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

For *In vitro* Diagnostic Use
Rx Only
For Use Under Emergency Use Authorization (EUA) Only
For Use by Individuals 18 Years of Age and Older when Self-collected
For Use by Individuals 14 Years of Age and Older when Self-collected Under Adult Supervision
For Use by Individuals 2 Years of Age or Older when Collected with Adult Assistance

Anterior nasal swabs collected at-home or collected unsupervised at a collection site using the Color COVID-19 Self-Swab Collection Kit with Saline will be sent to 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 requirements to perform high complexity tests and test the specimens collected with the Color COVID-19 Self-Swab Collection Kit with Saline using an in vitro diagnostic (IVD) molecular test that is indicated for use with the Color COVID-19 Self-Swab Collection Kit with Saline.

INTENDED USE

The Color COVID-19 Self-Swab Collection Kit with Saline is intended for use by any individual age 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance), including individuals without symptoms or other reasons to suspect COVID-19 for collection of anterior nasal swab specimens at home or in a healthcare setting when determined to be appropriate by a healthcare provider. Anterior nasal swab specimens collected using the Color COVID-19 Self-Swab Collection Kit with Saline 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 RNA that is indicated for use with the Color COVID Self-Swab Collection Kit with Saline.

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 with Saline.

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

SPECIAL CONDITIONS OF USE STATEMENTS

For *In vitro* Diagnostic Use

For Prescription Use Only
For Emergency Use Authorization (EUA) Only
For Use by Individuals 18 Years of Age and Older when Self-collected
For Use by Individuals 14 Years of Age and Older when Self-collected Under Adult Supervision
For Use by Individuals 2 Years of Age or Older when Collected with Adult Assistance

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

DEVICE DESCRIPTION AND TEST PRINCIPLE

Note that, throughout this document, the term "patient" includes the parent/guardian of a minor, as applicable.

Color Health, Inc. (Color) offers the Color COVID-19 Self-Swab Collection Kit with Saline 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 eligibility. 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 identity, exposure to SARS-CoV-2, 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 with Saline enables the collection of an anterior nasal swab sample that is transported in 0.9% saline 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 with Saline. The Color COVID-19 Self-Swab Collection Kit with Saline 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 two-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 with Saline consists of a sterile packaged spun polyester swab, collection tube filled with 1 mL of 0.9% saline, a standard

biohazard safety bag with leak proof adhesive closure and absorbent material, barcode card, instructions for use, rigid cardboard return shipping box and return shipping envelope with prepaid return label. Instructions included in the kit guide users on how to collect the anterior nasal swab specimen appropriately. Following collection, the swab is inserted into a sterile tube with saline, and the cap is screwed tightly onto the collection tube. The collected specimen is sealed in the biohazard bag and placed into a designated, secure collection bin or handed directly to on-site staff if collected at a designated location OR the specimen in the biohazard bag is placed into the rigid shipping box and into the return shipping envelop for transport to Color or a designated testing laboratory. For those specimens collected at home, the completed kit must be deposited at a drop box location on the same day the specimen is collected to ensure timely receipt at the testing laboratory. Each Color COVID-19 Test Self-Swab Collection Kit with Saline 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 process prior to acceptance for testing with an FDA authorized IVD molecular SARS-CoV-2 assay indicated for use with the Color COVID-19 Test Self-Swab Collection Kit with Saline.

REAGENTS AND MATERIALS

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

Component
Shipping Box –Rigid cardboard box*
Mailer shipping envelope with UN3373 label and prepaid return label*
Specimen biohazard bag with absorbent material
Sterile packaged spun polyester swab
Plastic sterile collection tube filled with saline (95kPa rated)
Barcode card
Instructions for collection^

*Not applicable to unsupervised on-site collection
The shipping envelope provided with the kit will be specific to the testing program and additional information on the shipping vendor will be provided to the program managers.
^-Collection instructions are specific to the on-site and at-home collection workflows. The anterior nasal swab collection process is identical; however, the preparation of the specimen for shipment differs. The rigid shipping component is part of the bulk packaging for the on-site collection, whereas the rigid component is part of the individual packaging of the shipping box for a sample collected at home.

MEDICAL OVERSIGHT AND PROCESS TO BE USED

Anterior nasal swabs can be collected in saline via two different workflows:

On-Site 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 eligibility for the anterior nasal swab collection kit.
2. The patient collects the anterior nasal swab 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 48 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 (both positive and negative SARS-CoV-2 results) are automatically shared with local Department of Public Health registries.

