EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
COLOR COVID-19 SELF-SWAB COLLECTION KIT

For in vitro Diagnostic Use
For Prescription Use only
For use under Emergency Use Authorization (EUA) only
For use by people 18 years of age or older

At-home self-collected nasal swabs or unsupervised self-collected nasal swabs at a collection site are collected with the Color COVID-19 Self-Swab Collection Kit and will be sent to High Complexity Laboratories that have been designated by Color Genomics, Inc. All laboratories will be certified under the Clinical Laboratory Improvement Amendments of 1988(CLIA), 42 U.S.C. §263a and meet the requirements to perform high complexity tests and run the specimens collected from the Color COVID-19 Self-Swab Collection Kit on an in vitro diagnostic (IVD) molecular test that is indicated for use with the Color COVID-19 Self-Swab Collection Kit for self-collection of nasal swab specimens.

INTENDED USE

The Color COVID-19 Self-Swab Collection Kit is intended for use by individuals for unsupervised self-collection of nasal swab specimens at home or in a healthcare setting when determined by a healthcare provider to be appropriate based on results of a COVID-19 medical questionnaire. Dry swab specimens collected using the Color COVID-19 Self-Swab Collection Kit are transported at ambient temperature for testing at an authorized laboratory. SARS-CoV-2 RNA from the nasal swab specimens is maintained in the specimen packaging and is suitable for use in molecular diagnostic testing performed using an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 that is indicated for use with the Color COVID-19 Self-Swab Collection Kit.

Testing is limited to laboratories designated by Color Genomics Inc. that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests. Testing is also limited to molecular diagnostic tests that are indicated for use with the Color COVID-19 Self-Swab Collection Kit.

The Color COVID-19 Self-Swab Collection Kit is only for use under the Food and Drug Administration’s Emergency Use Authorization.

SPECIAL CONDITIONS OF USE STATEMENTS

For Emergency Use Authorization (EUA) only
For Prescription Use only
For in vitro diagnostic use
For use by people 18 years of age or older

The Color COVID-19 Self-Swab Collection Kit is only authorized for use in conjunction with an in vitro diagnostic (IVD) molecular test for the detection of SARS-CoV-2 RNA that is indicated for use with dry nasal swab specimens collected with the Color COVID-19 Self-Swab Collection Kit.

DEVICE DESCRIPTION AND TEST PRINCIPLE

Color Genomics, Inc. (Color) offers the Color COVID-19 Self-Swab Collection Kit as part of a community-based distribution framework that is physician ordered. Healthcare providers (HCP) at specific institutions, who are licensed and have prescriptive authority in their respective states, use a COVID-19 eligibility questionnaire that is based on current CDC testing guidelines to evaluate patient acceptability. Ordering physicians must be licensed in the state where the kits will be provided or shipped. At the physician's discretion, the patient accesses the Color website (http://home.color.com/covid/check) and answers questions related to patient exposure, symptoms, as well as underlying health conditions and other risk factors. This task is to document the patient's responses and link the patient with a specific kit and barcode that will be used for accessioning at the testing laboratory.

The Color COVID-19 Self-Swab Collection Kit enables the self-collection of a nasal swab sample that is transported in dry conditions in a sterile collection container to either; (1) Color for processing with the Color Genomics SARS-CoV-2 RT-LAMP Diagnostic Assay or (2) another laboratory designated by Color that has an IVD molecular assay for detection of SARS-CoV-2 that is indicated for use with the Color COVID-19 Self-Swab Collection Kit. The Color COVID-19 Self-Swab Collection Kit can be provided at a designated on-site collection location that is part of a centrally coordinated program or can be ordered by a healthcare provider through Color's website and shipped to the patient's home via 2-day shipping. Color does not accept requests for kits from patients directly. Results of the IVD molecular assay for detection of SARS-CoV-2 are communicated to the ordering physician. If the ordering physician directs Color to do so, patients will also receive a notification via email or text message containing a link to Color's online HIPAA-compliant post-test portal to access their results. The authorizing physician and the sponsoring agency often give their patients the option to follow-up with a healthcare provider to discuss the test results.

