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

For Prescription Use Only
For In vitro Diagnostic Use
For Use Under Emergency Use Authorization (EUA) Only
For Use by People 18 Years of Age or Older

At-home self-collected anterior nasal swabs or unsupervised self-collected anterior 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 Health, 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 anterior nasal swab specimens.

INTENDED USE

The Color COVID-19 Self-Swab Collection Kit is intended for use by individuals 18 years or older including individuals without symptoms or other reasons to suspect COVID-19 for unsupervised self-collection of anterior nasal swab specimens at home or in a healthcare setting when determined to be appropriate by a healthcare provider. Dry anterior nasal 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 anterior 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 Health, 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 Prescription Use Only
For In vitro Diagnostic Use
For Use Under Emergency Use Authorization (EUA) Only
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 anterior nasal swab specimens collected with the Color COVID-19 Self-Swab Collection Kit.

**DEVICE DESCRIPTION AND TEST PRINCIPLE**

Color Health, 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 will 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 (color.com/covid/PARTNER/activate, where “PARTNER” can be customized to the specific program) 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 an anterior nasal swab sample that is transported in dry conditions in a sterile collection container to either; (1) Color for processing with the Color SARS-CoV-2 RT-LAMP Diagnostic Assay or (2) another laboratory designated by Color that has an authorized 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 authorized 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 return shipping envelope with a prepaid return label. Instructions included in the kit guide users on how to appropriately collect the anterior 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 return shipping envelope for transport to a designated testing laboratory. For those specimens collected at home, the completed Color COVID-19 Self-Swab Collection Kit must be deposited at a 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
Color Health, Inc. - Color COVID-19 Self-Swab Collection Kit
EUA Summary - Updated March 19, 2021

Specimens received for testing at Color and designated laboratories will undergo a thorough review and accessioning prior to acceptance for testing with an FDA authorized IVD molecular SARS-CoV-2 assay indicated to process dry anterior 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:

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soft shipping envelope with prepaid return shipping label and UN3373 Biological Substance Category B label*</td>
<td></td>
</tr>
<tr>
<td>Rigid biohazard safety bag for collected specimen</td>
<td></td>
</tr>
<tr>
<td>Sterile packaged spun polyester swab</td>
<td></td>
</tr>
<tr>
<td>Sterile collection tube</td>
<td></td>
</tr>
<tr>
<td>Barcode card</td>
<td></td>
</tr>
<tr>
<td>Instructions for self-collection</td>
<td></td>
</tr>
</tbody>
</table>

*Not applicable to unsupervised on-site collection

MEDICAL OVERSIGHT AND PROCESS TO BE USED

Anterior 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 (color.com/covid/PARTNER/activate, where “PARTNER” can be customized to the specific program) 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 (color.com/covid/PARTNER/activate) 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 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 their medical expertise to determine 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.

INSPECTION OF ANTERIOR NASAL SWAB SPECIMENS RECEIVED AT A DESIGNATED LABORATORY 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.
- The swab should be oriented correctly; bud at the bottom, shaft at the top.
- The expiration date on the kit is not exceeded.
- 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 online portal within the last 56 hours.
CONTROLS TO BE USED WITH THE AUTHORIZED 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 must 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 to public health agencies as required.

PERFORMANCE EVALUATION

1) **Color COVID-19 Self-Swab Collection Kit Sample Stability Studies:**
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 nasal spun polyester swabs when subjected to both summer and winter thermal excursions. Quantigen Biosciences has granted a right of reference to the stability data to any sponsor, such as Color Health, Inc. pursuing an EUA for which a claimed specimen type is dry spun polyester swabs. Therefore, the stability of anterior nasal samples collected using dry spun polyester swabs were not evaluated in the sample stability study.

2) **Dry Swab Resuspension Validation:**
To demonstrate that dry spun polyester swabs were acceptable specimen types for testing with the Color SARS-CoV-2 RT-LAMP Diagnostic Assay, performance of the assay was evaluated using dry swabs resuspended in 1.3 mL 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 into DNA/RNA Shield containing negative clinical anterior nasal swab 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-negative clinical anterior nasal swab matrix resuspended in 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.

| Table 1. Dry Swab Resuspension Study Results Stratified by Assay Target | Samples (n) | Detection Rate |
|---|---|---|---|---|
| **Swab Type** | **Concentration** | | **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 anterior
nasal swab for shipment. The study inclusion/exclusion criteria are detailed in Table 2. 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 (See Table 3).

**Table 2. Inclusion and Exclusion Criteria for Usability Study**

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

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**

<table>
<thead>
<tr>
<th>Characteristics of Study Population</th>
<th>N / N45 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>27 (60.0)</td>
</tr>
<tr>
<td>Male</td>
<td>18 (40.0)</td>
</tr>
<tr>
<td>Age (Years)</td>
<td></td>
</tr>
<tr>
<td>18 - 30</td>
<td>12 (26.7)</td>
</tr>
<tr>
<td>31 - 40</td>
<td>10 (22.2)</td>
</tr>
<tr>
<td>41 - 50</td>
<td>6 (13.3)</td>
</tr>
<tr>
<td>≥ 51 years</td>
<td>17 (37.8)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
</tr>
<tr>
<td>Hispanic or Latino/a</td>
<td>8 (17.8)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>7 (15.6)</td>
</tr>
</tbody>
</table>
Characteristics of Study Population | N / N\text{45} (%) \\
--- | --- \\
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 RT-LAMP Diagnostic Assay. Of those collection kits that were tested with the Color SARS-CoV-2 RT-LAMP Diagnostic Assay, RNase P 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 Color
SARS-CoV-2 RT-LAMP Diagnostic 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 Color SARS-CoV-2 RT-LAMP Diagnostic 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 RNase P (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.
The results from the usability indicate users 18 years of age and older are able to safely and appropriately collect a dry anterior nasal swab specimen with sufficient human biological material for downstream SARS-CoV-2 testing.

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 from asymptomatic individuals. 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 product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA;
- This product has been authorized only for the home collection and maintenance of anterior nasal swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and,
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of medical devices under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.