At-Home 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 eligibility for the anterior nasal swab collection kit.
2. Color will ship the anterior nasal swab collection kit to the patient's home via 2-day shipping.
3. The patient collects the anterior 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 (both positive and negative SARS-CoV-2 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 with Saline as part of centrally coordinated community programs that are under the direction of a supervising physician. Healthcare providers (HCPs) at specific institutions within the community-based framework use their medical expertise to determine patient eligibility. 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 IN SALINE RECEIVED AT COLOR OR A DESIGNATED LABORATORY FOR TESTING

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

- Sample collection tube must be intact and not visibly damaged.
- There are no signs of leakage in the biohazard bag.
- The tube barcode label must be present and readable by a barcode scanner.
- The tube cap must be properly secured onto the tube (i.e., screw cap closure).
- The medium must be in a liquid state and not congealed.
- The collection tube with saline contains exactly one swab.
- The swab is oriented correctly with the bud facing the bottom of the tube.
- The expiration date on the kit is not exceeded.
- Accession date/time is within 48 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 48 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 medium 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 such as RNase P or another endogenous human gene is needed to verify that nucleic acid is present and is used for every sample that is processed with the assay. This also serves as a positive extraction control to ensure that samples with negative results contained 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 recovery.

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.

In the case of positive results:

- 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 (both positive and negative SARS-CoV-2 results) are reported by Color and to public health agencies as required.

PERFORMANCE EVALUATION

1) **Analytical Comparison/Equivalence Studies:**
The LoD of the Color SARS-COV-2 RT-LAMP Diagnostic Assay (N-gene, E-gene and RNase P primers only) was established using whole heat-inactivated SARS-CoV-2 (ATCC VR-1986HK) spiked in negative anterior nasal swab clinical matrix in DNA/RNA Shield (Zymo Research, Cat # R1100-250). Please see EUA Summary for complete details (https://www.fda.gov/media/138249/download). The Color SARS-CoV-2 RT-LAMP Diagnostic Assay was shown to detect ≥ 95% of replicates prepared in clinical matrix with 1X DNA/RNA Shield medium at 0.75 copies/µL.

For anterior nasal swab specimens that are collected with the Color COVID-19 Self-Swab Collection Kit with Saline, swabs are placed in 0.9% saline solution. Therefore, a study was performed to compare the performance of the Color SARS-CoV-2 RT-LAMP Diagnostic Assay using samples in saline and 1X DNA/RNA Shield. The study was performed with contrived positive and negative samples that were prepared in parallel using pooled anterior nasal swab matrix in either DNA/RNA Shield or 0.9% saline. Negative anterior nasal swab matrices in DNA/RNA Shield and saline were spiked with inactivated whole SARS-CoV-2 from ATCC. Each spiked replicate

was processed through the entire assay, beginning with RNA extraction using the Chemagic Viral DNA/RNA Kit on the Chemagic 360 instrument, followed by testing with the Color SARS-CoV-2 RT-LAMP Diagnostic Assay. Results from the study are shown in Table 1 below and demonstrate that the Color SARS-CoV-2 RT-LAMP Diagnostic Assay generated similar results with samples prepared in 1X DNA/RNA Shield and 0.9% saline.

Table 1. Comparative Study Results Between 1X DNA/RNA Shield Medium and 0.9% Sterile Saline

X LoD	Concentration (copies/µL)	DNA/RNA Shield	0.9% Saline
		# of Replicates Detected / Total Replicates Tested	# of Replicates Detected / Total Replicates Tested
2X LoD	1.50	5/5	5/5
3X LoD	2.25	5/5	5/5
5X LoD	3.75	5/5	5/5
Negative	N/A	0/5	0/5

N/A; Not applicable

Another study evaluated the performance of the Color SARS-CoV-2 RT-LAMP Diagnostic Assay with dry swabs resuspended in 1.3 mL of lysis buffer from the Chemagic Viral DNA/RNA Kit. Please see EUA Summary for complete details (https://www.fda.gov/media/141797/download). Testing was conducted using low and moderate positive samples (2X and 5X LoD, respectively, based on the LoD established with 1X DNA/RNA Shield). The results indicate that the Color SARS-CoV-2 RT-LAMP Diagnostic Assay generated similar results with dry anterior nasal swabs resuspended in lysis buffer and swabs in 1X DNA/RNA Shield.

