)	\$40/test
Ship-from-Home Shipping Fee (per test)	\$20/test
<i>Optional Shipping Fee:</i> Positive sample transport from Color to VRDL for sequencing	\$150/shipment

Notes:

¹ Service by cumulative sample volume as listed in Contract 20-10792 Exhibit B:

First 2 million samples collected: \$8.15/sample collected

Subsequent 2 million samples collected: \$7.00/sample collected

Additional samples collected beyond initial 4 million: \$4.75/sample collected

² For each physical testing site operated under Color's CLIA license (covering rapid antigen testing), California Laboratory Field Services (LFS) requires that Color establish an individual, site-specific CLIA waiver, and maintain independent and robust documentation of staff training, lot qualifications, and test records. This waiver also requires extensive staff training, documentation, and operational management as detailed in Section (3a) of Services. Color must submit each site individually to LFS and secure approval by LFS prior to operation. Each site submission for antigen testing under Color's CLIA waiver to LFS includes a one-time fee of \$350 that Color must pay to LFS for each site location. Color will pass this LFS waiver fee of \$350 through to CDPH without markup.

³ Optionally, Color can provide unmonitored, self-administered PCR lab tests for participants to test themselves at-home or in remote locations. These kits can be provided at the State's request, and maybe utilized by individuals as reflex testing from self-reported, Over-the-Counter rapid antigen testing.

Implementation Responsibilities:

State/CDPH:

- Approves organizations to participate in program
- Secures MOUs and provides guidelines for participation
- Provides each organization's point of contact
- Manages collection kit onsite inventory:
 - Ships rapid test kits to collection sites

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- Provides system (e.g., ordering portal) to manage sites' requests for additional collection kits

Contractor/Color:

- Reaches out to approved organizations for planning and onboarding
- Assigns account manager from dedicated team
- Provides setup webform, tools, documentation, training, and support email/phone number
- Launches site and manages ongoing needs, coordinating with site's point of contact
- Supports advanced participant registration configurations
- Supports advanced results management configurations
- Provides State/CDPH with collateral supplies to include with rapid test kits

Collection sites:

- Provides location, necessary equipment and hardware, PPE and other consumables (as needed)
- Selects and manages staff for participant registration, sample collection, site set-up/take-down, security/safety (as needed)
- Prints signage and materials
- Manages materials storage, waste disposal
- Maintains all required insurance and permits