The Color COVID-19 Self-Swab Collection Kit consists of a sterile packaged spun polyester swab, collection tube, a rigid biohazard safety bag, barcode card, instructions for use, and a FedEx shipping envelope with a prepaid return label. Instructions included in the kit guide users on how to appropriately collect the nasal swab specimen. Following collection, the swab is inserted into a sterile dry tube without transport or preservative medium, and the cap is pushed on tightly to the collection tube. The collected specimen is sealed in the biohazard bag and placed into a designated, secure collection bin or handed directly to onsite staff if collected at a designated location OR the specimen in the rigid biohazard safety bag is placed into the FedEx return shipping envelope for transport to a designated testing laboratory. For those specimens collected at home, the completed Self-Swab Collection Kit must be deposited at a FedEx drop box location on the same day the specimen is collected to ensure timely receipt of an intact specimen. Each Color COVID-

19 Self-Swab Collection Kit is intended to be returned via 48-hour shipping (or same day shipping via a courier for those collections completed on-site) at ambient conditions.

Specimens received for testing at Color and designated laboratories will undergo a thorough review and accessioning prior to acceptance for testing with an IVD molecular SARS-CoV-2 assay indicated to process dry nasal swabs per the Instructions for Use. See Accessioning SOP for details.

REAGENTS AND MATERIALS

The Color COVID-19 Self-Swab Collection Kit consists of the following components:

Component
FedEx soft shipping envelope with prepaid return shipping label*
Rigid biohazard safety bag for collected specimen
Sterile packaged spun polyester swab
Sterile collection tube
Barcode card
Instructions for self-collection

*Not applicable to unmonitored on-site collection

MEDICAL OVERSIGHT AND PROCESS TO BE USED:

Nasal swabs can be collected via two different workflows:

On-Site Unmonitored Collection Workflow

1. At the physician's discretion, the patient completes the eligibility questionnaire via the Color website (http://home.color.com/covid/check) which adheres to the CDC COVID-19 screening guidelines. A healthcare provider (HCP) at specific institutions authenticates the information and determines patient suitability for the unmonitored nasal swab collection kit.
2. The patient collects their own nasal specimen following the instructions provided with the kit and returns the completed kit to the on-site collection bin.
3. All samples collected on-site are delivered to Color's laboratory or Color designated laboratories within 56 hours for processing.
4. Test results are communicated back to the patient and the ordering physician. Results are returned electronically or by fax to the ordering provider. If the ordering physician directs Color to do so, patients will also receive a notification via email or text message containing a link to Color's online HIPAA-compliant post-test portal to access their results.
5. Results are automatically shared with local Department of Public Health registries.

At-Home Unmonitored Collection Workflow

1. At the physician's discretion, the patient completes the eligibility questionnaire via the Color website (http://home.color.com/covid/check) which adheres to the CDC COVID-19 screening guidelines. A healthcare provider (HCP) at specific

institutions authenticates the information and determines patient suitability for the unmonitored nasal swab collection kit.
2. Color will ship the unmonitored collection kit to the patient's home via 2-day shipping.
3. The patient collects their own nasal swab specimen following the instructions provided with the kit and ships the completed kit to Color's laboratory or Color designated laboratories using a prepaid FedEx shipping pack.
4. Test results are communicated back to the patient and the ordering physician. Results are returned electronically or by fax to the ordering provider. If the ordering physician directs Color to do so, patients will also receive a notification via email or text message containing a link to Color's online HIPAA-compliant post-test portal to access their results.
5. Results are automatically shared with local Department of Public Health registries.

PATIENT INCLUSION/EXCLUSION CRITERIA:

Currently, Color offers the Color COVID-19 Self-Swab Collection Kit as part of centrally coordinated community programs that are under the direction of a supervising physician. Healthcare providers (HCP) at specific institutions within the community-based framework use a COVID-19 eligibility questionnaire that is based on current CDC testing guidelines to evaluate patient acceptability. Ordering HCPs must be licensed in the state where the kits will be provided or shipped. Color will ship a kit to a patient's home when directed to do so as a part of an established program but does not accept requests for kits from patients directly. In practice, the inclusion and exclusion criteria are established by the program and authorizing physician, but Color's guidance is as follows:

Exclusion:

- Patients with no symptoms and no known exposure risks
- Individuals with severe symptoms (will be directed to seek immediate care)

Inclusion:

- Patients with "mild" symptoms
- Individuals with known exposure, sick contact, or living in area of Community Spread, with no symptoms

INSPECTION OF NASAL SWAB SPECIMENS RECEIVED AT A DESIGNATED LABORTAORY FOR TESTING:

Specimens collected with the Color COVID-19 Self-Swab Collection Kit must be checked for the following criteria upon receipt at designated testing laboratories prior to processing as outlined in the "Specimen Receipt and Handling for the Color COVID-19 Self-Swab Collection Kit" accessioning SOP:

- Sample collection tube must be intact and not visibly damaged.
- The tube barcode label must be present and readable by a barcode scanner.
- The tube cap must be properly secured onto the tube.
- Accession date is within 56 hours of the collection date/time.

- Each laboratory's accessioning system must check that the specimen is approved by a physician, a consent form is present, and that the collection kit has been activated via the on-line portal within the last 56 hours.

CONTROLS TO BE USED WITH THE SARS-COV-2 MOLECULAR ASSAY

1) **No Template Control (NTC)**
   A negative (no template) control must be used to monitor for sample contamination during nucleic acid extraction and RT-PCR assay set-up. Molecular grade, nuclease-free water or DNA/RNA Shield media can be processed as a clinical sample beginning with extraction (optional) or can exclude the extraction step and be added during RT-PCR set-up.

2) **SARS-CoV-2 Positive Control**
   A positive SARS-CoV-2 control is needed to verify proper nucleic acid extraction, assay set-up, and SARS-CoV-2 reagent integrity. A positive control consisting of DNA/RNA Shield media spiked with human total extracted nucleic acid and synthetic viral SARS-CoV-2 RNA (Twist Synthetic SARS-CoV-2 RNA Control 1 (MT007544.1) or another applicable positive control at ≤5X LoD can be used. The positive control must be used on every assay plate starting at master mix addition.

3) **Endogenous Internal Control**
   An internal control targeting RNase P or another endogenous human control gene is needed to verify that nucleic acid is present in every sample and is used for every sample that processed with the assay. This also serves as a positive extraction control to ensure that samples resulting as negative contain nucleic acid for testing. Detection of the RNase P gene/other applicable endogenous human control in patient test samples verifies successful extraction of the sample, proper assay setup, sample integrity, and collection of human biological material.

4) **A Negative Extraction Control (optional)**
   Typically, a negative extraction control is a previously characterized negative patient sample. It serves both as a negative extraction control to monitor for any cross-contamination that could occur during the nucleic acid extraction process, as well as an extraction control to validate extraction reagents and successful RNA extraction.

INTERPRETATION OF RESULTS

All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted.

SARS-CoV-2 test results are divided into SARS-CoV-2 positive/detected, SARS-CoV-2 negative/not detected, and inconclusive.

- Test results are communicated back to the patient and ordering physician.
- Results are returned electronically or by fax to the ordering provider. If the ordering physician directs Color to do so, patients will also receive a notification via email or

text message containing a link to Color's online HIPAA-compliant post-test portal to access their results.

- The ordering physician and the sponsoring agency often give their patients the option to follow-up with a healthcare provider to discuss the test results.
- Results are reported by Color and to public health agencies as required.

PERFORMANCE EVALUATION

1) <u>Color COVID-19</u> Self-Swab **<u>Collection Kit Sample Stability Studies:</u>**

Shipping stability of dry spun polyester swabs has been demonstrated by Quantigen Biosciences with support from The Gates Foundation and UnitedHealth Group. The Quantigen study demonstrated 56-hour stability for dry anterior nares spun polyester swabs. Quantigen Biosciences has granted a right of reference to the stability data to any sponsor, such as Color Genomics pursing an EUA for which a claimed specimen type is dry spun polyester swabs. Therefore, the stability of anterior nares samples collected using dry spun polyester swabs were not evaluated in the sample stability study.

2) <u>Dry Swab Resuspension Validation:</u>

To demonstrate that dry spun polyester swabs were acceptable specimen types for testing with the Color Genomics SARS-CoV-2 RT-LAMP Diagnostic Assay, performance of the assay was evaluated using dry swabs resuspended in 1mL of lysis buffer included in the Chemagic Viral DNA/RNA Kit that is used to perform extraction on the automated Chemagic platform. Eluates underwent gentle shaking on an orbital shaker for 20 minutes at ambient conditions.