In conclusion, the results of the above listed studies indicate that the Color SARS-CoV-2 RT-LAMP Diagnostic Assay generated similar results with anterior nasal swab samples in 1X DNA/RNA Shield, 0.9% saline and dry anterior nasal swabs resuspended in lysis buffer.

2) **Color COVID-19 Self-Swab Collection Kit with Saline Sample Stability Studies:**
Shipping stability of spun polyester swabs in saline has been demonstrated by Quantigen Biosciences with support from The Gates Foundation and UnitedHealth Group. The Quantigen study demonstrated 48-hour stability for spun polyester nasal swabs transported in 0.9% saline under high ambient temperature conditions. Quantigen Biosciences has granted a right of reference to the stability data to any sponsor, such as Color Health pursuing an EUA for which a claimed specimen type is spun polyester swabs transported in 0.9% saline. Therefore, the stability of anterior nasal swab samples collected using spun polyester swabs in saline was not evaluated in the sample stability study.

Color will conduct a post-authorization study to verify the stability of SARS-CoV-2 RNA in specimens collected using the Color COVID-19 Self-Swab Collection Kit with Saline that are transported under low ambient temperature conditions, including multiple freeze-thaw cycles.

3) Collection Device Reagent Stability (Shelf-Life):

The 0.9% sterile saline collection tube within the Color COVID-19 Self-Swab Collection Kit with Saline is manufactured by a third party. The manufacturer's claimed shelf-life/expiration date is 12 months from the date of manufacturing when the product is stored at 2°C-25°C. All lots of sterile saline are tested by the manufacturer for microbial contamination, and the ability to maintain viability of pathogens in specimens after 72 hours of storage in accordance with CLSI methods.[1,2] Therefore, the kit's expiration date will be one year from the date of manufacture of the saline solution and is displayed on the back of the collection kit box. A specific accessioning criterion is to ensure that the kit's expiration date has not been exceeded.

4) Self-Collection Validation:

a. Usability Study on Adults Only (18 Years +)

A usability study was conducted to assess user comprehension of the instructions for use for the Color COVID-19 Self-Swab Collection Kit with Saline, including both specimen collection and packaging the anterior nasal swab for shipment. Participants were 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 2).

The usability study was conducted with 40 participants recruited from the San Francisco Bay area. The interviewer observed the participant using the collection kit through videoconferencing with the participant in a simulated-use environment (i.e., samples were collected at a research site using a collection bin that served as the drop box location for shipping). All participants prepared and packaged their specimens for shipment. At the conclusion of the usability study, the site bulk shipped the specimens to Color for processing. A total of 40 adults completed the study of which 35.0% were ≥51 years of age, 20.0% were between 41 - 50 years of age, 25.0% were between 31 - 40 years of age, and 20.0% were between 18 - 30 years of age; 60.0% of participants were female and 40.0% were male. Additional characteristics/demographics of study participants are provided in Table 2.

Table 2. Usability Study Demographics for Adults Only (18 Years +)

Characteristics of Study Population		**N / N40 (%)**
Gender	Female	24 (60.0)
	Male	16 (40.0)

[1] Clinical and Laboratory Standards Institute. 2014. Approved Standard-Second Edition M40-A2. Quality Control of Microbiological Transport Systems. CLSI, Wayne, PA.

[2] Clinical and Laboratory Standards Institute. 2004. Approved Standard - Third Edition M22-A3. Quality Control for Commercially Prepared Microbiological Culture Media. CLSI, Wayne, PA.

Characteristics of Study Population		N / N40 (%)
Age (years)	18 - 30	8 (20.0)
	31 - 40	10 (25.0)
	41- 50	8 (20.0)
	≥ 51 years	14 (35.0)
Ethnicity	Hispanic or Latino/a	4 (10.0)
Race	American Indian or Alaska Native	1 (2.5)
	Asian	11 (27.5)
	Black or African American	6 (15.0)
	Pacific Islander	1 (2.5)
	White or Caucasian	15 (37.5)
	Other	6 (15.0)
Marital Status	Divorced	4 (10.0)
	Married	17 (42.5)
	Never married	18 (45.0)
	Widowed	1 (2.5)
Employment Status	A Homemaker	1 (2.5)
	A Student	3 (7.5)
	Employed for wages full time	20 (50.0)
	Employed for wages part-time	3 (7.5)
	Out of work for 1 year or more	1 (2.5)
	Out of work for less than 1 year	4 (10.0)
	Retired	3 (7.5)
	Self-employed	4 (10.0)
	Unable to work	1 (2.5)
Educational Level	Grade 12 or GED (High school graduate)	4 (10.0)
	Some college, no degree	21 (52.5)
	Associate degree	1 (2.5)
	Bachelor's degree	13 (32.5)
	Graduate or professional degree	1 (2.5)

Of the 40 samples that were collected, 40/40 (100%) were received in acceptable condition for processing according to Color's laboratory accessioning SOP. Of those samples received at Color for testing with the Color SARS-CoV-2 RT-LAMP Diagnostic Assay, RNase P was detected in 40/40 (100%) of samples, indicating successful collection of human biological material that was extracted and amplified.

During the actual use testing, staff observed users following the instructions included with the collection kit; however, some participants had difficulty sealing the biohazard bag due to not reading the instructions in their entirety. This resulted in 4 kits with improperly closed biohazard bags noted upon accessioning at Color. Color considers undamaged specimens (intact tube and no leaks) to be acceptable regardless of biohazard bag status. Despite this, no additional deviations from the Instructions for Use were noted by staff observing the sample collection and furthermore, this failure mode did not affect the ability to receive the samples and process them for testing with the Color SARS-CoV-2 RT-LAMP Diagnostic Assay.

Answers to the post-collection usability 8-item questionnaire were also captured for the 40 sample kits that were received at Color for processing. The average proportion of correct results for the 8-item questionnaire was 99.6%. The pass-rate was 100% for all survey items except for the question pertaining to insertion of the swab tip into the nostril (97.5%). This failure rate was attributed to one participant's misunderstanding of the survey response options; all other study participants (39; 97.5%) correctly answered this question. Therefore, 39/40 participants successfully answered all questions 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 determined to be understandable, and the kit was found to be easy to use.

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. During the usability study Color staff observed some users experience difficulty with placing the collected specimen into the biohazard bag for shipping. These users discussed this scenario during the post-collection interview and indicated that they did not read the directions thoroughly. In response, step #9 pertaining to the biohazard bag on the current at-home instructions was bolded to emphasize the significance of this task.

The results from the usability study indicate users 18 years of age and older are able to collect an appropriate anterior nasal swab specimen in saline containing sufficient human biological material for downstream SARS-CoV-2 testing.

b. Usability Study Conducted on Minors (2-13 and 14-17 Year-Olds)
An additional usability study was completed to validate collection of an anterior nasal swab from minors. The usability study was conducted in a simulated environment using two cohorts of parent/minor pairs. The first cohort included parents with minors aged 2-13, where the parent collected the anterior nasal swab sample from the minor, packaged the specimen for shipping, and answered the post-collection questions. The second cohort included parents with minors aged

14-17, where the minor collected the sample from themselves, packaged the specimen for shipping, and answered the post-collection questions. Minors aged 14-17 could ask their parent for help with either the collection/shipping instructions or the post-collection survey questions if they desired.

A demographic questionnaire was administered to the parents as part of the screening questionnaire to ensure the usability study included a diverse cross-section of the intended use population. The questionnaire included the parent's gender, ethnicity, race, marital status, employment status, education level, and household income bracket. A subset of these demographics was collected for minors (2-17 years old), including age and gender.

Color personnel observed the participants using the collection kit in-person in a simulated environment. In total, 35 parent/minor pairs completed usability testing including 19 pairs in the 2-13 age group and 16 pairs in the 14-17 age group. The demographics of the parent participants for the 2-13 age category and 14-17 age category are shown in Table 3. The self-reported information from minors aged 2-13 and 14-17 years old, including gender and age, is shown in Table 4.

Table 3. Participant Demographics for Parents Included in the 2-13 Age Group and 14-17 Age Group