Contrived positive specimens at 2X and 5X LoD were prepared by spiking inactivated SARS-CoV-2 from ZeptoMetrix (isolate USAWA1/2020, Cat # 0810587CFHI) into DNA/RNA Shield (Zymo Research, Cat # R1100-250) containing negative clinical anterior nares matrix followed by spiking the matrix directly onto the spun polyester swabs. Five technical replicates at both 2X and 5X LoD concentrations were tested in addition to 5 negatives (unspiked-only DNA/RNA Shield media and lysis buffer). Results are summarized in Table 1. There was 100% agreement with expected results for all positive contrived samples for both swab types. All negative samples were non-reactive for SARS-CoV-2 assay targets for both swab types.

Table 1. Dry Swab Resuspension Study Results Stratified by Assay Target

Swab Type	Concentration	Samples (n)	Detection Rate		
			N-gene	E-gene	RNase P
Spun Polyester	2X LoD (1.5 copies/µL)	5	5/5	5/5	5/5
	5X LoD (3.75 copies/µL)	5	5/5	5/5	5/5
	Negative	5	0/5	0/5	5/5

3) Self-Collection Validation:

A usability study was conducted to assess user comprehension of the Color COVID-19 Self-Swab Collection Kit, including both collection and packaging the dry nasal swab for shipment. The study inclusion/exclusion criteria are detailed in Table 6. A demographic question was administered as part of the screening questionnaire to ensure recruitment of a user cohort reflective (or as closely as feasible) to that of the 2019 US population. Participants were also recruited to reflect a variety of ages and education levels, including participants with no high school diploma or equivalent, high school diploma or equivalent, and with higher education. Other demographics were also documented.

Table 2. Inclusion and Exclusion Criteria for Usability Study

Inclusion Criteria	Exclusion Criteria
1. Participant has not received Covid-19 diagnostic testing. 2. Participants are 18 years old or older. 3. Participant resides in the United States. 4. Participant speaks English. 5. Participant is able to attend study information session. 6. Participant has access to a working computer. 7. Participant has access to a stable internet connection. 8. Participant is willing to have the interview video recorded.	1. Participant has no access to a computer or internet connection. 2. Participant does not speak English. 3. Participant has prior medical or laboratory training. 4. Participant has prior experience with self-collection.

Usability studies were conducted with two cohorts of individuals; 30 participants in cohort one and 15 participants in cohort two. The interviewer observed the participant using the collection kit through videoconferencing with the participant in their home environment. A total of 45 adults completed the study of which 37.8% were ≥51 years of age, 13.3% were between 41 - 50 years, and 22.2% were between 31 - 40 years old, 26.7% were between 18-30; 60.0% of participants were female and 40.0% were male. Additional characteristics/demographics of study participants is provided in Table 3.

Table 3. Usability Study Demographics

Characteristics of Study Population		N / N45 (%)
Gender	Female	27 (60.0)
	Male	18 (40.0)
Age (Years)	18 - 30	12 (26.7)
	31 - 40	10 (22.2)
	41- 50	6 (13.3)
	≥ 51 years	17 (37.8)

Characteristics of Study Population		**N / N45 (%)**
Ethnicity	Hispanic or Latino/a	8 (17.8)
Race	Asian	7 (15.6)
	Black or African American	6 (13.3)
	White or Caucasian	26 (57.8)
	Other	6 (13.3)
Marital Status	Divorced	9 (20.0)
	Married	24 (53.3)
	Never married	12 (26.7)
Employment Status	A Homemaker	5 (11.1)
	A Student	1 (2.2)
	Employed for wages full time	25 (55.6)
	Employed for wages part-time	3 (6.7)
	Out of work for less than 1 year	3 (6.7)
	Retired	5 (11.1)
	Self-employed	2 (4.4)
	Unable to work	1 (2.2)
Educational Level	Grade 12 or GED (High School graduate)	4 (8.9)
	Some College, no degree	9 (20.0)
	Associate degree	6 (13.3)
	Bachelor's degree	20 (44.4)
	Graduate or professional degree	6 (13.3)
Geographic Location	Midwest	7(15.6)
	Northeast	11 (24.4)
	Southeast	11 (24.4)
	Southwest	5 (11.1)
	West	11 (24.4)