Participants – Adults Paired with Minors Aged 2-13 Years Old		**N (%)**	**Participants – Adults Paired with Minors Aged 14-17 Years Old**		**N (%)**
Total		**19 (100)**	**Total**		**16 (100)**
Gender	Female	9 (47.4)	**Gender**	Female	10 (62.5)
	Male	10 (52.6)		Male	6 (37.5)
Ethnicity	Hispanic or Latino/a	1 (5.3)	**Ethnicity**	Hispanic or Latino/a	4 (25.0)
	Non-Hispanic or Latino/a	18 (94.7)		Non-Hispanic or Latino/a	12 (75.0)
Race	Asian	9 (47.4)	**Race**	Asian	2 (12.5)
	White or Caucasian	9 (47.4)		White or Caucasian	14 (87.5)
	Other	1 (5.3)	**Marital Status**	Married	14 (87.5)
Marital Status	Married	15 (79.0)		Divorced	2 (12.5)
	Divorced	2 (10.5)	**Employment Status**	Employed for wages full time	7 (43.8)
	Never married	2 (10.5)		Employed for wages part time	2 (12.5)
Employment Status	Employed for wages full time	14 (73.7)		Self-employed	2 (12.5)
	Self-employed	2 (10.5)		Out of work for less than 1 year	2 (12.5)
	Out of work for 1 year or more	2 (10.5)		Homemaker	3 (18.8)
	Homemaker	1 (5.3)	**Educational Level**	Some College, no degree	2 (12.5)
Educational Level	Grade 12 or GED (High school graduate)	2 (10.5)		Associate degree	2 (12.5)
	Bachelor's degree	7 (36.8)		Bachelor's degree	7 (43.8)
	Graduate or professional degree	10 (52.6)		Graduate or professional degree	5 (31.3)
	50,000-74,999	2 (10.5)		50,000-74,999	2 (12.5)
	75,000-99,999	3 (15.8)		75,000-99,999	1 (6.3)

Household Income Bracket	150,000-199,999	12 (63.2)	**Household Income Bracket**	100,000-149,999	4 (25.0)
	200,000+	2 (10.5)		150,000-199,999	5 (31.3)
				200,000+	4 (25.0)

Table 4. Minor Participant Demographics in the 14-17 and 2-13 Age Groups

Participants – Minors Aged 14-17 Years Old		**N (%)**	**Participants – Minors Aged 2-13 Years Old**		**N (%)**
Total		**16 (100)**	**Total**		**19 (100)**
Gender	Female	6 (37.5)	**Gender**	Female	7 (36.8)
	Male	10 (62.5)		Male	12 (63.2)
Age (years)	14	6 (37.5)	**Age (years)**	2	1 (5.3)
	15	2 (12.5)		3	1 (5.3)
	16	5 (31.3)		4	2 (10.5)
	17	5 (31.3)		5	2 (10.5)
				6	1 (5.6)
				7	3 (16.7)
				8	3 (16.7)
				9	1 (5.6)
				10	2 (11.1)
				11	1 (5.6)
				12	1 (5.6)
				13	1 (5.6)

Of the 35 collected anterior nasal swab specimens, 34/35 (97.1%) samples were received in acceptable condition as defined by Color's accessioning standard operating procedure. One sample was not processed with the Color SARS-CoV-2 RT-LAMP Diagnostic Assay due to an incomplete closure of the collection tube's cap resulting in sample leakage within the biohazard bag. In addition, one biohazard bag was not sealed appropriately and there were four exterior FedEx shipping envelopes that were incorrectly sealed (partially sealed or not sealed at all). During the debriefing interviews, 3/4 participants who failed to seal their envelopes indicated that they did so because it was a simulated study. Therefore, no additional mitigation measures were determined to be necessary to prevent this scenario in the future. None of the deviations affected the ability of the laboratory to accession and process the samples. Of the 34 samples that were processed, 34/34 samples showed detection of human RNase P (100%) which indicates successful collection of human biological material.

During the usability study, staff observed participants (defined as "parents" in the 2-13 age group and "minors" in the 14-17 group) collecting an anterior nasal swab sample according to the collection kit instructions. One participant initially failed to place the collected sample within the biohazard bag into the rigid cardboard shipping box. However, the individual re-read the instructions, recognized their error and correctly packaged their sample for shipment. No other deviations from the instructions were noted by research staff. The 34 collected samples were successfully accessioned and processed with the Color SARS-CoV-2 RT-LAMP Diagnostic Assay.

Following sample collection, participants completed an 8-item questionnaire. Results were analyzed qualitatively to determine if the design of the kit and/or instructions for use needed to be modified to reduce the use-related risks to acceptable levels. Cognitive debriefing interviews were conducted following the usability testing to gather users' perspectives on each critical task.

In the 2-13 age group, where parents answered the post-collection questions, the rate of correct or positive responses was 98.7% (150/152). The rate was 100% for all eight questions except for one question to which the participant provided an unfavorable response and another question that a different participant answered incorrectly. The proportion of correct or positive responses for both these questions was 94.7% (18/19). Overall, the participants' responses to the post-collection questions, and the cognitive debriefing interviews provided evidence that the instructions were understandable, and that parents were able to collect an adequate anterior nasal swab specimen from children as young as 2 years old for downstream testing with the Color SARS-CoV-2 RT-LAMP Diagnostic Assay.

In the 14-17 age group, where the minors answered the post-collection questions, the rate of correct or positive responses was 99.2% (127/128). The rate was 100% for all eight questions except for one question to which the participant answered incorrectly. The rate of correct responses for this specific question was 93.8% (15/16). Overall, the participants' responses to the post-collection questions and the cognitive debriefing interviews provided evidence that the instructions were understandable, parents were able to collect an adequate anterior nasal swab specimen from children as young as 2 years old and that minors aged 14-17 were able to self-collect an anterior nasal swab specimen successfully under adult supervision. As a precaution, Color did incorporate an additional warning on the collection instructions emphasizing that the swab must only touch the inside of the nostrils and if compromised in any way, a new collection kit should be requested.

c. Additional Usability Study on 2-4 Year-Olds

Due to modifications made to the collection instructions pertaining to differences in the depth of insertion of the swabs between a young child and an adult (See note under step 5 in the IFU), a supplemental usability study was completed using 19 parent/minor pairs where the minors were 2-4 years old. Usability testing under observation by Color personnel was conducted in a simulated home environment in which the parent collected the anterior nasal swab sample from the minor child, packaged the specimen for shipping, and answered the post-collection questions.

A demographic questionnaire was administered to the parents as part of the screening questionnaire. The questionnaire included the parent's gender, ethnicity, race, marital status, employment status, education level, and household income bracket. A subset of these demographics was collected for the minors including age and gender. In total, 19 parent/minor pairs completed usability

testing. The demographics of the parents and the paired minors are shown in Table 5 and Table 6, respectively.

Table 5. Participant Demographics for Parents Included in the 2-4 Age Group

Participants		**N (%)**
Total		**19 (100)**
Gender	Female	11 (57.9)
	Male	8 (42.1)
Ethnicity	Hispanic or Latino/a	0 (0.0
	Non-Hispanic or Latino/a	19 (100.0)
Race	Asian	12 (63.2)
	White or Caucasian	4 (21.1)
	Other	1 (5.3)
	Black or African American	2 (10.5)
Marital Status	Married	16 (84.2)
	Divorced	1 (5.3)
	Never married	2 (10.5)
Employment Status	Employed for wages full time	19 (100.0)
Educational Level	Some college, no degree	1 (5.3)
	Bachelor's degree	11 (57.9)
	Graduate or professional degree	7 (36.8)
Household Income Bracket	10,000-24,999	1 (5.3)
	50,000-74,999	1 (5.3)
	100,000-149,999	4 (21.1)
	150,000-199,999	6 (31.6)
	200,000+	7 (36.8)

Table 6. Minor Participant Demographics in the 2-4 Age Group

Participants		**N (%)**
Total		**19 (100)**
Gender	Female	6 (31.6)
	Male	13 (68.4)
Age (years)	2	3 (15.8)
	3	9 (47.4)
	4	7 (36.8)
Ethnicity	Hispanic or Latino/a	0 (0.0
	Non-Hispanic or Latino/a	19 (100.0)
Race	Asian	12 (63.2)
	White or Caucasian	4 (21.1)
	Other	1 (5.3)
	Black or African American	2 (10.5)

Of the anterior nasal swab specimens collected, 19/19 (100%) were received in acceptable condition as defined by Color's accessioning standard operating

procedure. Human RNase P nucleic acid was detected in all 19 samples (100%), which indicates successful collection of human biological material.

During the usability study, staff observed parent participants collecting a dry anterior nasal swab sample according to the updated collection kit instructions. No deviations from the instructions were noted by research staff and all 18 samples were processed with the Color SARS-CoV-2 RT-LAMP Diagnostic Assay.

Following sample collection, parent participants completed a 9-item questionnaire. Results were analyzed qualitatively to determine if the design of the kit and/or instructions for use needed to be modified to reduce the use-related risks to acceptable levels. Cognitive debriefing interviews were conducted following the usability testing to gather users' perspectives on each critical task.

The overall rate of correct or positive responses provided by the parent participants was 99.4% (170/171). The rate was 100% for eight of the nine questions. For one question, the correct response rate was 94.7% (18/19). Overall, the participants' responses to the post-collection questions and the cognitive debriefing interviews provided evidence that the modified instructions pertaining to differences in the depth of swab insertion between very young children and older individuals were understandable. Additionally, the analysis of real-world data from a 30-day report for the Color COVID-19 Self-Swab Collection Kit with Saline and complaint history indicated that the collection kit is performing as expected.

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.