Of the 30 kits that were shipped to study participants for self-collection in cohort one, 29/30 (97%) of the sample kits were received in acceptable condition for processing according to the laboratory accessioning SOP. One specimen was damaged due to incomplete closure of the collection tube and was not processed with the Color SARS-CoV-2 LAMP Diagnostic Assay. Of those collection kits that were tested with the LAMP assay, RNaseP was detected in 28/29 (96.7%) samples, indicating successful collection of human biological material that was extracted and amplified. There was no known reason or explanation for the lack of RNase P detection for one of the 29 tested samples.

During the actual use testing, staff observed users following the instructions included with the collection kit; however, some participants had challenges with identifying the kit components. Participants used a prototype kit that differed slightly in the labeling from the final kit. A few participants had difficulty identifying or using the rigid biohazard safety bag, which appeared different in the prototype from the drawing provided on the instructions card (lack of a biohazard sticker). Due to these challenges, one participant did not use the rigid biohazard safety bag, and one did not properly seal the bag for transport. No other deviations from the Instructions for Use were noted by staff observing the sample collection. Despite this challenge, this task did not affect the ability to properly receive and process the samples with the LAMP assay. As noted previously, one participant did not properly secure the collection tube lid prior to shipping and was damaged during transport to the laboratory, possibly indicating that the participant did not completely understand the tube closure step of the instructions. The two samples that either did not use the biohazard bag or used the biohazard bag incorrectly were still successfully processed with the LAMP assay.

Answers to the user 10-item questionnaire were also collected for the 30 sample kits that were received at Color for processing. Results of the usability testing were analyzed qualitatively to determine if the design of the kit and/or kit instructions needed to be modified to reduce the use-related risks to acceptable levels. Cognitive debriefing interviews were conducted following the actual-use testing to gather users' perspectives on each critical task or use scenario.

For the usability study cohort one, the overall participant pass-rate was 97% for the 10-item survey. Pass-rate was 100% for all questions except questions 2 and 3 which were 80% and 90%, respectively. Fail rates for questions 2 and 3 was attributed to slight differences between the kit prototype and final product and unclear survey questions. Color staff observed some user's difficulty in identifying the biohazard bag, and the participants did mention the difference in appearance of the bag used in the prototype versus the depiction in the collection instructions during the interview that was conducted following the actual use observation. The feedback obtained from participants in the first study cohort was used to refine the survey questions to make them more understandable. Note that no changes or modifications to the current instructions needed to be made based on discussions with the participants. However, the kits used in the second cohort did include a biosafety bag that matched the appearance of the bag in the collection instructions included with the Color COVID-19 Self-Swab Collection Kit.

Of the 15 kits that were shipped to study participants for self-collection in cohort two, 15/15 (100%) of the sample kits were received in acceptable condition for processing at the Color lab according to the accessioning SOP. All 15 processed samples were positive for human RNaseP (100%), indicating successful collection of human biological material that was extracted and amplified. 15/15 participants successfully answered all 10 questions of the post-study questionnaire and noted agree/strongly agree for understanding the instructions and finding them easy to follow and locate within the kit. Based on the usability study data and feedback, the collection

instructions were understandable, and the Color COVID-19 Self-Swab Collection Kit was easy to use.

4) **Additional Requirement:**
In addition to validation studies, Color and designated laboratories will submit a report to the FDA (within 30 days of authorization) summarizing any testing performed with the Color COVID-19 Self-Swab Collection Kit including how many kits were requested, activated via the online portal, sent for home collection, or collected at a community-based site or distribution center. Designated laboratories will also document the number of kits that were shipped and returned to the laboratory according to the kit instructions, how many specimens were rejected during accessioning and the reasons for rejection, and the positivity rate of the first Color COVID-19 Self-Swab Collection Kit lot.

WARNINGS:

- This self-sample collection kit has not been FDA cleared or approved.
- This self-sample collection kit has been authorized by FDA under an EUA for use by designated laboratories.
- This self-sample collection kit has been authorized only for the self-collection and maintenance of nasal swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- This self-sample collection kit in combination with the authorized test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of medical devices during the COVID-19 outbreak under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the authorization is terminated or revoked sooner.